EFFECTS OF HEALTH INSURANCE BENEFIT PLAN DESIGN ON HEALTHCARE RESOURCE UTILIZATION; MEDICATION POSSESSION FOR ORAL ANTI-DIABETIC MEDICATION; AND RECEIPT OF APPROPRIATE PROCESSES OF CARE IN ADULT WORKING AGE PATIENTS WITH TYPE 2 DIABETES MELLITUS

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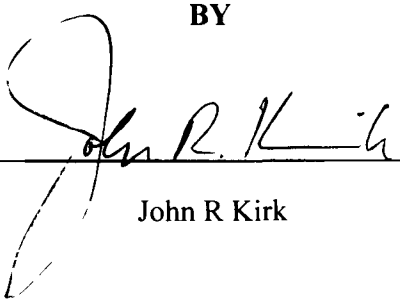

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ABSTRACT

The objective of this study was to evaluate the main effect of health insurance plan type on ER (ER) visit or hospital admission in privately insured patients with Type 2 diabetes between the ages of 18 to 64 years. The data source was the 2000-2001 MarketScan database, which is comprised of administrative claims data for over 2.5 million privately insured individuals in the United States. The outcomes of interest were the odds of an ER visit or a hospital admission, odds of having a good medication possession ratio (MPR) for oral anti-diabetic medications and odds of receiving prescriptions for angiotensin converting enzyme (ACE) inhibitors and 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors (statins). Multiple logistic regression models were specified to control for demographic and clinical characteristics of the target patient population. Patients enrolled in FFS plans were significantly more likely to experience an ER visit or an inpatient stay compared to patients in capitated plans. Patients in capitated plans were more likely to have good MPR compared to FFS, PPO and POS plan types. Patients enrolled in capitated plans were significantly more likely to use statins compared to patients in FFS, PPS and POS plans. Compared with capitated plans, patients in FFS plans were more likely to receive prescriptions for ACE inhibitors. Capitated plans seek to reduce resource utilization.

1. BACKGROUND AND SIGNIFICANCE

Diabetes presents a major resource utilization and cost burden on the healthcare system. Many chronic conditions, such as Type 2 diabetes mellitus, are sensitive to timely and appropriate ambulatory care which can prevent or delay disease progression to episodes requiring ER visits, hospital admissions, more complicated treatment regimens, premature mortality and increased healthcare costs. As the average age of the population continues to advance and life expectancy increases, the prevalence of Type 2 diabetes and obesity will increase each year along with associated healthcare resource utilization and costs [1-4]. Compared to patients without diabetes, patients with diabetes are more likely to be absent from work and to have physical limitations on the job. Patients with diabetes are also more likely to have reduced performance with the potential for significant impact on productivity [5, 6]. Likewise, patients with diabetes are 2 to 3 times more likely than non-diabetics to report loss of employment due to disability or poor health status, and are approximately 4 times more likely to report limitations in the work place [6]. Individuals who are overweight and inactive have a higher risk of developing diabetes. An obese, inactive person is approximately 5 times more likely to be diabetic than an active person with a normal body mass index (BMI). For every 1 kilogram increase in body weight, the likelihood of presenting with diabetes increases by 9% [7]. This trend remains after controlling for co-morbid heart disease, hypertension and hyperlipidemia [8]. As patients with diabetes age and accumulate additional co-morbidities, their cost of care increases [9], [10]. Prevention and proper ambulatory care management of diabetes should have positive social and economic benefits for both patients and employers. Maintaining glycemic control as close to normal and as safely as possible is the goal of treatment regimens. Over time, most if not all oral medications will lose their efficacy due to declining β-cell function. Treatment regimens are individualized

and may become relatively complex. Patient adherence to their prescribed anti-hyperglycemic medications is important for the maintenance of glycemic control [11]. In addition to appropriate HbA1c monitoring, other processes of care include routine retinal eye examinations, control of hypertension and correction of dyslipidemia [12]. As disease severity increases, especially with patient age, renal function as measured by proteinuria should also be monitored [12]. Patients experiencing more severe retinal changes should be referred to an ophthalmologist who is knowledgeable and experienced in the management of diabetic retinopathy.

Hypertension is known to contribute to the development and progression of chronic complications of diabetes. Control of hypertension has been demonstrated conclusively to reduce the rate of progression of diabetic nephropathy and to reduce the associated complications of hypertensive nephropathy, cerebrovascular disease, and cardiovascular disease. The presence of diabetes increases the risk for atherosclerotic vascular disease. Patients with Type 2 diabetes also have increased risk for obesity and lipid abnormalities independent of the level of glycemic control. Therefore, guidelines for diabetes management treatment of dyslipidemia to reduce the risk of cardiovascular events associated in patients with and without documented coronary heart disease. Good process of care of patients with diabetes includes regular physical activity [13], and a meal plan to lower glucose levels and to normalize lipid patterns. If diet and exercise are not sufficient, lipid-lowering treatment is indicated. Statins are frequently used in patients with diabetes. The primary goal of therapy for adult patients with diabetes is to lower LDL-cholesterol to $\leq$ 100 mg/dL.

Having health insurance coverage and access to healthcare certainly improves the outcomes associated with Type 2 diabetes. The type of health insurance plan in which patients are enrolled may also affect patient outcomes. Various forms of health insurance exist and may be generally

referred to as Fee-for-Service (FFS) or capitated [14]. Much of the current literature indicates that, in general (FFS) healthcare plans are associated with increased utilization compared to capitated plans; however, little data are available comparing healthcare plan types in patients with Type 2 diabetes.

Under FFS arrangements, also known as traditional indemnity insurance, the financial risk is held by the payer, that is, the insurance carrier. FFS is generally associated with provision of more care, more out-patient office visits, and more procedures [15]. FFS is also associated with better continuity of care, higher likelihood of adhering to clinical practice guidelines [14].

Under capitation arrangements, per member per month fees are pre-paid to the physician practice by the insurer. The financial risk is held by the provider [14, 16-18]. Under capitation, physicians tend to increase their patient panel size (number of patients using a certain practice for health care) and to decrease the amount of time spent with each patient during an encounter [18, 19]. Practices delivering healthcare predominantly from capitated contracts were positively correlated with physician compensation based upon quality of care ($p = 0.02$) [15]. If true, these features of capitation arrangements would suggest differences in quality of care and in the specific types of care delivered to the patient. It is generally accepted that capitated HMOs provide health care at approximately 10% lower cost compared to FFS [18].

The probability of receiving assessment for glycemic control, proteinuria, eye exams and foot exams during office visits is greater when physicians are paid by salary compared to reimbursement in either FFS or capitation arrangements [20]. Rates of receipt of appropriate diabetes care and patient satisfaction were predicted to be significantly higher among patients whose physicians were compensated by direct salary rather than by either FFS or capitation

arrangements [20]. The incentive under FFS is to provide more reimbursable services, not necessarily providing services that would reflect better diabetes care.

Little is known about the effects of different types of private insurance care plans on healthcare resource utilization and medication adherence in privately insured, working age adults with Type 2 diabetes. Limited research has been done when health insurance plan type, out-patient and in-patient claims, pharmacy claims and benefit plan design features data are available together in the same data set. This study extends the literature by examining the affects of health insurance plan type (FFS, point-of-service (POS), preferred provider organization (PPO) or capitated) on healthcare resource utilization, such as ER visits or hospitalization for complications of diabetes, and medication adherence in plans with or without provisions for prescription drug coverage. The proposed study population has been included in studies of ambulatory care sensitive conditions but generally only where patients with Type 2 diabetes have been aggregated with patients having one of a comprehensive set of other conditions, for example, asthma, hypertension and congestive heart failure, among others [21, 22]. The proposed study population excludes the elderly and children from low-income families since these population segments are eligible for Medicare and Medicaid coverage, respectively.

The dependent variables of interest in this study were odds of an ER visit; odds of admission; odds of medication possession coverage of 80% or more; and odds that patients with Type 2 diabetes received prescriptions for ACE inhibitors and statins as indicated in the clinical practice guidelines. After controlling for other covariates, the main effect of interest is the effect of health insurance plan type on the dependent variables. Although it is possible that health insurance plan type may have an effect on medication adherence which in turn could affect resource utilization, the literature indicates that higher out-of-pocket cost to patients may be the

primary reason for reduced adherence, not health insurance plan type per se [23-25]. Actual out-of-pocket costs vary widely by individual plan and plan type. In addition, there are sources of selection bias that may influence the comparison of health insurance plan types [14]. From the perspective of the patient, an otherwise healthy individual may select a managed care plan for readily available primary care. An individual with one or more chronic conditions may select a FFS plan that allows free access to specialty providers without a referral. From the perspective of the provider, practice style may affect whether to join a managed care practice that conforms to clinical practice guidelines [14]. A propensity score will also be used to adjust for selection bias.

In addition, a commonly used framework for evaluating access to healthcare, the behavioral model of access [26-28], will be used to analyze relationships between health insurance plan type, healthcare resource utilization, medication adherence and processes of care in patients with Type 2 diabetes.

The objective of this study is to determine whether there are differences among private health insurance plan types in terms of health care resource utilization; medication possession and appropriate processed of care in privately insured patients with Type 2 diabetes between the ages of 18 to 64 years. Although many studies have been reported that describe the effects of health insurance plans on healthcare resource utilization in patients with Type 2 diabetes, limited data are available when out-patient and in-patient encounter claims, pharmacy claims and benefit plan design features are available together in the same data set. Similarly, to our knowledge use of a propensity score analysis of the effect of health insurance plan type in this Type 2 diabetic population has not been reported. This study extends the literature by examining the affects of

health insurance type (FFS, POS, PPO or capitated) on healthcare resource utilization, including ER visits and hospitalization for complications of diabetes.

2. LITERAURE REVIEW

The literature was reviewed with respect to studies that compared types of health insurance plans as they relate to the dependent variables for resource utilization, medication possession and processes of care. The review included studies done from the perspective of the insurance plans themselves; from the perspective of physician payment arrangements and incentives to use resources efficiently; and from the perspective of cohorts of patients with diabetes.

2.1. Health Insurance Plan Types

Private health insurance available in the US is based on how physicians are paid for delivering care [14, 18, 19]. Plans pay physicians under FFS or capitation arrangements, or by direct salary. Patients, in turn, enroll in health insurance plans based on their health status and level of cost sharing associated with a particular plan. Health insurance pays for more than 80% of all healthcare expenditures in the US. The insurance market seeks to simultaneously control costs, minimize use and improve the quality of care in a parsimonious manner. Most strategies to control costs and improve quality are focused on altering physician behavior because their decisions impact approximately 80% of all medical spending [29]. In the study period of 2000-2001 approximately 40% of the employer sponsored, privately insured population was enrolled in a PPO [30]. Competition with HMOs and the reduced number of traditional FFS plans was changing the managed care health insurance market in the United States [31].

To help contextualize the results of the present study, it is helpful to distinguish between the types of health insurance plans that were operating in the years 2000 and 2001.

Traditional indemnity plans were typified by Blue Cross and Blue Shield plans. Policies were divided into basic coverage and comprehensive major medical coverage. Basic coverage

included the cost of visits to the doctor, hospitalization, surgery and other medical expenses. When the cost limits were reached, the major-medical part of the policy took over. Thereafter, major medical coverage paid the bulk of the charges as the result of a chronic illness or serious injury to protect against costly medical charges. Comprehensive major medical coverage is a policy that combines basic and major-medical insurance in a single health insurance plan to eliminate gaps in coverage. These plan types are referred to as traditional FFS health care plans. It was common for traditional FFS health care plans to include provisions to share the cost of care with the patient in the form of deductibles, co-payments and coinsurance. A deductible is the amount paid by the enrollee before the insurance company makes any payment. Copayments and coinsurance are fixed proportions that enrollees pay at the time services are rendered. Generally, higher deductibles and coinsurance levels are associated with lower policy premiums. Insurance companies charged employers annual premiums and paid providers on a FFS basis. The cost of a covered service is negotiated between the insurer and the provider. The provider is paid by the insurer each time a particular service is delivered. Patients selected their physician of choice, generally in the local community, received the health care needed along with the bill for services rendered. The charges were submitted to the insurer who would pay the bill (or reimburse expenditures) according to what was accepted as "reasonable and customary" [30]. Rising costs for health care in this type of health insurance coverage gave rise to managed care, and the decline of traditional FFS membership [32]. The number of enrollees in FFS health insurance policies is declining. Traditional FFS health insurance plans preceded managed care.

Managed care is now the dominant form of health care delivery in the US. Unlike FFS plans, managed care plans generally employ resource utilization review as part of performance evaluation and physician compensation. There are several organizational types of managed care

plans. Health maintenance organizations (HMOs) were the earliest form of managed care. Acting as both fiscal agent and provider, HMOs integrate the delivery of health care and provision of health insurance. The central concept is that an annual flat payment is made to a group of providers who delivers care to the HMO membership. HMO practices include use of gatekeepers who manage referrals to see specialists, utilization review to measure adherence to clinical practice guidelines, use of drug formularies and retrospective denial of payments deemed unnecessary [33]. To be profitable, the group of providers had to operate within the annual payment, or capitation arrangement. Otherwise, the practice would lose money. There are four types of HMOs: staff, group, network and independent practice association (IPA). The traditional model is the staff model where the providers are employed by the fiscal agent to provide services to its membership. In the group model, providers band together as a group and contract with the fiscal agent to deliver care to the membership. The network model is similar to the group model except that the fiscal agent has contracts with multiple physician practice groups and can provide a broader range of services by including physician specialties. In the network model, physicians may deliver care to patients who are not part of the HMO membership. In the IPA model, the fiscal agent contracts with a range of private, office-based providers who may have solo practices or operate in specialty groups to deliver care to the HMO membership. As in the network model, IPA providers may also deliver care to non-HMO patients. As originally conceived, capitation arrangements in HMOs models were expected to reduce the cost of health care while providing coverage that lower premiums, fewer co-payments and fewer uncovered services compared to the traditional FFS insurance products. Physicians practicing in HMOs were incentivized to use resources efficiently to remain within the annual capitation payment. Hospital admissions were avoided when possible. However, over time HMOs came under

question as to whether they were emphasizing cost over quality and there were concerns among patients about the restrictions placed on the freedom to select a provider. It is generally accepted that HMOs provide health care at approximately 10% lower cost compared to FFS plans [18].

Evolution in the managed care market led to development of an insurance plan type that was open to members seeking care outside of the restricted list of providers. This plan type is the Point of Service (POS) plan that imposed requirements on members to use certain providers in the network to minimize out-of-pocket costs to the enrollee. A POS plan is another type of managed care group health insurance with characteristics of both an HMO and a PPO. There is more flexibility than in the HMO plans and less than in a PPO. The POS plan type is a hybrid managed care plan that has attributes of both HMOs and traditional indemnity products. Members are allowed to seek health care outside of the network for but at a higher out-of-pocket cost to the patient. In terms of market share in 2000-2001, although the POS managed care plan type had membership that exceeded traditional FFS plans, membership was relatively low compared to other managed care plan types. Members could select out-of-network providers when a specialist was needed, like in a PPO plan. However, additional paperwork was required to submit claims for reimbursement. Most POS plans required members to go through a primary care physician before seeing an out-of-network specialist. The decision to see an out-of-network physician rested on whether the freedom to select a provider was worth the extra premium price. POS plans emphasized prevention and health education similar to that with an HMO, where members were encouraged to participate in programs that lead to healthier choices and lifestyles.

The Exclusive Provider Organization (EPO) is another common type of managed care system. The EPO network is made up of providers which members must choose from, although exceptions may be made for emergency situations. Most EPOs require enrollees to choose a

primary care physician to handle most medical issues and to grant referrals to specialists. EPOs are generally focused on preventative care. EPO carriers are able to negotiate lower rates with health care providers than other types of plans because EPO members are restricted to in-network doctors only. Co-payments are made at each encounter. Monthly premiums and deductibles are common. EPOs are similar to HMOs, in that both types of plans require policyholders to see in-network providers and do not reimburse policyholders if they visit non-network providers. The difference is that EPO rates are based on negotiated fee-for-service rates, while HMOs are capitated on a per-person per-month basis. EPO premiums are generally les expensive than HMOs. EPOs are structurally similar to PPOs; however, EPO members cannot seek reimbursement for claims for non-network office visits, which are permitted by PPO and POS plans. EPOs are beneficial because of their low premiums and copayments and because they can guarantee that policyholders will utilize in-network providers only. EPO networks are also better suited for rural areas, where larger HMO networks have not penetrated. The main disadvantage of an EPO is that it is very restrictive. The network of providers tends to be smaller than in HMOs, and it is nearly impossible to see an out-of-network provider without having to pay 100% all of the medical fees out of pocket. EPOs are well-suited for people who are in good health and have limited need to see out-of-network specialists.

Preferred Provider Organizations (PPOs) offer plans that compete directly with HMOs, especially in markets where insurers are able to persuade providers to offer discounts in return for increased patient volume. PPOs are groups of non-HMO physicians/providers that seek to maintain patient volume in the face of competition form HMOs. PPOs are managed care plans that either limit members to use of a restricted list of providers or provide economic incentives for to use providers who have agreed to offer discounts on services to insurers. Payers negotiate

directly with physicians and hospitals to agree on discounted rates. The expectation of the PPO is greater patient volume. Like HMOs, PPOs use gatekeepers for referrals to specialists, conduct utilization review and generally have requirements for second opinions in certain situations. In PPO plans physicians are paid by a variation of FFS arrangements. The costs of services to be provided are negotiated upfront to set reimbursement rates. Different insurers could have different reimbursement rates. Unlike traditional FFS plans where physicians set costs according to local market pressures, PPOs negotiate with payers to agree on the fee for each service. Advantages of a PPO include the flexibility of seeking care with an out-of-network provider even though out-of-pocket costs are higher for the patient. PPO networks also have prescription services which provide prescription drugs at a reduced cost. The overall premium for a PPO is less than for individual health coverage and often includes more covered medical services. PPOS are available in large networks of medical providers representing large geographic areas. PPOs are not a restrictive as POS and EPO plan types.

2.2. Physician Payment Arrangements

Physicians may be paid in three basic forms: salary, capitation and fee-for-service (FFS). These arrangements are implicit. However, relatively few Managed Care Organizations (MCOs) directly employ physicians and pay them a fixed salary [16]. Although FFS arrangements require administrative resources to process claims for each service delivered, FFS payment resulted in increased utilization (office visits, referrals to specialists and use of diagnostic services) compared to capitation or salary [17]. Under FFS arrangements, the financial risk is held by the payer, that is, the insurance carrier. Contracts may exist between the insurer and the practice, the insurer and individual physician or the practice and individual physician [14]. Under FFS insurance, patients pay a portion of the cost their care and tend to demand marginally

more care sine they do not have to pay the entire cost for the services they received. Physicians are incented to meet the demand by increasing the quantity of medical services delivered. Optimal service use may be exceeded and efficient resource use could be lost [18, 19]. Providers bill charges or an agreed upon fee schedule to the payer (i.e., insurance carrier) for reimbursement for services rendered. FFS is generally associated with provision of more care, more out-patient office visits, and more procedures. Research has shown that practices delivering healthcare predominantly from FFS contracts are positively correlated with physician compensation based upon individual productivity [15]. FFS is also associated with better continuity of care and higher likelihood of adhering to clinical practice guidelines [17].

Managed care insurance plans attempt to remove or minimize excess resource use by applying fixed payments in form of capitation or salary to compensate physicians. The literature indicates that hospital admission rates were reduced by 20% when enrollees changed from traditional FFS insurance to a managed care capitated plans. Rates were also shown to vary among the various forms of managed care plans [18]; however, less is known about the relationships between other managed care plan types, such as PPOs, POS and independent practice associations (IPAs). Studies generally compare capitated HMOs with FFS plans to estimate differences in resource utilization. In addition, studies have tended to focus on physicians and the supply side of health care [19].

Under capitation arrangements, per member per month fees are pre-paid to the physician practice by the insurer. The financial risk is held by the provider [14, 16]. Under capitation, contracts between insurer and practice are most common. Arrangements between the practice and physician are rare [14]. Capitation encourages practices to accept larger patient panels to increase per-patient income while increasing workload and shortening encounters. Should the

existing patient panel consume more resources than the pre-paid amount, the practice loses money. The incentive is to deliver care in a parsimonious and efficient manner. The number hospital admissions is lower, length of stay is shorter, the number of out-patient office visits is lower, fewer prescriptions are written and more referrals to specialists decrease the risk of litigation for malpractice [17, 18]. Under capitation, physicians tend to increase their patient panel size (number of patients using a certain practice for health care) and to decrease the amount of time spent with each patient during an encounter [18, 19]. Practices delivering healthcare predominantly from capitated contracts were positively correlated with physician compensation based upon quality of care [15]. If true, these features of capitation arrangements would suggest differences in quality of care and in the specific types of care delivered to the patient. In addition, capitated or partially capitated plans would have higher total expenditures for direct medical costs than FFS plans [17].

Salary payment to physicians may not provide any incentive to deliver more or less services; however, income is steady and has lower variability compared to FFS or capitation.

In addition to compensating physicians by implicit means under FFS, capitation or salary arrangements, managed care organizations also use explicit financial incentives. Explicit incentives include bonuses and withholdings [34]. Both PPOS and IPAs in the HMO market accept contracts that include explicit provisions for financial incentives, e.g., bonuses [19]. Physicians may be inclined to either increase or decrease the amount of services provided to a patient depending on their overall financial incentives [16].

2.3. Effects of Health Care Insurance Plan Type in Patients with Diabetes

2.3.1. Health Care Utilization

In general, it has been shown that there is a continuum between traditional FFS plans, PPOs, open HMOs (i.e., POS plans) and closed HMOs [35]. In this continuum, the trend is for plans to have increasing levels of management; decreasing levels of cost sharing; increasing levels of primary care utilization; and reduced utilization of specialists. Although there are differences among the various types of managed care plans in terms of resource utilization, the differences may be limited. In fact, managed care plan types may not be all that different when it comes to reasonable use of ER services and inpatient stays.

In patients with Type 2 diabetes, it has been shown that for-profit Group/Network HMO models were more likely to deliver more comprehensive care to patients with diabetes than IPA models [36]. In another study it was shown that physician payment methods result in differing processes of care for patients with diabetes [20]. The probability of receiving assessment for glycemic control, proteinuria, eye exams and foot exams during office visits is greater when physicians are paid by salary compared to reimbursement in either FFS or capitation arrangements [20]. Rates of receipt of appropriate diabetes care and patient satisfaction were predicted to be significantly higher among patients whose physicians were compensated by direct salary rather than by either FFS or capitation arrangements [20]. Capitation is perceived by physicians to discourage provision of services. Providers paid on a FFS basis are not compensated for certain activities, such as, writing referrals, ordering lab tests or counseling patients on the use of aspirin [20]. The incentive is to provide more reimbursable services, not necessarily providing services that would reflect better diabetes care. In a retrospective cohort study of the impact of physician payment method on the quality of care for patients with Type 2 diabetes, the mean quality score was 2.4

(SD 1.2) on a 6-point scale. The quality score outcome variable was based on receipt of standard processes of care in accordance with 6 accepted quality indicators: level of HbA1c, LDL-C, blood pressure control and assessments for nephropathy, retinopathy and foot disease. Quality scores were lower for patients whose physicians were paid according to FFS arrangements compared to other forms of payment method and who were required to act as gatekeepers [16, 29]. These data support the hypothesis that the care of patients with diabetes may be influenced by how physicians are compensated within the benefit plan design features of healthcare insurance coverage.

In a study comparing traditional indemnity plans with IPAs, other types of managed care insurance plans and public plans (Medicare and Medicaid) [37], enrollees in the managed care plans who were under 65 years of age were significantly less likely to experience an ER visit or have an inpatient stay compared to enrollees in the indemnity plans. In this study, the analyses were stratified according to age (i.e., $\geq$ 65 years and < 65 years) to adjust of selection bias. In another study by the CDC Diabetes in Managed Care Work Group, three managed care organizations were compared with respect to resource utilization (ER visits and inpatient stays) as well as ACE inhibitor use for control of hypertension [38]. Utilization rates increased with the number of diabetes related complications and co-morbidities This trend was also observed in that there were more HbA1c tests and dilated eye examinations done as complications and co-morbidities increased.

2.3.2. Medication Adherence

Limited data are available in the literature describing the relationship between health insurance plan type and MPR. Medication adherence is the extent to which patients follow the recommendations of their health care provider [39, 40]. Medication possession can be

considered as a surrogate measure of the level of glycemic control experienced by each patient [11]. These measures assume that a prescription filled is a prescription ingested [41].

For patients with diabetes, reduced adherence to prescription drug therapy may result in worsening conditions and lead to increased out-patient office visits, use of ER services and hospital admission [42]. In a meta-analysis of studies of adherence done between 1948 and 1998, twenty-three (23) studies were identified that included patients with diabetes. The analysis showed that the average adherence rate was 67.5% (95% CI: 58.5, 75.8) [40]. In another recent meta-analysis of adherence to medications prescribed for the treatment of patients with diabetes [39], eleven (11) retrospective studies that included nineteen (19) cohorts showed that the average adherence rate in the diabetic population ranged from 36% to 93%. Adherence rates were decreased in patients with depression (85% vs 93%); were increased with use of once-daily products compared twice daily products (61% vs 52%); and were increased with use of monotherapy compared to polytherapy (49% vs 36%). As a secondary objective, this study also intended to estimate the association between medication adherence and glycemic control. Although limited data for HbA1c are generally available in retrospective cohort studies, it has been shown that non-adherence (<80%) is associated with higher HbA1c [39, 43]. Interestingly, patients with adherence rates ≥80% are considered to be complaint with healthcare provider recommendations. Therefore, over time most patients do not comply with their prescribed medication regimen, especially younger patients with fewer co-morbidities who may be less symptomatic than older patients or patients who have had the longer [43]. Correlation between medication adherence and cost sharing has been recently reported [44]. In this review, the economic impact of pharmacy utilization and glycemic control were summarized. A comparison was made between anti-diabetic medication use by MCOs and indemnity plans. While patients

enrolled in MCOs are more likely to be treated with newer medications, MCOs are also more likely to use cost-sharing in the form of member co-payments, which can reduce medication adherence. It was also reported that in a typical MCO approximately 23% to 32% of patients with diabetes receive insulin therapy, a rate that has fallen significantly since the mid-1990s due to approval of new classes of drugs that improve insulin resistance. During the same time frame, rates for glycemic control has declined from 44.5% to 35.8% despite more treatment options [44]. This trend has been attributed to several factors, including diagnosis at an earlier age, increasing overall prevalence and increase life expectancy in the general population [2, 45].

Other studies described in the literature evaluating the association of medication adherence rates and health insurance plan types in patients with diabetes are limited. In an observational study of the effect that different levels of medication adherence had on the risk of an inpatient stay, health insurance plan type was included in the logistic regression model along with stratified levels of adherence. Insurance plan types were HMO, PPO and traditional FFS [42]. In this study, all-cause inpatient stays were inversely proportional to level of adherence. Diabetics with lower MPR values had significantly increased risk of an inpatient stay; however, insurance plan type had no effect on the risk of an inpatient stay. Other studies confirm that decreasing MPR values are associated with negative clinical outcomes [46] and resource utilization [41] within a single managed care plan. In an observational study of 2995 patients with diabetes within an IPA model HMO, MPR decreasing MPR values were negatively correlated with HbA1c concentrations. As MPR increased glycemic control improved [46]. In a longitudinal cohort study of 775 older patients with diabetes within a Medicare HMO, patient-reported clinical condition, prior health care utilization, life style and quality of life data were combined with administrative claims data. Prior utilization, increasing comorbidity score and use of injectable

medications for treatment of diabetes were each associated with poorer medication adherence [41, 47]. In another observational study of patients 18 years of age and older who were enrolled in a single managed care organization, it was shown that 30% of patients diagnosed with diabetes had a medication possession ratio of <80% and that for each 10% increase in MPR, HbA1c levels were decreased by 0.16% [11]. Sustained exposure to anti-diabetic medication regimens may decrease risk of hospital admission [11], presumably due to the benefits of continuous glycemic control and prevention of episodes related to complications requiring medical care.

2.3.3. Methods of Calculating Medication Adherence

A number of methods for computing medication adherence have been documented in the literature. Measures of adherence have been used as both outcome and predictor variables. In a retrospective cohort analysis of 11,532 patients with diabetes enrolled in a large managed care organization [43], medication adherence was estimated as the proportion of days covered (PDC), where:

PDC = Number of days of supply/number of observation days in the study

As a categorical predictor variable, patients with PDC < 80% were considered non-adherent and those with PDC ≥ 80% were considered adherent. Outcomes were all-cause hospital admission and all-cause mortality. The PDC was estimated based on 7 months of continuous claims data. In this study, patients considered as non-adherent (PDC < 80%) were associated with increased risk of hospital admission (OR = 1.58, 95% CI: 1.38, 1.81) and mortality (OR = 1.81, 95% CI: 1.46, 2.23) compared to patients considered adherent (PDC ≥ 80%) [43]. For each 25% improvement in adherence rate, HbA1c was shown to decrease by 0.05% (95% CI: -0.08%, -0.01%).

In another study, the medication possession ratio (MPR) was used as a predictor of hypoglycemic event counts in a longitudinal retrospective analysis of claims data for 1156 patients converting from insulin injections using a vial and syringe to a pre-filled insulin pen [48]. The MPR was estimated as:

MPR = $\sum$ (days supply)/number of days between 1st and last refill plus days supply for the last refill

The MPR was based on episodes of care. The proportion of patients with MPR >80 % was was significantly improved after conversion to insulin pen therapy (MPR >80%: 69% ± 33% vs 62% ± 28%; $p < 0.01$). In multivariate Poisson regression models of incident rate ratios, improved MPR was a significant predictor of the risk for hypoglycemic events (IRR = 0.34 (95% CI: 0.11, 0.75, $p < 0.05$). This improvement was also associated with significant decreases in measure of utilization including emergency department visits (OR = 0.44, 95% CI: 0.21, 0.92) and physician office visits (OR = 0.39, 95% CI: 0.24, 0.64, $p < 0.05$). The association with hospital admission was not significant. Empirical data showing the impact of different managed care plan designs and patient cost-sharing provisions are limited.

In a study of 2995 patients with diabetes identified with pharmacy claims and who were participating in a diabetes disease management program within an IPA model HMO in South Carolina, the relationship between medication adherence and HbA1c was evaluated [46]. The MPR was estimated as:

MPR = Total days of supply/number of days in the study period

A significant, inverse correlation was found between MPR and HbA1c ($r = -0.285$, $p < 0.001$). As MPR increased, glycemic control improved. This relationship was consistent across orally administered drug classes with and without insulin use.

As with most retrospective studies, claims data are not reliable for measuring adherence to parenteral insulin regimens due the multiple-use nature of some insulin dosage forms [11, 47]. Non-adherence measures may be useful to health plans to optimize disease management program effectiveness.

In a study of 3260 Medicare beneficiaries with chronic, cardiovascular disease medication adherence was used as the dependent variable in a study designed to evaluate health literacy using the Test of Functional Health Literacy in Adults (S-TOFHLA) instrument [49]. Medication adherence was estimated using the Cumulative Medication Gap (CMG), where:

CMG = Number of days medication NOT available between refills/Number of days between 1st and last refills in the study period

The CMG was expressed as the weighted average of each individual gap in the study period. Overall, 40% of patients had low adherence rates with CMG $\geq$ 20%. Patients with poor health literacy skills had 1.37 times the odds (95% CI: 1.08, 1.74) of low refill behavior compared to those with adequate health literacy skills. The CMG measure of medication adherence was reported to be a preferred measure because it does not allow an early medication lapse to be masked by stockpiling. Also, this measure does allow early stockpiling to carry forward to fill a later refill gap.

In all cases described above, it was generally held that adherence to an individual's treatment regimen occurred when the adherence rate or MPR were ≥ 80%, or in the case of medication gaps, when the CMG was ≥ 20%.

2.3.4. Patient Out-of-Pocket-Costs

Diabetes is a costly chronic disease whether considered nationally, at the level of the healthcare system or employers, or that of the patient [50, 51]. Diabetes has been shown to rank among the top 10 most costly conditions to employers in the United States [52]. The American Diabetes Association has estimated that combined national medical expenditures and loss of productivity at work due to diabetes related episodes in 2002 were approximately $132 billion with $31.6 billion paid for services for patients between the ages of 45 – 65 years of age. These expenditures occurred among more than 12 million individuals diagnosed with diabetes [53]. Healthcare spending for patients with diabetes is twice that for patients without the disease, indicating a disproportionate economic burden on diabetics and their families. Approximately 7.5 million patients with diabetes were prescribed oral antihyperglycemic medications and 4 million patients were on insulin [53]. In terms of utilization of healthcare resources, patients with diabetes accounted for approximately 5.8 million in-patient days, 16.7 million out-patient office visits and nearly 1 million ER visits. Over the last decade, total costs are increasing, utilization of in-patient services is decreasing and the economic burden is being shifted to the patient, other facilities or other community based programs outside of hospital organizations. Patients with diabetes spend up to 3 times as much of their disposable income on health care compared to the average consumer [25].

Employers are moving toward lower cost healthcare benefit plan designs with increased cost shifting to the patient in the form of out-of-pocket costs [23]. The goal of cost shifting is to minimize excessive utilization; however, the relationship between OOP costs and utilization of healthcare exhibits price elasticity wherein as OOP costs increase utilization decreases, perhaps to the point where diabetes management processes are impacted in a clinically relevant manner, leading to worsening long-term outcomes and higher overall costs to the system [23, 54]. It has been estimated that a 10% increase in OOP cost results in a 1% to 4% decrease in prescription drug use depending on the class of drug and therapeutic area [24]. Increasing OOP cost is a disincentive to use appropriate and timely disease management services. For example, it has been reported that compared to services offered at absolutely no OOP cost, full-cost services where the patient pays the full amount resulted in lower usage of several key processes of diabetes care; dilated eye examinations, attendance at diabetes educational sessions and practicing self-monitoring of blood glucose were reduced by 12%, 53% and 27%, respectively [23, 55]. These findings were not affected by demographic characteristics, income level, socioeconomic status or comorbidity burden.

Increased OOP costs for prescription drugs also have other untoward effects. The uptake rate for new market entries of prescription drugs is lower because these products tend to be priced at a premium and may not receive quick acceptance on formularies. Discontinuation of current medications may occur or patients may stretch out the time to refill a prescription to save money. The effect of lengthening the time between refills is to create a gap in the therapeutic gain that would be garnered from continuous treatment [24]. On the other hand, some prescriptions may not be filled, whereas, some products have multiple indications for different diseases; however,

this should not be the case for drugs approved for the treatment of patients with diabetes. Lack of medication adherence results in increased illness burden and long term healthcare costs [25].

For patients with diabetes this is especially concerning because time spent out of glycemic control has a cumulative effect over time. Glycemic burden leads to more expensive episodes of complications due to diabetes [56]. In a multivariate analysis of patients with diabetes, cost related adherence to prescribed medications was associated with poorer glycemic control as well as decreased physical and mental functioning as measured by the SF-36 instrument [57]. Specifically, self-reported cost related adherence problems indicated a 0.6% (95% (CI: 0.2%, 0.9%) absolute increase in HbA1c and a -4.5 (95% CI (2.4, 6.6)) point decrease in the SF-36 physical component summary score, which would be analogous to a diagnosis of other chronic conditions such as angina or heart failure [57]. In another study of the use of oral hypoglycemic medications in which increases in the level of cost sharing was the intervention, it was shown that following a large increase (>$10 co-payments) there was a decrease in average daily medication use of -18.5% compared to projected usage had no such increase been enacted [58]. This study suggests that there is a threshold for increases in OOP costs above which patients begin to stretch out prescriptions, skip refills or discontinue medications altogether. For patients with diabetes this can be harmful in the long run because over time therapy with prescription drugs fails as β-cell function declines. Dose increases, use of combinations and the addition of insulin are common in the maintenance of glycemic control. If patients choose to forego proper treatment due to cost related barriers (perceived or real) then time would inevitably be spent out of glycemic control which has a cumulative effect over time leading to more expensive episodes involving of acute complications [45, 56, 59]. In a case study done using healthcare data from a large US employer it has been demonstrated that simple cost shifting to employees lead to large

increases in healthcare expenditures because patients with diabetes were not complying with their regimens. By reallocating anithyperglycemic drugs to tier 1 status on the company formulary, OOP costs were significantly reduced and medication adherence improved. Use of insulin and oral combination therapies decreased from 28% to 55%. Similarly, over time improved medication adherence was shown to decrease the occurrence rates of diabetes related complications and an overall 7% decrease in pharmacy costs with the avoidance of the use of other medications to treat complications [25].

Cost sharing measures are passed along to the health plan member ship in the form of co-payments or coinsurance for prescription drug benefits. Co-payments are flat dollar amounts paid by the patient (e.g., $5, $10 or $15 per prescription). Coinsurance is a percentage rate (e.g., 10%, 20% or 50% of the total charge for filling a prescription).

The goal of treatment is to attain and maintain tight glycemic control to delay the progression of diabetes and to spare the associated increase in cost of care. Maintaining glycemic control, i.e., HbA1c $\leq$ 7 %, requires vigilance on the part of the treating physician as well as the patient. Time spent in an out-of-glycemic-control state is cumulative [45, 59]. By nature of the disease, diabetes progresses over time as β-cell function declines. The likelihood of a patient expressing an HbA1c of more than 8%, then returning to $\leq$ 7% is only 20% [59]. Once diagnosed and a treatment regimen is established, continued monitoring of glycemic control parameters remains an important element of disease management. Over time, most treatment regimens will ultimately fail on glycemic control indicating that changes in regimen are necessary [56]. Physicians may tend to allow patients to remain out of control which, over time, can lead to episodes of complications requiring medical care, more complex treatment regimens and increased costs [45]. Preventing or delaying the gradual upward drift in HbA1c can decrease

cost of care for managing complications. Vigilance is also required to avoid drug-treatment induced hypoglycemia, which is associated with increased utilization and cost of care. It has been reported that episodes of hypoglycemia are responsible for significant proportions of excess emergency visits, hospital admissions and claims for short term disability [13]. The odds of experiencing episodes of hypoglycemia increase with time since diagnosis, especially in patients also experiencing complications of diabetes. Cost sharing is accompanied by the potential to reduce medication adherence and expose patients to unnecessary periods of poor glycemic control.

Patients with diabetes are more prone to having more co-morbidities than patients without diabetes, the presence of which further increase OOP costs. Similarly, care-seeking behaviors and medication adherence rates are diminished as OOP costs rise and disposable income decreases.

2.3.5. Glycemic Control and Processes of Care

Glycemia, measured as plasma concentration of glycosylated hemoglobin (% HbA1c), is considered to be controlled when continually maintained at a concentration <7% [60, 61]. The amount of time patients spend out of adequate glycemic control is cumulative with deleterious effects on the body [59]. In fact, the likelihood that a patient whose diabetes has progressed to an HbA1c level > 8% will return to <7% is only 0.2 (20%) [59]. Increases of HbA1c of 1% were associated with increased costs over a period of 3 years [62]. Similarly, reduced resource utilization, such as hospital admissions, ER visits and outpatient office visits, were reported within 1 year of improved glycemic control, along with decreased costs. Patients with worse levels of glycemic control were associated with greatest cost reductions [63]. Unfortunately, studies have shown that on average physicians tend to allow a lack of glycemic control to persist

before taking action to change the treatment regimen and restore adequate glycemic control [59]. Glycemic control is accomplished through both appropriate self-management and in the delivery of appropriate processes of diabetes care by healthcare providers. HbA_{1c} reflects the average level of glycemia over the preceding 2-3 months. Therefore, regular measurements of HbA_{1c} are necessary to detect values exceeding 7%. HbA_{1c} testing is recommended at least twice a year in patients who are meeting treatment goals. In patients who are not meeting treatment goals HbA1c concentrations should be measured more frequently [12, 61].

In addition to appropriate HbA1c monitoring, other processes of care include routine retinal eye examinations, control of hypertension and correction of dyslipidemia [12, 64]. Hypertension and diabetes are common comorbidities. When they occur together, the risks of both cardiovascular and renal complications are significantly increased [65]. In a retrospective study of patients with Type 2 diabetes enrolled in 10 health insurance plans in 9 states it was shown that patients with comorbid hypertension and Type 2 diabetes frequently did not meet the treatment goal of 130/80 mmHg. More aggressive management of blood pressure was recommended [65]. The standard of care for correction of dylipidemia is treatment with statins. Long-term medication adherence is important for achieving the benefits associated with statin treatment [66, 67]. However, it has been shown that persistence with statin prescription filling behavior declines over time. Persistence was not affected by regimen complexity [66] but was shown to be lowest among women and in those under the age of 65 years [67]. As disease severity increases, especially with patient age, renal function as measured by proteinuria should also be monitored [12]. Patients experiencing more severe retinal changes should be referred to an ophthalmologist who is knowledgeable and experienced in the management of diabetic retinopathy. Hypertension is known to contribute to the development and progression of chronic complications of diabetes.

Control of hypertension has been demonstrated conclusively to reduce the rate of progression of diabetic nephropathy and to reduce the associated complications of hypertensive nephropathy, cerebrovascular disease, and cardiovascular disease. The presence of diabetes increases the risk for atherosclerotic vascular disease. Patients with Type 2 diabetes also have increased risk for obesity and lipid abnormalities independent of the level of glycemic control. Therefore, guidelines for diabetes management treatment of dyslipidemia to reduce the risk of cardiovascular events associated in patients with and without documented coronary heart disease. Good process of care of patients with diabetes includes regular physical activity [13], and a meal plan to lower glucose levels and to normalize lipid patterns. If diet and exercise are not sufficient, lipid-lowering treatment is indicated. Statins are most frequently used in patients with diabetes. The primary goal of therapy for adult patients with diabetes is to lower LDL-cholesterol to $\leq$ 100 mg/dL.

Over time, uncontrolled diabetes can affect renal function [12, 68]. Persistent proteinuria, an early stage of diabetic nephropathy, is a significant marker for cardiovascular disease. As patients with diabetes age, the degree of proteinuria can increase potentially leading to end stage renal disease. Hypertension can exacerbate the progression of renal disease [12]. Acute episodes associated with the advancement of these complications and co-morbidities due to diabetes can lead to increased healthcare resource utilization.

In a study of working age patients with diabetes [69] comparing HMOs, PPOs, POS and a traditional indemnity health insurance plans, HMOs and the indemnity plan consistently covered dilated retinal eye examinations which is an important component of diabetes care. The frequencies for PPOs and POS plans were reported to be 71% and 60%, respectively. These results suggest that there are differences among insurance plan types in terms of the processes of

care that are covered within each plan type. In a study based on TRIAD (Translating Research into Action for Diabetes) [36], HMO organizational models were compared with respect to delivery of appropriate processes of care. Processes of care included dilated retinal eye examinations, lipid profiles and blood pressure control. For-profit HMO models were more likely to deliver appropriate processes of care compared to IPA models. It was suggested that group model HMOs were more likely to implement disease management strategies than IPAs which consist of multiple independent practice practices that share minimal infrastructure.

2.3.6. Oral Prescription Drug Therapies

In the 2000-2001 study period, a number of prescription drugs and numerous insulin preparations were approved for use in the treatment of Type 2 diabetes in the US. As indicated by the information contained in Table 1, approved prescription drug classes included the sulfonylureas, biguanides, thiazolidinediones, α-glucosidase inhibitors and meglitinides. In the 2000-2001 study period an extended release formulation of metformin was available. In addition, the only fixed dose combination dosage form approved for use in the US was the combination tablet containing metformin plus the sulfonylurea, glyburide (Glucovance®). Otherwise, the treatment of Type 2 diabetes was done with concurrent use of individual monotherapies.

Table 1: Approved treatments for Type 2 diabetes (2000-2001)

Drug Class[1]	Active Ingredient
Sulfonylureas	Tolbutamide Tolazamide Glipizide Glyburide Chlorpropamide Glybenclamide
Thiazolidinediones	Rosiglitazone Pioglitazone Troglitazone
Biguanides	Metformin
Meglitinides	Repaglinide
A-glucosidase inhibitors	Acarbose

[1] Adapted from Cohen 2003 [70]

Treatment regimens using these products should strive to maintain glycemia at or near normal without inducing hypoglycemia [13]. Interventions to improve glycemic control are intended to preserve or improve β-cell function, reduce glucose production in the liver and improve peripheral tissue uptake of glucose. Diligence is required because over time it is known that currently available treatment options, while providing appropriate initial glycemic control, will eventually fail as the disease progresses. Measures of glycemia drift upward and β-cell function declines [45, 56, 71]. Based on differing mechanisms of action, different treatments have different effects on β-cell function.

Initial treatment includes increasing insulin secretion from the pancreas using one of the sulfonylureas, which act by stimulating β-cell secretion of insulin. However, the chronic pharmacologic enhancement of insulin secretion in the presence of increased insulin resistance ultimately exhausts the ability of β-cells of secrete enough insulin to maintain normal glucose levels [45]. The meglitinide, repaglinide, also stimulates insulin secretion from the pancreas. The thiazolidinediones (e.g., pioglitazone and rosiglitazone), which interact with nuclear receptors to increase skeletal muscle sensitivity to insulin improving metabolic consumption of glucose, have been shown to consistently improve β-cell function, whereas, sulfonylurea monotherapy (e.g., glibenclamide and chlorpropamide) becomes inadequate after approximately 3 years from the diagnosis of Type 2 diabetes [45]. Over time treatment regimens get more complex, generally beginning with diet and exercise, progressing to oral therapy with prescription drugs as either monotherapy or in various combinations of oral medications with ultimate progression to the addition of insulin [56, 59].

Maintaining glycemic control is accomplished by patients routinely accessing health care resources in conjunction with providers delivering appropriate processes of care during each encounter [72, 73]. Both of these aspects, patients seeking care and providers delivering care are facilitated by the features of health care insurance plans. Benefit plan designs differ in terms of accessibility and out-of-pocket costs to patients with diabetes and the method by which providers are compensated for services rendered [15, 23]. These factors operate at the same time. However, processes of care have been shown to vary according to the design of health insurance plan types in which patients with diabetes are enrolled [20, 36]. It is possible that different health insurance plan types are associated with increasing rates of failure to maintain adequate glycemic control as a result of patient- and provider-related factors. Different methods of delivering processes of care may lead to different outcomes.

2.3.7. Access to Health Care

Ambulatory care sensitive (ACS) conditions, such as Type 2 diabetes, are chronic conditions for which timely and effective out-patient care could potentially reduce the risk of high acuity episodes requiring preventable emergency room visits, hospital admissions and more complex treatment regimens, that result in greater resource utilization, increased healthcare costs and possibly premature morbidity or mortality. As originally conceived, ACS conditions were used to assess the quality of ambulatory care [74, 75]. Access to ambulatory care can be interpreted as reference to possession of health insurance; however, access can also be considered as a construct with a number of dimensions that are linked to the patient and to the provider. Certain factors relate to the delivery of healthcare by healthcare professionals and are related to the continuous, timely, necessary and satisfactory delivery of services [51]. Such factors include:

level of reimbursement, attitude toward risk and propensity to admit, clinical training received, level of integration with community out-patient services and patient willingness to comply with treatment prescribed. Social, non-medical barriers associated with the patient include: lower health literacy, language barrier, educational level, cultural beliefs or attitudes regarding healthcare, home environment stability, time off from work, loss of income due to time off for an office visit, child care, transportation and limited provider settings [76].

A theoretical framework that has been used to evaluate access to healthcare is the Behavioral Model developed in the 1970's [26-28]. Since origination, this model has been applied in diverse settings in studies of differing populations, including Medicare beneficiaries with Type 2 diabetes [77], patients with mental illness or homelessness [78, 79], panic attacks [80]and rheumatoid arthritis [81]. The behavioral model is based upon three factors that impact access to healthcare services: enabling factors which are social in nature (e.g., health insurance coverage and geographic location of residence); predisposing factors, which are inherent in the individual patient and cannot be modified (e.g., age and gender); and need-based factors which can be either perceived by the individual or deemed important by the physician (e.g., self-reported health status or comorbidity burden). The variables that comprise each factor are determinants of access to healthcare are contained in Table 2.

Table 2: Determinants of health care resource utilization, medication possession and appropriate processes of care in patients with Type 2 diabetes derived from the 2000-2001 MarketScan dataset

Need-based Factors	Predisposing Factors	Enabling Factors
Prior Utilization Emergency department visit In-patient stay Receipt of Care Treatment of hypertension Treatment of dyslipidemia Insulin use	Age Sex Comorbidity score Mental health disorder Regimen Complexity	Type of health insurance plan Capitated/Partially capitated Non-capitated POS PPO Traditional FFS Medication possession ratio (MPR)

Need-based factors can be either perceived by the patient or determined by a physician. Need factors include the level of diagnosed and concurrent co-morbidities. Prescription drug use is also a need factor. In this regard, the complexity of the regimen and adherence to prescribed medication therapy are representative of disease progression and care seeking behavior, respectively. Care seeking behaviors also include encounters with the healthcare system, where among other processes of care, prescriptions are obtained. The number of office visits scheduled and kept [82, 83], the frequency of visits to an emergency department [84] and frequency of hospital admission, which can be attributed to the underlying health status of the patient and the severity of their illness [85] are need factors. These variables represent care seeking behavior and the extent to which patients and providers act to regain glycemic control [81]. Avoiding the more severe episodes resulting from lack of glycemic control is important [86].

Predisposing factors are variables inherent in individuals that cannot be readily modified or intervened. Predisposing variables include age, gender and marital status [82].

Enabling factors are sociologic and economic variables that can facilitate access to healthcare. Enabling variables include enrollment in and type of health insurance. Embodied in this determinant, from the perspective of the patient are; freedom to select providers and out-of-pocket costs, whereas from the perspective of the provider are; method of payment for services rendered, quality of care delivered and job satisfaction. Prescription drug coverage, or not, is also an enabling determinant of access to healthcare. Adherence to prescribed medication regimens is central to adequate glycemic control [11].

The Behavioral Model may be used to evaluate the association between type of insurance benefit plan design and steps taken to maintain glycemic control. This model provides a framework that allows determinants to be categorized under each factor described above so the outcomes of statistical analyses can be interpreted according to how variability is explained. For example, if the need based factors are the primary determinants of utilization, then access to healthcare services should be relatively equitable across the patient sample.

2.3.8. Adjustment for Comorbidity

Comorbidity is defined as the concurrent manifestation of two or more diseases that are etiologically independent and not causally linked to the index disease of interest [87]. Co-morbidities may not be related to the reason for hospital admission and are likely to impact mortality and resource utilization. Such conditions can be either acute or chronic in nature [88]. It is important to note that complications, e.g., presence of ketoacidosis in patients with diabetes, are not considered co-morbidities. The presence of increasing numbers of co-morbidities with various levels of severity can be viewed as a partial measure of the underlying health status of individuals in a population [88, 89]. Unlike randomized clinical trials it is not possible to control for differences in patient baseline characteristics by randomization. The goal of adjusting

statistical analyses for the presence of baseline co-morbidities in health services research studies is to minimize the risk of confounding and interpreting inferences with reliability and accuracy [88].

The statistical requirement to control for comorbidity in health services research studies involving patients with diabetes has been understood for many years [90, 91]. In the literature no single stand-out measure of comorbidity based upon administrative claims data has been routinely applied even though many studies have been conducted in this patient population.

Although chart review has been considered the gold standard, this approach can be time consuming and impractical, especially when using large sample sizes [92]. Administrative claims data offer a quicker and less expensive means of estimating the burden of comorbidity. Although use of comorbidity data derived from administrative databases has been criticized for lacking the accuracy required for clinical research compared to controlled clinical trials [92], claims data have been proven to be a reasonable, inexpensive source from which measures of comorbidity can be established [93, 94]. Co-morbidities are captured in administrative claims data in form of ICD-9-CM diagnosis codes, or in some datasets, as prescriptions for medications [95] used to treat co-morbid conditions. In the latter case, prescription drug use patterns can be mapped to diagnoses according to the therapeutic classes of drugs used. Unlike controlled clinical trials which are designed to adjust for differences in baseline disease severity by use of randomization, administrative claims data do not inherently account for baseline differences [88]. Measures of comorbidity have been reviewed in the context of randomized controlled clinical trials [96] and in the context of administrative claims datasets [88].

In an early adaptation of the Charlson [91, 97] comorbidity index in Medicare beneficiaries undergoing lumbar spinal surgery (n = 27,111), the original co-morbidities identified by medical

chart review were mapped to relevant ICD-9-CM diagnosis and procedure codes [98]. The resulting index, after controlling for patient age, was positively associated with multiple outcomes including postoperative complications, mortality, blood transfusion, discharge to nursing home, length of hospital stay, and hospital charges. The Deyo adaptation of the Charlson index has been used as measure of comorbidity in multiple studies [99]. The Charlson index has also been adapted by various authors in attempts to improve the predictive ability of the score [100-102]. The D'Hoore modification is based only on the first three digits of the ICD-9 diagnosis codes [101]. For example, in patients with Type 2 diabetes, the D'Hoore approach would not distinguish between complicated and uncomplicated cases in patients with Type 2 diabetes. The D'Hoore approach to adapting the Charlson index for use with claims data is a simpler score to derive [82, 83, 101].

2.3.9. Propensity Scores and Adjustment for Selection Bias

Patients with Type 2 diabetes select healthcare plans based on the benefits garnered under the plan, as well as, their perceived level of medical care need. At the same time, physicians are paid differently under different types of healthcare plans and their treatment patterns differ, accordingly. These factors work simultaneously. The potential confounding of these factors is also considered. Unfortunately, observational studies based on insurance claims data differ from randomized clinical trials in that it not possible to balance these baseline characteristics of a cohort by randomization prior to attempting to estimate the effect of an intervention of interest [103-105]. In observational studies, patient characteristics are likely to vary in different groups in ways related to patient clinical status, health care seeking behavior and the physician practice patterns [104]. Biases may exist in the claims data that must be accounted for in the analysis.

One technique that has been developed to overcome potential biases is the concept of the propensity score. The propensity score is a conditional probability that a particular individual would be assigned to a particular outcome, which is usually dichotomous. According to propensity score theory, confounding covariates in a retrospective observational dataset can be adjusted for by using logistic regression modeling to compute the predicted probability that individuals with similar likelihoods (or propensities) would be assigned to one of the dichotomous outcomes in the regression model given the covariates available in the dataset [103]. According to Rubin [103] it is important that the outcome variable used play no role (p. 759) and that the prediction of treatment group must involve only the covariates (not the main effects of interest in the study), which generally include demographic characteristics of the cohort (e.g., age and sex) as well as indicators of clinical status (e.g., comorbidity burden and disease severity) [104]; however, the covariates used in the propensity score modeling should be identified as confounders with the dichotomous outcome. As noted by Shah, the test of a good propensity score analysis is not necessarily its goodness of fit or discriminatory nature but whether it adequately balances confounders that can lead to selection bias in the dataset [106].

Propensity scores may be used in three ways in observational studies [104, 106]. These methods are: stratification, matching, and covariate adjustment.

In the stratification approach to propensity score analyses a statistical model (or a propensity score model) is developed, generally a logistic regression model, that includes a rationale set of predictor variables based on the hypotheses being tested and the dataset that is available. The goal is to minimize selection bias. The stratification approach does not require any particular relationship between the dependent variable and the predictors (e.g., linearity). Stratification can also be done using many covariates with confounding characteristics [103]. Each individual

represented in the dataset is assigned a score [103, 104, 107]. The propensity score model is separate from any other models specified for the analyses of the main effects of interest in the current study. The predicted probabilities obtained from the propensity score model are used to stratify the dataset into groups that are of the same size and have substantially similar distributions of predicted probabilities. These groupings are generally in the form of quintiles. The dataset is effectively subdivided into 5 smaller datasets that are matched on propensity score.

Differences between propensity scores within the quintiles can be examined to determine whether they are significant. This is done by determining standardized differences between groups for each covariate used in the propensity score model [104]. The following equations are used:

For continuous variables:

$$\mathbf{d = 100(Mean_{treatment} - Mean_{control}) / Square\ root\ ((s^2_{treatment} - s^2_{control})/2)}$$

For categorical variables:

$$\mathbf{d = 100(p_{treatment} - p_{control}) / Square\ root\ [[p_{treatment}(1-p_{treatment})] + [p_{control}(1-p_{control})]/2)]}$$

Values of "d" exceeding 10% represent meaningful imbalance between treat groups within a quintile.

Once balance within the quintiles has been established, standard regression modeling can be done within each quintile. Comparisons can then be made across the quintiles and compared to the analysis done on the entire dataset. The quintiles 1 to 5 represent an indexed probability of being in one of the groups of the dichotomous dependent variable in the propensity score model. Stratification using quintiles may be expected to remove 90% or more of confounding bias from

the dataset [103]. This is not possible using traditional regression models based on the entire dataset without balancing with a propensity score.

Matching often results is the exclusion of observations when there is no corresponding match in the dataset [104]. Likewise, when balance among confounding variables is achieved with stratification, there is no benefit to include the propensity score directly in statistical models as a covariate [106]. In the propensity score matching method, individuals within in the dichotomous dependent variable used in the propensity score model are matched according to the probability of being assigned to one of the outcomes. Some individuals may need to be excluded from the analysis if a suitable match cannot be made in the opposing outcome group [108]. The matching process may control for a large number of confounders similar to the outcome expected in the randomization into a controlled clinical trial.

In the covariate adjustment approach, again the same predicted probabilities are entered directly into the model specified for the main effects of interest as a single continuous variable that represents the set of covariates used to generate the propensity score. Each individual has a propensity score. Main effects and other covariates may also be used in the analysis [109]. Regression model adjustment for the propensity score is the only method in which the propensity scores are actually used in regression modeling of the main effects of interest in an observational study.

There are many possible combinations of propensity scoring methods, therefore inclusion of specific confounding covariates in the model should be justified [109]. There is no consensus in the literature as to which method is preferable [104, 109]; however, there is consensus that an appropriate propensity score analysis can supplement typical regression analyses on large administrative claims datasets.

As indicated above, the rationale of propensity score analyses must be specified. In the present study in working age individuals with Type diabetes, a frame work for variable selection could be based on the TRIAD (Translating Research Into Action for Diabetes) study [110]. TRIAD was a multicenter prospective cohort study in diverse population of patients with diabetes who were over 18 years of age. TRIAD compared managed care structure to processes of care among 6 study sites and 10 insurance plans, including: staff, network and IPA HMO models, POS plans and PPO plans. Processes of care included: lipid profiling, blood pressure control and other procedures indicated in clinical practice guidelines [12, 61]. The hypothesis tested in TRIAD was whether increased experience with managed care reduced limitations on referrals to specialists, adherence to clinical practice guidelines and use of disease management programs would lead to better processes of care and ultimately better clinical outcomes. TRIAD also acknowledged the potential confounding that may be inherent in studies using administrative claims data. Good diabetes management involves integration of primary care, specialty services and patient self-care. These types of benefits may vary by health insurance plan type. Arrangements for physician payment and specific strategies used an insurance plan may use to limit referrals to specialists may also vary by plan type [110, 111].

The literature based on the TRIAD study was reviewed with respect to published studies that included variables for resource utilization, medication adherence and receipt of appropriate processes of care to develop a set of predictor variables to include in a propensity score model. In a study designed to evaluate whether patients screened for diabetic kidney disease were initiated on an ACE inhibitor or angiotensin converting enzyme inhibitor (ARBs), it was shown that in 5378 patients screened 63% of patients were already being treated with either an ACE inhibitor or an ARB, while the rest of the cohort was untreated [112]. Eighteen percent (18%) of

the cohort was using insulin. This study demonstrated that initiation of blood pressure control may not occur early enough, if at all; however, the study did not evaluate whether there were differences in prescribing patterns by insurance plan type. Because blood pressure control is an important aspect of diabetes management it may be possible that insurance plan selection by patients with diabetes was influenced in way that prevented earlier treatment. Also, the decision to use insulin was not evaluated by insurance plan type; however, it appeared that a decision to initiate insulin was independent of initiating therapy for blood pressure control. Both blood pressure control and glycemic control with insulin may be confounded by selection bias and may be useful in a propensity score analysis. In another study designed to evaluate risk factors for mortality in patients with diabetes, it was shown that increasing age, male gender, smoking and renal disease were significant risk factors for mortality [113]. This study also suggested that increasing comorbidity and blood pressure control were also contributors to the risk of death. Increasing age, severity of comorbidity and blood pressure control may confound each other and could introduce selection bias if patients with more advanced diabetes enrolled in health insurance plans that provided less restrictive access to specialists or other out-of-network providers. Based on these data, age, comorbidity score and blood pressure control may also be relevant in a propensity score analysis. Although diabetes tends to be more prevalent in women than men [114] this study demonstrated that male gender was a risk factor for mortality; however, it was not clear that gender in a diabetic population would influence health insurance plan choice.

In another study based on the TRIAD population, patients with Type 2 diabetes and HbA1c levels $\geq$ 7.2% were evaluated to assess the effects of changes in treatment regimen on clinical outcomes [115]. The effects of treatment intensification were measured using a survey and

medical record review at baseline and after 2 years of follow-up. Predictors of treatment intensification included: age, comorbidity score, the number of visits to a primary care physician and whether a hospital admission occurred. Other baseline characteristics included gender, race, income, education and HbA1c level. Treatment intensification was defined as initiating new class or increasing the number of classes of oral medications or starting insulin. Both increasing age and increasing comorbidity score were associated with worsening glycemic control. Increased utilization in the form of increasing number of primary care physician visits and a hospital admission were associated with improved glycemic control. Changing regimen complexity could influence selection of a health care plan. In addition, this study suggests that age, level of comorbidity, insulin use and regimen complexity could be confounding factors in health insurance plan type selection.

3. STUDY OBJECTIVES AND HYPOTHESES

After controlling for the covariates, the objective of this study was to determine whether health care resource utilization, medication possession rates, and the use of ACE inhibitors and statins differed by health insurance plan type in which adult privately insured patients with Type 2 diabetes were enrolled. FFS plans are generally believed to be associated with delivery of more services than capitated plans. Capitated plans tend to be very restrictive about paying for provider services outside of the accepted list of providers in the network would have lower odds of enrollees making an ER visit or experiencing an inpatient stay compared to members of traditional FFS plans that are based on revenue resulting from increased service utilization. Likewise, capitated plans are generally understood to focus on preventive services to reduce costly episodes of acute care in the future, and often include prescription drug coverage. The first hypothesis was that compared to less restrictive plan types, members of capitated plans would have decreased odds of experiencing an ER visit or inpatient stay. The second hypothesis was that compared to less restrictive plan types, members of capitated plans would have increased odds of having good medication possession behavior. The third hypothesis was that based on these same characteristics of different plan types both capitated and FFS plans would tend to increase the odds of adhering to the standard processes of care as determined by ACE inhibitor and statin use. Capitated plans were expected to be consistent with current clinical practice guidelines which indicate control of hypertension and dyslipidemia, whereas FFS plans were expected to be associated with increased prescription drug use, including prescription of ACE inhibitors and statins to patients with Type 2 diabetes. Thus it was hypothesized that no differences would be observed among the plan types for ACE inhibitor and statin use.

Alternatively, ACE inhibitor and statin use in year 2001 may not have been uniform among different health insurance plan types.

4. METHODS

4.1. Data Source

The 2000-2001 MarketScan Commercial Claims and Encounters administrative claims database (available from MedStat; Ann Arbor, MI) was used in this retrospective study of adult patients with Type 2 diabetes. This 2-year database contains inpatient, outpatient and pharmacy insurance claims information on approximately 2.5 million covered lives in the United States. Patients of working age between 18 and 64 years were included in the study cohort. The individual patient was the unit of analysis. To be eligible for inclusion in the analytic file, patients must have been continuously enrolled in their health insurance plan throughout the study period.

4.2. Population

A patient's index date is the first date in the claims data at which the inclusion criteria were met for a diagnosis of Type 2 diabetes. The Index Date must have occurred in the first half of the year 2000. Patients were excluded if they had an inpatient admission prior to the index date of the study or were pregnant or admitted for child birth. Patients with Type 2 diabetes were identified in the dataset according to both outpatient and inpatient claims for reimbursement using the methodology reported by O'Connor [116]. A patient was considered to be diagnosed with Type 2 diabetes if the claims record included at least one of the three following criteria: at least one inpatient hospitalization with a diagnosis of diabetes; two outpatient encounters with a primary ICD-9-CM diagnosis code specific for diabetes; or a prescription for an anti-hyperglycemic medication in 2000 – 2001. A primary diagnosis of diabetes was defined as the ICD-9-CM code 250.x. Microvascular complications of diabetes included ICD-9-CM codes

250.5 (renal), 362.0x (ophthalmic), 366.41 (ophthalmic), 250.6 (neurological) and 357.2 (neurological). This method has demonstrated a sensitivity of 0.91 and a specificity of 0.99 for the identification of patients with Type 2 diabetes in an HMO claims database [116].

4.3. Main Effects

In the analyses presented below, health insurance plan type was the main effect of interest. Possession of health insurance coverage is an enabling factor according to the Behavioral Model of access to health care. The MarketScan dataset includes provisions to collect variables for seven (7) different health insurance plan types: Traditional FFS plans - Basic/Major Medical and Comprehensive policies, and Managed Care plans: EPOs, HMOs, POS (with either capitation or FFS physician payment arrangements) and PPOs. With the potential availability of 7 different plan types, it was necessary to consider appropriate ways to consolidate the plan types into fewer categories, as has been done in other studies using the MarketScan dataset [117]. Categories were created to reflect decreasing levels of restrictiveness on seeking care from specialists or other out-of network providers, where capitated plans would be expected to be most restrictive and traditional FFS plans would be least restrictive. PPO and non-capitated POS plans would be intermediate with respect to restrictiveness. The four consolidated insurance plan type categories were:

1 - HMO plans (capitated) and POS plans (capitated/partially capitated) and;

2 - Non-capitated POS plans (POS);

3 - Preferred Provider Organizations (PPO) plans;

4 - Traditional FFS arrangements: Basic/Major Medical and Comprehensive plans (FFS)

In the analyses below, the plan types were referred to as "capitated", "POS", "PPO" and "FFS" to reflect decreasing level of restrictiveness for accessing out-of-plan health care service use.

4.4. Dependent Variables

4.4.1. Health Care Resource Utilization

Parameters used to estimate the relationship between health care resource utilization and health insurance plan type were the odds of ER visits and inpatient stays in the cohort of patients with Type 2 diabetes that occurred in the year 2001. Resource utilization was considered a need-based factor according to the Behavioral Model of access to health care. Categorical variables were constructed for the resource utilization variables as part of the process of identifying patients with Type 2 diabetes in the study cohort.

4.4.2. Medication Possession

The dependent variable in this study was odds that patients with Type 2 diabetes had "good" medication possession behavior. Medication possession was considered an enabling factor according to the Behavioral Model of access to health care. Medication possession [42] is a measure of patient access to and acquisition of prescription drugs for certain conditions. MPR was considered an enabling factor according to the Behavioral Model of access to health care. In this study, medication possession was evaluated in a cross-sectional analysis of the entire 2-year study period because the observation of prescription filling behavior requires at least 6-9 months of longitudinal claims data [11, 118]. Oral anti-diabetic medications were identified in the MarketScan dataset using product NDC numbers for products that were commercially available in the first six months of the study period (Table 1) [70]. Medication possession ratios (MPR) were generated by first computing a continuous variable based on oral anti-diabetic medications

included in the dataset, where the MPR is the sum of days of supply of a particular oral anti-diabetic medication divided by the number of days between the first and last prescription fill dates plus the number of days for the last refill:

MPR = Σ(days supply)/#days between 1st & last refill + days supply for last refill

This continuous variable was then dichotomized according to the definition of "good" medication possession, i.e., whether the MPR was greater than or equal (good) to 0.8, or not (poor). If more than one medication was found for a single patient, separate MPR values were computed for each active ingredient, then averaged for those patients on multiple medications. This was the index MPR for oral antihyperglycemic medication. MPR values were computed only for oral anti-diabetic medications, not for ACE inhibitors, statins or insulin. Computing accurate MPR values for insulin use was not possible using administrative data because the variability in daily insulin regimens was not captured in the administrative dataset [11, 46, 47].

Because it is not possible to know with certainty that patients actually take their medication despite a high MPR, a sensitivity analysis was done to examine the effect of dichotomizing the MPR using different cut-off values to define "good" and "poor" medication possession behavior and to further evaluate the influence of plan type on medication possession. This was done by dichotomizing the continuous MPR variable the additional cut-off values: ≥ 0.5, ≥ 0.7, ≥ 0.9, and 1.0. Models 1 and 2 specified for MPR were then repeated at each new cut-off for the definition of "good" Models were used to examine the effect by plan type at each level of "good" for the definition of medication possession.

4.4.3. Processes of Care – ACE Inhibitor and Statin Use

Use of ACE inhibitors and statins in study year 2001, represented the standard of care of patients with Type 2 diabetes [12]. Receipt of the standard of care is an enabling factor according to the Behavioral Model of access to health care. Two additional dependent categorical variables were constructed to reflect whether patients were receiving treatment for hypertension and dyslipidemia as specified in the 2000 treatment practice guidelines as a function of health insurance plan type [119]. ACE inhibitor and statin use in 2001 were evaluated by health insurance plan type. Prescriptions for ACE inhibitors and statins were identified using the National Drug Codes (NDC numbers) contained in the MarketScan dataset for these medications that were commercially available in the study period. MPR values were not computed for these therapies.

4.5. Covariates

A series of covariates was used to adjust for potential biases and confounders in the analyses. This set of variables was referred to as "the covariates" in the analyses presented below.

Models were adjusted for demographic variables, age and sex. Age was used as a continuous variable.

The MarketScan dataset covers years 2000-2001. To account for the possibility that individuals who were eligible for entry into the analytic file in year 2000 and may remain in the dataset but switched to another plan type during the study period, a categorical variable was created to indicate whether individuals remained in their existing plan or switched to another plan type.

A categorical variable was created to indicate prior resource utilization according to whether patients experienced either an ER visit or inpatient stay, or not [120] in study year 2000. This

variable was created in the process of identifying patients with Type 2 diabetes and was used to adjust models of the effect of health insurance plan type for prior health care resource utilization.

Except when MPR was the dependent variable in the analysis of medication possession (see section 4.4.2), this categorical variable was used as a covariate in all other models. To adjust for the possibility that oral medication regimens for glycemic control could be changed or intensified in the remaining 18 months of the study period, the actual count of all non-index medications prescribed for treatment of Type 2 diabetes was determined after the index MPR was computed [115]. This variable was constructed as a simple count of the number of new drugs added to or switched from the index regimen. Non-index medication counts were aggregated into values of 0 (no new medications for diabetes added), 1 (one medication added), or ≥ 2 (two or more medications added). The counts were used in the main statistical models of the effect of insurance plan type as a continuous variable.

The presence of comorbidities reflects the concurrent manifestation of two or more diseases that are etiologically independent and not causally linked to the index disease of interest [87]. It is important to note that complications, e.g., presence of ketoacidosis in patients with diabetes, are not considered co-morbidities. The presence of increasing numbers of co-morbidities with various levels of severity can be viewed as a partial measure of the underlying health status of individuals in a population [88, 89]. Unlike randomized clinical trials it is not possible to control for differences in patient baseline characteristics by randomization. The goal of adjusting statistical analyses for the presence of baseline co-morbidities in health services research is to minimize the risk of confounding and to be able to interpret inferences with greater reliability and accuracy [88]. Although review of the recent literature suggests that the Charlson Comorbidity Index [97], as adapted by Deyo [98] has been the most frequently used measure of

comorbidity in studies of patients with diabetes [41, 121-123]; the D'Hoore modification was used in the present study based on its simplicity [82, 83, 99, 101]. This comorbidity score is based on only the first three digits of the ICD-9 codes in the claims dataset. Therefore the D'Hoore modification captures all patients with diabetes but cannot distinguish between complicated versus uncomplicated diabetes. In the present study it was not essential to make this distinction, and the D'Hoore modification has similar characteristics compared to other adaptations of the Charlson score [99]. Likewise, the literature does not recommend use of a particular measure of comorbidity when administrative claims data are used even though many studies have been conducted in patients with diabetes. Because the Charlson comorbidity index includes diabetes which has a weight of 2 in this scoring system, all patients in the final analytic file were assigned a default comorbidity weight of at least 2 [124]. Higher scores are correlated with increased risk of 1-year mortality. The comorbidity score was a continuous variable computed for study year 2000. Comorbidity burden was considered a need based factor in the Behavioral Model of access to health care.

Diabetic patients diagnosed with mental health conditions, especially depression, have been shown to receive more healthcare services on a cumulative basis than diabetics without mental disorders but are less likely to receive complete diabetes-specific care [125]. The proportion of patients with poorer glycemic control increases with the presence of concurrent mental health conditions [126]. Patients with diabetes have twice the odds of having depression compared to the general population and have been shown to have increased resource utilization, such as increased rates of hospital admission, ER visits and out-patient office visits, along with increased costs [127]. Likewise, patients with mental health conditions may be less able to adhere to diabetes self-management behaviors, such as, diet, medication compliance and keeping out-

patient office visit appointments. [122]. Although a significant proportion of patients, i.e., >2% with mental health conditions is not anticipated to be found in the population represented in the MarketScan database, a categorical indicator variable was constructed for the analyses to adjust for whether a patient with Type 2 diabetes was also diagnosed with a mental health condition [125, 126, 128]. For this study, patients will be considered to have a mental health condition, if any of the following ICD-9-CM codes are present in any of the diagnosis fields (dx1 – dx15) in the MarketScan dataset [129]:

Anxiety disorder: 293.84, 293.89, 300.00-300.09, 300.2-300.30, 300.90, 308.30, 309.81

Substance abuse disorder: 291-292.90, 303-305

Although it was not possible to determine the exact insulin regimen that diabetics used during the study period, a categorical variable was constructed to adjust the models for insulin use, or not. This variable was used to control for disease progression and regimen complexity [11].

As in study year 2001 for the processes of care dependent variables described above, use of ACE inhibitors and statins in study year 2000 also represented the standard of care of patients with Type 2 diabetes [12]. To adjust the logistic regression models for treatment of dyslipidemia and hypertension in 2000, categorical variables were constructed to reflect whether patients were receiving prescriptions for statins and ACE inhibitors as specified in the 2000 treatment practice guidelines [119]. Prescriptions for statins and ACE inhibitors were identified in pharmacy records contained in the MarketScan dataset using the National Drug Codes (NDC numbers) for these medications that were commercially available in the study period. MPR values were not computed for these therapies.

4.6. Propensity Score Analysis to Control for Selection Bias

Each of the models specified below for health care resource utilization, MPR and current processes of care were also evaluated using a propensity score analysis. In the propensity score analysis, a separate unique logistic regression model was developed based on published data from the TRIAD study [110]. Propensity scores were derived from a logistic regression model of the odds of choosing between health care plan types based on how restrictive plans are with respect to seeking care from out-of-net-work providers. The four plan type categories, non-capitated, POS, PPO and FFS were recoded into two groups – the most restrictive plan types - (HMO and capitated POS plans) and the least restrictive plan types – (traditional FFS plans, PPO and non-capitated POS plans). The propensity scores were patient level probabilities that an individual selected a particular insurance plan type given their health status at the time. The variables derived from the TRIAD study for inclusion in the propensity score model were: age, comorbidity score, insulin use, ACE inhibitor use and regimen complexity. These variables represent factors that could influence selection of a particular health insurance plan type and confound the analyses. For the propensity score analysis, non-index medication count was used as a categorical variable where 0 indicated no additional medications for glycemic control were added to a regimen, and 1 indicated that one or more new classes of drugs were added to a regimen.

The predicted probabilities from the regression model (i.e., the propensity scores) were then used to stratify the dataset into quintiles. Quintile 1 represents individuals with the lowest propensity (probability) of being enrolled in more restrictive plan types (i.e., more likely to be in a FFS plan type). Quintile 5 represents individuals with the highest propensity (probability) of being enrolled in more restrictive plan types (i.e., more likely to be in a capitated plan type). The effect

of health insurance plan type on each of the dependent variables was compared between the overall dataset and within each quintile of the dataset adjusted for individual propensity scores. The distribution of propensity scores within each quintile were anticipated to substantially overlap within the re-coded groups ranging from lowest to highest levels of restrictiveness to access health care form out-of-network providers.

4.7. Analyses and Model Specification

4.7.1. Health Care Resource Utilization

Multiple logistic regression models were used to estimate the odds of an ER visit or an inpatient stay according to insurance plan type, the main effect of interest. For each dependent variable, the models were adjusted for insurance plan type with and without further adjustment for the covariates. Four equations were specified:

Model 1 – Odds of ER visit in year 2001; adjusted for plan type only

Model 2 – Odds of ER visit in year 2001; adjusted for plan type and the covariates

Model 3 – Odds of admission in year 2001; adjusted for plan type only

Model 4 – Odds of admission in year 2001; adjusted for plan type and the covariates

4.7.2. Medication Possession

Cross-Sectional Analysis of Medication Possession Ratios

Multiple logistic regression models were specified to estimate the odds of MPR exceeding 0.8 for oral antihyperglycemic therapy in the study period by insurance plan type. Two equations were specified:

Model 1 – Odds that MPR is ≥ 0.8; adjusted for plan type

Model 2 – Odds that MPR is ≥ 0.8; adjusted for plan type and the covariates

Effect of varying the cut-off value to define "good" MPR

A sensitivity analysis was done to examine the effect of dichotomizing the MPR using different definitions of "good" and "poor" to further evaluate the influence of plan type on medication possession. The continuous MPR variable was also dichotomized at ≥ 0.5, ≥ 0.7, ≥ 0.9, and 1.0. Then Models 1 and 2 for MPR specified in this section were repeated at each new cut-off for the definition of "good" Models were used to examine the effect by plan type at each level of "good" and "poor" definition of medication possession.

4.7.3. Processes of Care

According to the ADA Standards of Care for the year 2001, the appropriate processes of care were specified as control of hypertension and correction of dyslipidemia, regular determination of HbA1c, retinal eye examination, lipid profile testing [130]. The standard of care for hypertension and dyslipidemia is routine use of ACE inhibitors and statins. The data set was queried to ascertain whether patients filled prescriptions for an ACE inhibitor or a statin, as available in the study period. The products available were identified by NDC number. Multiple logistic regression models were specified to estimate the odds of ACE inhibitor and statin use in study year 2001 by plan type, as follows:

Model 1 – Odds of ACE inhibitor use in year 2001; adjusted for plan type only

Model 2 – Odds of ACE inhibitor use in year 2001; adjusted for plan type and the covariates

Model 3 – Odds of Statin use in year 2001; adjusted for plan type only

Model 4 – Odds of Statin use in year 2001; adjusted for plan type and the covariates

All of the logistic regression models were analyzed using SPSS version 17.0. The variables were constructed using SAS version 9.1. The capitated plan type was referent in all regression analyses of the effect of health insurance plan type.

5. MAIN RESULTS SUMMARY

5.1. Health Insurance Plan Type Consolidation

Although the MarketScan data base was designed to capture data from up to seven (7) different health insurance plan types, the 2000-2001 dataset used for this study only contained data from five (5) categories for patients with Type 2 diabetes as indicated by the information contained in Table 3. In this dataset there were no occurrences of either the Basic/Major Medical or EPO plan types.

Table 3: Unconsolidated health insurance plan types for patients with Type 2 diabetes contained in the 2000-2001 MarketScan dataset

	Frequency	Percent
HMO (capitated)	2781	4.5
POS (capitated)	14251	22.9
EPO (FFS)	0	--
POS (FFS)	11496	18.5
PPO (FFS)	19063	30.6
Comprehensive FFS	14621	23.5
Basic/Major Medical	0	--
Total	62212	100.0
Missing	31	--
Total	62243	100.0

Based on the frequencies of the plan types that were available in the data set, the capitated plan types (HMO and capitated POS) were consolidated into a single category (all capitated plans). Thus, the consolidation of the capitated plan types used in the main analyses of the effects of health insurance plan type on each of the dependent variables resulted in four categories as shown in Table 4.

Table 4: Consolidated health insurance plan types used in the main analyses

	Frequency	Percent
All Capitated	17032	27.4
POS (FFS)	11496	18.5
PPO (FFS)	19063	30.6
Comprehensive FFS	14621	23.5
Total	62212	100.0
Missing	31	--
Total	62243	100.0

5.2. Characteristics of the Study Cohort

The characteristics of the study cohort are contained in Table 5. As expected with the inclusion criterion that individuals must be enrolled continuously in their health insurance plan type throughout the study period, fewer people were observed in year 2001 compared to year 2000. The average age of the cohort was 52.9 years and was 53.4% male. The frequency of inpatient stays in study year 2001 was 14% compared to 7.5% in study year 2000). The observed frequency of ER visits was very low in both study years with a total of only 168 visits documented in 2001. The frequency of diagnosis for mental health conditions was higher in year 2001 (9.6%) compared year 2000 (1.6%). The proportion of individuals using insulin was slightly lower in study year 2001 (24.7%) compared to 2000 (29.3%). The frequency of both statin and ACE inhibitor use was also higher in year 2001 (35.0% and 33.6%, respectively) compared to year 2000 (26.4% and 28.6%, respectively). The proportion of individuals enrolled in FFS healthcare plans was lower in study year 2001 (19.8%) compared to 2000 (23.5%). The proportion of individuals in the other three healthcare plan types was similar in both study years 2000 and 2001. Approximately 6% of patients with Type 2 diabetes (n = 3174) switched plan

types between 2000 and 2001. The comorbidity scores were approximately the same in both study years. All individuals in the sample had a minimum score of 2 as a result of having Type 2 diabetes. The mean comorbidity scores were 2.13 and 2.44 in study years 2000 and 2001, respectively. Other than having Type 2 diabetes, the comorbidity burden was relatively low in the study cohort. MPR was expressed in several ways. First, the average MPR overall was 82.4%, which indicates that on average medication possession was good. Second when the cut-off for "good" and "bad" medication possession was varied from 50% to 100% the proportion of patients with "good" MPR decreased as the cut-off value increased to 100%. Non-index medication count was used to adjust for the existence of more complicated treatment regimens. Values for non-index medication count ranged from 0 to 5 in the dataset; however, the frequencies for the addition of 3, 4 and 5 new medications to any treatment regimen were very low. Therefore frequencies greater than 2 were aggregated to values of 0, 1 and ≥ 2 for use in the analyses. Only 7.0% of the study cohort was taking two or more non-index oral medications for Type 2 diabetes. Non-index medication count was used as a continuous variable in the main analyses of the effect of insurance plan type. In the propensity score analysis, non-index medication count was dichotomized into two categories where values of 0 and 1 referred to no additional medications added (0) and one or more new medications added (1) as an estimate of regimen complexity. The variable for the propensity score was computed as the predicted probability of whether an individual was enrolled in more restrictive plans (i.e., capitated plans) or less restrictive plans (i.e., FFS plans). On average, the propensity score was 0.459. In other words, the likelihood that an individual was enrolled in a more restrictive plan type was approximately a 45.9%. The propensity score ranged from 0.313 to 0.978.

Table 5: Characteristics of the study cohort

Variable	Frequency, year 2000	Frequency, year 2001
Age in years, mean (SD)	**52.9** (9.2)	
Sex (% male)	**53.4%**	
In-Patient Stay (% with ≥ 1 overnight stays)	**7.5%** (4686/62243)	**14.0%** (7298/52250)
ER Visit (% with ≥ 1 ER visits)	**0.04%** (27/61257)	**0.3%** (168/51131)
Mental Health Condition (%)	**1.6%** (994/62243)	**9.6%** (4932/51263)
Insulin Use (%)	**29.3%** (18209/62243)	**24.7%** (15347/51501)
Statin Use (%)	**26.4%** (16407/62243)	**35.0%** (18048/51501)
ACE Inhibitor Use (%)	**28.6%** (17822/62243)	**33.6%** (17297/51501)
Insurance Plan Type Category		
Capitated (referent)	**27.4%** (17032/62212)	**27.9%** (14361/51446)
POS	**18.5%** (11496/62212)	**18.1%** (9313/51446)
PPO	**30.6%** (19063/62212)	**34.2%** (17573/51446)
FFS	**23.5%** (14621/62212)	**19.8%** (10199/51446)
Switched Plans (%)	**6.2%** (3174/51446)	
Comorbidity Score, mean (SD)	**2.13** (0.57)	**2.44** (1.45)
Medication Possession (% "Good")		
Overall Mean MPR (SD)	**0.824** (0.205)	
MPR ≥ 50%	**90.8%** (38752/42689)	
MPR ≥ 70%	**77.7%** (33172/42689)	
Index MPR ≥ 80%	**67.0%** (28587/42689)	
MPR ≥ 90%	**50.4%** (21501/42689)	
MPR ≥ 100%	**19.0%** (8107/42689)	
Non-Index Medication Count (%)		
0	**62.5%** (26883/42966)	
1	**30.5%** (13088/42966)	
≥ 2	**7.0%** (2995/42966)	
Regimen Complexity[1]		
No new oral medications added	**62.6%** (26883/42966)	
≥ 1 new medications added	**37.4%** (16083/42966)	
Propensity Score (Range)	**0.459** (0.313-0.978)	
(n = 42966)		
Quintile 1 (n)	9068	
Quintile 2 (n)	8414	
Quintile 3 (n)	8518	
Quintile 4 (n)	8558	
Quintile 5 (n)	8408	

[1] Regimen complexity was defined as whether subjects in the cohort had at least 1 new oral medication added to their non-index medication regimen

The pattern of the plan type switches is shown in Table 6. Of the total 3174 plan type switchers, 66.3% were due to patients leaving traditional FFS plans. The most frequent switch was from the Comprehensive FFS plan type to the PPO plan type (55.8% of all switches in the study period).

Table 6: Frequency of plan type switching among patients with Type 2 diabetes

Plan Type in 2000	Switched to:	N	%
HMO (capitated)	Comprehensive FFS	2	2.6
	POS (FFS)	18	24.0
	PPO (FFS)	35	46.7
	POS (capitated)	20	26.7
	Total	75	100
POS (capitated)	Comprehensive FFS	137	32.8
	HMO (capitated)	12	2.9
	POS (FFS)	192	45.9
	PPO (FFS)	77	18.4
	Total	418	100
POS (FFS)	Comprehensive FFS	4	1.6
	HMO (capitated)	2	0.7
	PPO (FFS)	35	13.6
	POS (capitated)	217	84.1
	Total	258	100
PPO (FFS)	Comprehensive FFS	201	62.7
	HMO (capitated)	10	3.1
	POS (FFS)	20	6.5
	POS (capitated)	89	27.7
	Total	320	100
Comprehensive (FFS)	HMO (capitated)	2	0.1
	POS (FFS)	94	4.5
	PPO (FFS)	1772	84.2
	POS (capitated)	235	11.2
	Total	2103	100
Total No. Switches			3174

The frequencies of each dependent variable (study year 2001) by insurance plan type are contained in Table 7. These data indicate that there were significant differences between health insurance plan type and the primary outcomes of this study, and confirms that the frequency of ER visits in the study period was low. The POS insurance plan type had the lowest frequencies and proportions of each dependent variable. The capitated insurance plan type had the highest medication possession rate compared to the other insurance plan types.

Table 7: Frequency and proportion of individuals for each dependent variable by health insurance plan type

Dependent variable [1]	FFS	Capitated	POS	PPO	Total	p-value[2]
ER Visit	60 (0.5%)	53 (0.4%)	18 (0.2%)	37 (0.2%)	168	<0.001
In-Patient Stay	1791 (14.7%)	1940 (13.4%)	1237 (13.2%)	2325 (14.4%)	7293	0.001
Index MPR, 80%	6320 (64.5%)	8429 (70.1%)	4942 (64.4%)	8882 (67.5%)	28573	<0.001
ACE Inhibitor Use	4149 (34.7%)	4653 (32.6%)	3019 (32.6%)	5464 (34.2%)	17285	<0.001
Statin Use	4318 (36.1%)	5380 (37.7%)	2633 (28.4%)	5708 (35.7%)	18039	<0.001

[1] Dependent variables are for year 2001, except for the MPR analysis which was cross-sectional over the two year study period

[2] Chi-Square statistics for differences between plan types

5.3. Development of the Propensity Score Analysis

A propensity score was computed for each individual in the cohort. These propensity scores were used to adjust for possible selection bias in health plan type enrollment. A predisposing variable (age), need-based variables (insulin use, comorbidity score and regimen complexity) and an enabling variable (prescription for an ACE inhibitor) were entered into the logistic regression model. The regression parameter estimates are contained in Table 8.

Table 8: Logistic regression analysis results for computing propensity scores: Odds ratios (Capitated plan type was referent)

			95% C.I. for OR[1]	
Variable	**p-value**	**OR**	**Lower**	**Upper**
Age	0.000	0.97	0.967	0.972
ACE Inhibitor Use	0.015	0.95	0.91	0.99
Insulin Use	0.000	1.22	1.16	1.29
Comorbidity Score	0.000	1.44	1.38	1.50
Regimen Complexity	0.009	1.06	1.01	1.10

[1] OR = Odds Ratio

The predicted probabilities obtained from this logistic regression model were saved and used to stratify the dataset into quintiles. As shown in Figure 1 the ranges of actual values of the propensity scores were broader in quintile 1 and quintile 5. However, the box plots demonstrate reasonable overlap of propensity scores within all 5 quintiles. Quintile 1 represents individuals with the highest likelihood of enrolling in a traditional FFS health insurance plan. Conversely, quintile 5 represents individuals with the lowest likelihood of enrolling in a traditional FFS health insurance plan. Descriptive statistics of the propensity score quintiles are contained in Table 9. These data also indicate that quintile 1 and quintile 5 had broader ranges of propensity scores compared to quintiles 2, 3 and 4.

Table 9: Descriptive statistics for the five quintiles of the propensity score

	Predicted Probability of Enrollment in a Capitated Plan		
Quintile (n)	**Minimum**	**Maximum**	**Mean (SD)**
1 (9068)	0.3130	0.3394	0.3813 (0.0170)
2 (8414)	0.4010	0.4300	0.4160 (0.0087)
3 (8518)	0.4309	0.4653	0.4478 (0.0099)
4 (8558)	0.4666	0.5089	0.4855 (0.0127)
5 (8408)	0.5094	0.9780	0.5694 (0.0578)

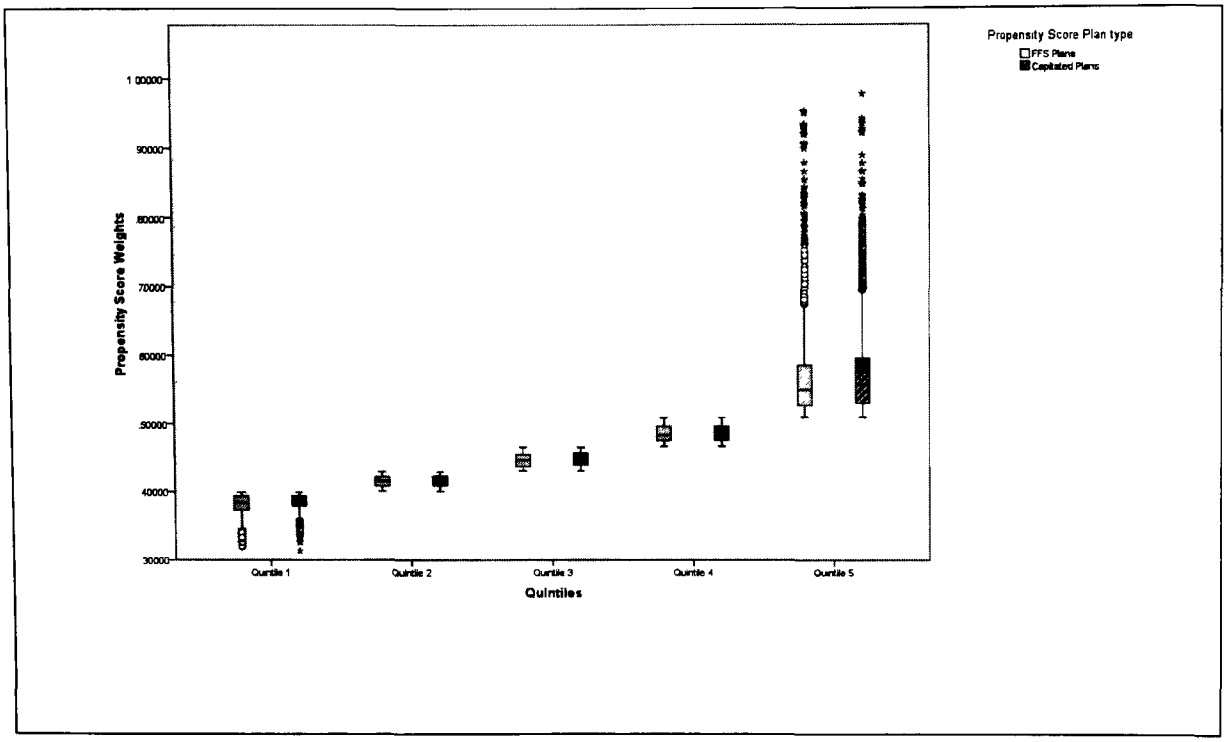

Figure 1: Propensity score overlap within quintile

Standardized distances were computed for each instance [104]. As shown in Table 10, there were only two instances of statistical imbalance where the standardized difference was ≥ 10 in any of the propensity score quintiles based on standardized differences between capitation, or not. Both instances occurred for comorbidity score and were in quintile 4. Therefore, the propensity scores were considered to be reasonably well balanced within each quintile.

Table 10: Evaluation of the balance between quintiles based on standardized differences for continuous and categorical variables used to compute propensity scores

Propensity Score Quintile	**1**		**2**		**3**		**4**		**5**	
Variable	**Cap**	**FFS**	**Cap**	**FFS**	**Cap**	**FFS**	**Cap**	**FFS**	**Cap**	**FFS**
Age (mean ± SD)	62.0 (2.3)	62.2 (2.2)	58.8 (2.5)	58.8 (2.5)	54.9 (2.6)	54.9 (2.5)	51.1 (3.9)	50.8 (3.4)	44.5 (8.4)	44.1 (8.0)
Standardized Difference[1]	7.5		3.2		0.0		8.5		4.4	
ACE inhibitor use (%)	5.6	10.6	8.5	11.8	9.7	11.7	10.6	10.5	12.0	9.0
Standardized Difference	2.4		1.3		0.2		0.2		0.6	
Insulin Use (%)	15.0	28.5	7.3	9.8	7.0	8.2	5.5	4.9	8.0	5.7
Standardized Difference	4.0		0.2		0.6		4.7		1.9	
Comorbidity Score (mean ± SD)	2.00 (0.00)	2.00 (0.00)	2.00 (0.06)	2.00 (0.07)	2.02 (0.15)	2.01 (0.12)	2.09 (0.29)	2.05 (0.23)	2.51 (0.99)	2.41 (1.02)
Standardized Difference	0.0		0.0		7.5		**15.5**		**10.0**	
Regimen Complexity (%)	7.6	13.3	8.5	11.6	9.4	11.5	9.8	10.4	10.3	7.5
Standardized Difference	1.0		0.2		2.0		3.3		2.5	

[1] Standardized differences for each variable within each quintile used to compute propensity scores [104, 107]

5.4. Health Care Resource Utilization

The results of logistic regression analysis of ER visits in study year 2001, unadjusted for the covariates (Model 1) are contained in Table 11. These data indicated that there was no significant difference between the odds of an ER visit for individuals in FFS plans compared to capitated plans; whereas, individuals in both PPO and POS plans were significantly less likely to experience an ER visit (OR = 0.62, p = 0.027 and OR = 0.52, p = 0.019, respectively).

The covariates were then used to adjust Model 1. The results obtained from the adjusted model (Model 2) are shown in Table 12 below. After adjusting for the covariates, the data indicated that the significant differences observed between PPO and POS plans compared to capitated plans were no longer significant. However, after adjustment individuals in FFS plans were 64% more likely to experience an ER visit in 2001 (OR = 1.64, p = 0.043) compared to individuals in capitated plans. None of the covariates were significant predictors of the odds of an ER visit.

Table 11: Model 1: Logistic regression analysis of ER visit in study year 2001 (adjusted for plan type only)

			95% C.I. for OR[1]	
Plan Type	**p-value**	**OR**	**Lower**	**Upper**
FFS	0.118	1.34	0.93	1.95
PPO	0.027	0.62	0.41	0.95
POS	0.019	0.52	0.31	0.90
Capitated (referent)	--	--	--	--

[1] OR = Odds Ratio

Table 12: Model 2: Logistic regression analysis of ER visits in study year 2001 by plan type (adjusted for both insurance plan type and the covariates)

			95% C.I. for OR[1]	
Variable	**p-value**	**OR**	**Lower**	**Upper**
FFS	0.043	1.64	1.02	2.65
PPO	0.240	0.73	0.43	1.24
POS	0.055	0.50	0.24	1.01
Capitated (referent)	--	--	--	--
Switched Plans	0.073	2.91	0.91	9.31
Age (years)	0.075	0.98	0.95	1.00
Sex	0.524	0.88	0.60	1.30
Prior Inpatient Stay (2000)	0.637	0.82	0.37	1.85
Mental Health Condition	0.280	0.53	0.16	1.69
Comorbidity Score	0.976	0.99	0.65	1.52
Insulin Use	0.239	0.75	0.46	1.21
MPR ≥ 80%	0.424	0.84	0.55	1.28
Non-index Medication Count	0.434	1 12	0.84	1.50
Statin Use	0.080	0.70	0.47	1.04
ACE Inhibitor Use	0.804	1.06	0.69	1.60

[1] OR = Odds Ratio

The results of logistic regression analysis of inpatient stays in study year 2001, unadjusted for the covariates (Model 3) are contained in Table 13. These data indicated that individuals in both FFS and PPO plans were significantly more likely to experience an inpatient stay compared to

those in capitated plans (OR = 1.11, p = 0.002 and OR = 1.08, p = 0.015, respectively). There was no significant difference between POS and capitated plans in the model adjusted for plan type only.

The covariates were then used to adjust Model 3. The results obtained from the adjusted model (Model 4) are shown in Table 14. After adjusting for the covariates, the data indicated that the significant difference observed between FFS and capitated plans remained significantly different (OR = 1.11, p = 0.022). Among the covariates used to adjust the model, increasing age (OR = 1.02, p < 0.001), higher comorbidity score (OR = 1.37, p < 0.001), MPR greater than 80% (OR = 1.25, p < 0.001) and increasing non-index medication count (OR = 1.10, p < 0.001) were each associated with significantly increased odds of an inpatient stay in study year 2001. Prior inpatient stay (OR = 0.43, p < 0.001), insulin use (OR = 0.58, p < 0.001), statin use (OR = 0.93, p = 0.028) and ACE inhibitor use (OR = 0.85, p < 0.001) were each associated with decreased odds of an inpatient stay in study year 2001.

Table 13: Model 3: Logistic regression analysis of inpatient stays in study year 2001

			95% C.I. for OR[1]	
Plan Type	**p-value**	**OR**	**Lower**	**Upper**
FFS	0.002	1.11	1.04	1.19
PPO	0.015	1.08	1.02	1.16
POS	0.660	0.98	0.91	1.06
Capitated (ref)	--	--	--	--

[1] OR = Odds Ratio

Table 14: Model 4: Logistic regression analysis of inpatient stays in study year 2001 by insurance plan type (adjusted for insurance plan type and the covariates)

			95% C.I. for OR[1]	
Variable	**p-value**	**OR**	**Lower**	**Upper**
FFS	0.022	1.11	1.02	1.22
PPO	0.143	1.06	0.98	1.16
POS	0.350	0.95	0.87	1.05
Capitated (referent)	--	--	--	--
Switched Plans	0.724	1.03	0.89	1.18
Age (years)	0.000	1.02	1.02	1.03
Sex	0.058	0.94	0.88	1.00
Prior ER Visit	0.512	0.62	0.15	2.59
Prior Inpatient Stay (2000)	0.000	0.43	0.39	0.49
Mental Health Condition	0.143	0.84	0.66	1.06
Comorbidity Score	0.000	1.37	1.29	1.45
Insulin Use	0.000	0.58	0.54	0.63
MPR ≥ 80%	0.000	1.25	1.17	1.33
Non-index Medication Count	0.000	1.10	1.05	1.16
Statin Use	0.028	0.93	0.87	0.99
ACE Inhibitor Use	0.000	0.85	0.79	0.91

[1] OR = Odds Ratio

Table 15 contains a summary by quintile for ER visits in year 2000 in the propensity score analysis for this dependent variable. Because the frequency of several of the covariates was low, the logistic regression analyses within the quintiles were done without inclusion of plan switchers, prior inpatient stays and presence of a mental health condition. In addition, in quintile 1 all comorbidity scores were constant at a Charlson Score of 2 indicating that this subset of individuals had only Type 2 diabetes and no record of other chronic diseases that comprise the score. As in the overall dataset the FFS plan type was associated with increased odds of an ER

visit only in quintile 3 (OR = 4.01, p = 0.036). Likewise, none of the covariates were predictors of the odds of an ER visit in any of the quintiles. Table 16 contains a summary by quintile for inpatient stay in year 2001 in the propensity score analysis for this dependent variable. The increased odds of experiencing and inpatient stay for individuals for FFS plans were not observed in the propensity score analysis. In fact, there were no differences between the plans types with respect to inpatient stays in year 2001 after the dataset was stratified into quintiles. Among the covariates used to adjust the models, prior inpatient stay, insulin use and MPR $\geq$ 80% were each significantly associated with the odds of an inpatient stay in study year 2001 across the propensity score quintiles. Patients experiencing prior utilization in the form of inpatient stays were significantly less likely to experience an additional subsequent inpatient stay in study year 2001. The odds of experiencing an inpatient stay in study year 2001 when an inpatient stay occurred in year 2000 was on average 56% lower than when there was no prior inpatient stay. This compares favorably to the odds of an inpatient stay in the entire cohort where the odds ratio was OR = 0.43 ($p < 0.001$). A similar relationship was observed for insulin use where the odds of a inpatient stay were approximately 40% lower for insulin users, whether in the overall dataset and on average across the quintiles. Conversely, in this analysis the odds of an inpatient stay increased by approximately 25% when the MPR was greater than 80%. Increasing age was associated with slightly increased odds of an inpatient stay only in quintile 5 (OR = 1.03, $p < 0.001$). Male sex was associated with decreased odds of an inpatient stay in quintile 5 only (OR = 0.65, $p < 0.001$).

Table 15: Odds ratios for ER visit in study year 2001 by insurance plan type in the overall dataset and within each quintile of the propensity score; all values are Odds Ratios (p-value)

Variable	Overall Dataset	Quintile 1	Quintile 2	Quintile 3	Quintile 4	Quintile 5
FFS	1.64 (p=0.043)	0.98 (ns)	1.14 (ns)	4.01 (p=0.036)	1.30 (ns)	1.44 (ns)
PPO	0.73 (ns)	0.77 (ns)	0.66 (ns)	1.96 (ns)	0.25 (ns)	0.79 (ns)
POS	0.50 (ns)	0.49 (ns)	0.90 (ns)	0.58 (ns)	0.33 (ns)	0.30 (ns)
Capitated (referent)	--	--	--	--	--	--
Switched Plans[1]	2.91 (ns)	--	--	--	--	--
Age	0.98 (ns)	0.89 (ns)	0.88 (ns)	0.89 (ns)	0.87 (ns)	0.99 (ns)
Sex	0.88 (ns)	1.51 (ns)	1.01 (ns)	0.88 (ns)	0.63 (ns)	0.75 (ns)
Prior ER Visit[1]	--	--	--	--	--	--
Prior Inpatient Stay[1]	0.82 (ns)	--	--	--	--	--
Mental Health Condition[1]	0.53 (ns)	--	--	--	--	--
Comorbidity Score	0.99 (ns)	--[2]	1.00 (ns)	7.95 (ns)	2.48 (ns)	0.99 (ns)
Insulin Use	0.75 (ns)	0.87 (ns)	1.51 (ns)	0.98 (ns)	1.18 (ns)	0.78 (ns)
MPR 80%	0.84 (ns)	1.51 (ns)	0.49 (ns)	0.61 (ns)	1.02 (ns)	1.01 (ns)
Non-Index Medication Count	1.12 (ns)	0.73 (ns)	0.90 (ns)	1.55 (ns)	0.88 (ns)	1.21 (ns)
Statin Use	0.70 (ns)	0.42 (ns)	0.78 (ns)	0.83 (ns)	0.88 (ns)	0.56 (ns)
ACE Inhibitor Use	1.06 (ns)	1.19 (ns)	0.99 (ns)	1.30 (ns)	0.54 (ns)	1.12 (ns)

[1] Model adjustment for prior ER visit in year 2000, prior inpatient stay in year 2000, presence of a mental health condition and plan switchers were not used to adjust the models for ER visit in year 2001 due to the low frequency of this dependent variable

[2] Comorbidity score was constant in Quintile 1; all values equal 2

Table 16: Odds ratios for inpatient stay in study year 2001 by insurance plan type in the overall dataset and within each quintile of the propensity score; all values are Odds Ratios (p-value)

Variable	Overall Dataset	Quintile 1	Quintile 2	Quintile 3	Quintile 4	Quintile 5
FFS	1.11 (p=0.022)	1.10 (ns)	1.06 (ns)	1.18 (ns)	1.13 (ns)	1.00 (ns)
PPO	1.06 (ns)	0.93 (ns)	1.09 (ns)	1.12 (ns)	1.08 (ns)	1.13 (ns)
POS	0.95 (ns)	0.79 (ns)	1.00 (ns)	1.00 (ns)	0.95 (ns)	0.95 (ns)
Capitated (referent)	--	--	--	--	--	--
Switched Plans	1.03 (ns)	1.19 (ns)	0.96 (ns)	1.11 (ns)	0.88 (ns)	1.08 (ns)
Age	1.02 (p<0.001)	0.99 (ns)	0.99 (ns)	1.05 (ns)	1.01 (ns)	1.03 (p<0.001)
Sex	0.94 (ns)	1.02 (ns)	1.07 (ns)	0.90(ns)	1.05 (ns)	0.65 (p<0.001)
Prior ER Visit[1]	0.62 (ns)	--	--	--	--	--
Prior Inpatient Stay	0.43 (p<0.001)	0.49 (p<0.001)	0.38 (p<0.001)	0.47 (p<0.001)	0.44 (p<0.001)	0.42 (p<0.001)
Mental Health Condition	0.84 (ns)	0.75 (ns)	0.65 (ns)	0.81 (ns)	0.94 (ns)	0.88 (ns)
Comorbidity Score	1.37 (p<0.001)	--[2]	2.41 (ns)	1.45 (ns)	1.77 (p=0.044)	1.26 (p<0.001)
Insulin Use	0.58 (p<0.001)	0.60 (p<0.001)	0.79 (ns)	0.51 (p = 0.001)	0.60 (p=0.005)	0.55 (p<0.001)
MPR 80%	1.25 (p<0.001)	1.12 (ns)	1.18 (p=0.022)	1.37 (p<0.001)	1.29 (p=0.001)	1.28 (p=0.001)
Non-Index Medication Count	1.10 (p<0 001)	1.20 (ns)	1.00 (ns)	1.07 (ns)	1.08 (ns)	1.16 (p=0.008)
Statin Use	0.93 (p=0.028)	0.98 (p=0.05)	1.08 (ns)	0.81 (p=0.008)	0.88 (ns)	0.85 (ns)
ACE Inhibitor Use	0.85 (p<0.001)	0.86 (ns)	0.79 (p<0.005)	0.83 (p=0.039)	0.81 (p=0.014)	0.94 (ns)

[1] Prior ER Visit in year 2000 was not used in the propensity score analysis due to low frequency of this covariate

[2] Comorbidity score was constant in Quintile 1; all values equal 2

5.5. Medication Possession Ratios

5.5.1. Effect of Health Insurance Plan Type on Odds of MPR ≥ 80

Logistic regression analysis (Model 1) for MPR ≥ 80% by health insurance plan type, unadjusted for the covariates indicated that there were significant differences in MPR by insurance plan type (Table 17). Before adjusting for the covariates, patients enrolled in either FFS (OR = 0.77, p < 0.001), PPO (OR = 0.88, p < 0.011) or POS (OR = 0.77, p < 0.001) plan types were all significantly less likely to have MPR ≥ 80% compared to patients enrolled in capitated plan types.

Table 17: MPR 80%, Model 1: Logistic regression analysis of MPR in the study period (unadjusted for the covariates)

			95% C.I. for OR[1]	
Plan Type	**p-value**	**OR[2]**	**Lower**	**Lower**
FFS	<0.001	0.77	0.73	0.82
PPO	<0.001	0.88	0.84	0.93
POS	<0.001	0.77	0.73	0.82
Capitated (referent)	--	--	--	--

[1] OR = Odds Ratio
[2] Chi-square p < 0.001

After adjusting for the covariates (Model 2, Table 18), the significant differences in MPR by insurance plan type remained. Patients enrolled in either FFS (OR = 0.75, p < 0.001), PPO (OR = 0.81, p < 0.011) or POS (OR = 0.81, p < 0.001) plan types were all significantly less likely to have MPR ≥ 80% compared to patients enrolled in capitated plan types. Among the covariates, the likelihood of having MPR ≥ 80% increased among those who switched insurance plans in the study period (OR = 1.57, < 0.001). These individuals were approximately 60% more likely to have MPR ≥ 80%. Likewise, increasing age (OR = 1.04, p <0.001), male sex (OR = 1.25, p

<0.001), and prior in-patient stay (OR = 1.21, p <0.001) were each associated with having MPR ≥ 80%. The likelihood of having MPR ≥ 80% was significantly lower in patients who had increasing non-index medication count and who were prescribed statins (OR = 0.78, p < 0.001) or ACE inhibitors (OR = 0.94, p = 0.012). The presence of a mental health disorder, insulin use and comorbidity score were not significant in this analysis.

Table 18: MPR 80%, Model 2: Logistic regression analysis of MPR by insurance plan type (adjusted for the covariates)

			95% C.I. for OR[1]	
Variable	**p-value**	**OR**	**Lower**	**Upper**
FFS	<0.001	0.75	0.71	0.80
PPO	<0.001	0.81	0.76	0.86
POS	<0.001	0.81	0.76	0.87
Capitated (referent)	--	--	--	--
Switched Plans	<0.001	1.57	1.43	1.71
Age	<0.001	1.04	1.04	1.05
Sex	<0.001	1.25	1.20	1.31
Prior Inpatient Stay	<0.001	1.21	1.09	1.34
Mental Health Condition	ns	1.11	0.92	1.33
Insulin Use	ns	1.04	0.98	1.11
Comorbidity Score	ns	1.00	0.75	1.05
Non-Index Medication Count	0.015	0.96	0.93	0.99
Statin Use	<0.001	0.78	0.75	0.82
ACE Inhibitor Use	0.012	0.94	0.90	0.99

[1]OR = Odds Ratio

5.5.2. Propensity Score Analysis

Table 19 contains a summary by quintile for MPR $\geq$ 80% in the propensity score analysis for this dependent variable. The decreased odds of individuals in FFS, PPO and POS plan types having MPR $\geq$ 80% remained across the quintiles. Interestingly, the FFS plan type was not significantly different than the capitated plan type in quintile 5, where the odds of individuals enrolling in a FFS plan was lowest. Similarly, the POS plan type was not significantly different than the capitated plan type in quintiles 1 and 2, where the odds of individuals enrolling in a FFS plan was highest. Among the covariates in the propensity score, individuals who switched plans in the study period were consistently more likely to have MPR $\geq$ 80% across the quintiles. As in the logistic regression model adjusted for the covariates (Table 18), increasing age and sex were associated with increased odds of having MPR $\geq$ 80%. Prior inpatient stay was only significant in quintile 5 and was consistent with the result in the overall cohort (Table 19). In the overall dataset, ACE inhibitor use was associated with decreased odds of having MPR $\geq$ 80%; however, in the propensity score analysis, there were no differences between FFS or capitated plans across the quintiles. Conversely, the association between the odds of having MPR $\geq$ 80% and statin use was significantly lower in FFS plan types across the quintiles.

Table 19: Propensity Score analysis for medication possession ratio (MPR) greater than of equal to 80%; all values are Odds Ratios (p-value)

Variable	Overall Dataset	Quintile 1	Quintile 2	Quintile 3	Quintile 4	Quintile 5
FFS	0.75 (<0.001)	0.63 (<0.001)	0.65 (<0.001)	0.78 (<0.001)	0.82 (0.005)	0.91 (ns)
PPO	0.81 (<0.001)	0.76 (<0.001)	0.82 (0.003)	0.86 (0.022)	0.72 (<0.001)	0.86 (0.025)
POS	0.81 (<0.001)	0.84 (ns)	0.86 (ns)	0.77 (0.001)	0.76 (<0.001)	0.86 (0.019)
Capitated (referent)	--	--	--	--	--	--
Switched Plans	1.57 (<0.001)	1.30 (0.023)	1.57 (<0.001)	1.60 (<0.001)	1.57 (<0.001)	1.84 (<0.001)
Age	1.04 (<0.001)	1.06 (<0.001)	1.05 (0.047)	1.06 (0.002)	1.06 (<0.001)	1.04 (<0.001)
Sex	1.25 (<0.001)	1.20 (0.001)	1.29 (<0.001)	1.26 (<0.001)	1.26 (<0.001)	1.25 (<0.001)
Prior Inpatient Stay	1.21 (<0.001)	0.95 (ns)	1.14 (ns)	1.23 (ns)	1.17 (ns)	1.40 (<0.001)
Mental Health Condition	1.11 (ns)	0.68 (ns)	1.07 (ns)	1.06 (ns)	1.03 (ns)	1.42 (0.025)
Insulin Use	1.04 (ns)	1.03 (ns)	0.95 (ns)	0.99 (ns)	0.88 (ns)	1.00 (ns)
Comorbidity Score	1.00 (ns)	--[1]	0.76 (ns)	0.69 (ns)	0.81 (ns)	1.05 (ns)
Non-Index Medication Count	0.96 (0.015)	0.98 (ns)	0.98 (ns)	1.02 (ns)	0.93 (ns)	0.94 (ns)
Statin Use	0.78 (<0.001)	0.73 (<0.001)	0.86 (0.008)	0.76 (<0.001)	0.78 (<0.001)	0.79 (<0.001)
ACE Inhibitor Use	0.94 (0.012)	0.95 (ns)	0.92 (ns)	0.96 (ns)	1.00 (ns)	0.92 (ns)

[1] Comorbidity scores in quintile 1 were constant; all values equal 2

5.5.3. Sensitivity Analysis

In the sensitivity analysis of the effect of varying the cut-off values for the definition of "good" and "poor" MPR, cut-off values of ≥ 50%, ≥ 70%, ≥ 90% and 100% were used. The generally accepted minimal value that is associated with adverse clinical outcomes is MPR < 80% [11]. The 100% cut-off value was chosen because a significant proportion of individuals represented in the dataset had an MPR of 100%. As shown in Table 20, the proportion of individuals with "poor" MPR increases as the cut-off value increases. "Poor" medication possession ratios were lowest at the MPR 50% cut-off value with approximately 6% to 13% of patients in the "poor" category, whereas the greatest proportion of individuals in the "poor" category was at the 100% cut-off value. As indicated by the p-values, there was a significant difference between insurance plan type and the MPR cut-off value used to define "good" and "poor" MPR. Capitated insurance plans consistently had the lowest rate of "poor" MPR compared to the other plan types.

Table 20: Frequencies of MPR values meeting the definition of "poor" by health insurance plan type and cut-off value

MPR Cut-Off	Health Insurance Plan Type				χ^2	p-value
	Capitated	FFS	PPO	POS		
50	6.6%	13.1%	8.8%	9.2%	271.2	< 0.001
70	19.3%	25.5%	21.7%	24.0%	136.8	< 0.001
80	29.9%	35.5%	32.5%	35.6%	105.9	< 0.001
90	46.8%	51.3%	49.4%	52.3%	71.8	< 0.001
100	79.2%	81.8%	81.5%	82.1%	39.2	< 0.001

The data contained in Table 21 show the effect of varying the cut-off for the definition of "poor" MPR within the dependent variables for utilization (in-patient stay and ER visit) and processes of care (ACE inhibitor and statin use). There were significant differences between plan types for inpatient stays, ACE inhibitor use and statin use; however, there were no significant differences among the plan types for ER visits. The capitated plan types consistently had the lowest frequencies of "poor" MPR for each of the dependent variables in the analysis. In all cases, the frequencies for the proportion of patients with "poor" MPR increased as the cut-off value increased.

Table 21: MPR Sensitivity Analysis: Cross-tabulation for MPR cut-off values for medication possession ratios (MPR) for inpatient stays, ER visits, statin use and ACE inhibitor use by health insurance plan type; all frequencies denote "poor" medication possession ratios

MPR cut-off	Health Insurance Plan Type				χ^2	p-value[1]
	Capitated	FFS	PPO	POS		
In-Patient Stay, 2001						
50	8.2% (108)	17.2% (103)	11.2% (171)	10.9% (85)	50.3	< 0.001
70	23.9% (315)	30.5% (352)	25.0% (382)	29.9% (233)	20.0	< 0.001
80	35.2% (463)	41.6% (480)	36.8% (562)	40.9% (318)	14.4	0.002
90	52.5% (691)	58.4% (675)	55.4% (847)	59.1% (460)	12.7	0.005
100	82.8% (1091)	87.1% (1006)	85.5% (1306)	83.5% (650)	10.2	0.017
ER Visit, 2001						
50	12.5% (4)	10.5% (4)	8.0 (2)	0.0% (0)	1.5	0.684
70	28.1% (9)	23.7% (9)	16.0% (4)	10.0% (1)	2.1	0.545
80	34.4% (11)	36.8% (14)	24.0% (6)	20.0% (2)	1.9	0.595
90	46.9% (15)	60.5% (23)	56.0% (14)	30.0% (3)	3.5	0.316
100	78.1% (25)	86.8% (33)	92.0% (23)	70.0% (7)	3.7	0.300
ACE Inhibitor Use						
50	6.1% (220)	13.7% (415)	8.4% (342)	8.8% (194)	120.3	< 0.001
70	18.2% (658)	26.4% (798)	21.2% (858)	23.7% (520)	69.6	< 0.001
80	28.6% (1036)	37.4% (1132)	32.1% (1300)	34.6% (760)	61.9	< 0.001
90	45.3% (1638)	53.2% (1609)	51.0% (2066)	52.0% (1143)	49.7	< 0.001
100	78.4% (2837)	84.9% (2569)	83.7% (3393)	83.6% (1835)	59.7	< 0.001
Statin Use						
50	5.0% (213)	11.9% (389)	6.5% (285)	6.3% (123)	140.8	< 0.001
70	15.3% (648)	23.5% (769)	17.6% (771)	18.2% (357)	84.9	< 0.001
80	25.8% (1089)	34.1% (1115)	27.9% (1219)	29.0% (571)	65.0	< 0.001
90	42.3% (1789)	50.4% (1650)	45.7% (1996)	45.6% (896)	48.6	< 0.001
100	76.7% (3239)	82.8% (2710)	80.5% (3520)	80.1% (1574)	45.8	< 0.001

[1] p-values refer to differences between insurance plan types at each cut-off value for defining "poor" MPR

The logistic regression models used for the 80% cut-off for defining "good" MPR were repeated at each of the additional cut-off values used for the sensitivity analysis. Models were used to compare the effect of insurance plan type on MPR before and after adjustment for the covariates. The results of the analyses are contained in Table 22 and

Table 23. For all values of the cut-off used patients enrolled in capitated plan types were consistently more likely to have MPR $\geq$ 80% compared to FFS, PPO and POS plan types. This relationship was observed with and without adjustment for the covariates. Among the covariates used to adjust the models the subset of individuals who switched plans were associated with increased odds of having MPR $\geq$ 80% regardless of the cut-off value. The same relationship was seen for increasing age, male sex and prior in-patient stay. This finding is consistent with the propensity score analysis described above. Statin use and non-index medication count were associated with a significantly decreased likelihood of having a "good" MPR. Neither the presence of an existing mental health nor increasing comorbidity score were significant predictors of having a "good" MPR at any cut-off value. Non-index medication count was associated with significantly decreased likelihood of having a "good" MPR only when the cut-off values were at 90% and 100% (Table 23). Statin use was associated with decreased odds of having MPR $\geq$ 80% at all values of the cut-off, whereas, ACE inhibitor use was associated with decreased odds of having MPR $\geq$ 80% when the cut-off was set at either 90% or 100%.

Table 22: MPR Sensitivity Analysis: Logistic regression analysis of MPR in the study period when the cut-off value for defining "poor" MPR was set at 50% and 70%

	MPR Cut-Off Value							
	MPR 50%				MPR 70%			
Variable	**OR**[1]	**p-value**	**OR**	**p-value**	**OR**	**p-value**	**OR**	**p-value**
FFS	0.47	<0.001	0.49	<0.001	0.70	<0.001	0.70	<0.001
PPO	0.74	<0.001	0.68	<0.001	0.86	<0.001	0.78	<0.001
POS	0.70	<0.001	0.76	<0.001	0.75	<0.001	0.80	<0.001
Capitated (referent)	--	--	--	--	--	--	--	--
Switched Plans	--	--	2.46	<0.001	--	--	1.83	<0.001
Age	--	--	1.05	<0.001	--	--	1.05	<0.001
Sex	--	--	1.33	<0.001	--	--	1.26	<0.001
Prior Inpatient Stay	--	--	1.36	<0.001	--	--	1.23	<0.001
Mental Health Condition	--	--	1.25	ns	--	--	1.26	0.021
Insulin Use	--	--	1.10	0.048	--	--	1.08	0.035
Comorbidity Score	--	--	1.04	ns	--	--	0.97	ns
Non-Index Medication Count	--	--	1.00	ns	--	--	0.97	ns
Statin Use	--	--	0.74	<0.001	--	--	0.75	<0.001
ACE Inhibitor Use	--	--	0.91	0.020	--	--	0.92	0.002

[1] OR = Odds Ratio

Table 23: MPR Sensitivity Analysis: Logistic regression analysis of MPR in the study period when the cut-off values for defining "poor" was set at 90% and 100%

	MPR Cut-Off Value							
	MPR 90%				MPR 100%			
Variable	OR[1]	p-value	OR	p-value	OR	p-value	OR	p-value
FFS	0.84	<0.001	0.81	<0.001	0.84	<0.001	0.76	<0.001
PPO	0.90	<0.001	0.82	<0.001	0.86	<0.001	0.78	<0.001
POS	0.80	<0.001	0.84	<0.001	0.83	<0.001	0.81	<0.001
Capitated (referent)	--	--	--	--	--	--	--	--
Switched Plans	--	--	1.43	<0.001	--	--	1.15	<0.001
Age	--	--	1.04	<0.001	--	--	1.04	<0.001
Sex	--	--	1.21	<0.001	--	--	1.18	<0.001
Prior Inpatient Stay	--	--	1.26	<0.001	--	--	1.34	<0.001
Mental Health Condition	--	--	1.14	ns	--	--	1.23	ns
Insulin Use	--	--	1.04	ns	--	--	0.96	ns
Comorbidity Score	--	--	0.99	ns	--	--	1.04	ns
Non-Index Medication Count	--	--	0.96	0.027	--	--	1.08	0.001
Statin Use	--	--	0.79	<0.001	--	--	0.86	<0.001
ACE Inhibitor Use	--	--	0.97	ns	--	--	0.99	ns

[1] OR = Odds Ratio

5.6. Processes of Care – ACE Inhibitor and Statin Use

Results of logistic regression Model 1 for ACE inhibitor use are contained in Table 24. These data indicate that individuals in capitated were significantly less likely to fill prescriptions for ACE inhibitors compared to those in FFS and PPO plan types (OR = 1.10, p = < 0.001 and OR = 1.07, p = 0.004, respectively). There was no difference between POS and capitated plans.

Table 24: Model 1: Logistic regression analysis of ACE inhibitor use in study year 2001 (unadjusted for the covariates)

			95% C.I. for OR[1]	
Variable	**p-value**	**OR**	**Lower**	**Upper**
FFS	< 0.001	1.10	1.04	1.16
PPO	0.004	1.07	1.02	1.13
POS	ns	1.00	0.95	1.06
Capitated (referent)	--	--	--	--

[1] OR = Odds Ratio

After adjusting Model 1 using the covariates, the significant difference observed between capitated plans and PPO was lost (see Model 2, Table 25). As in the Model 1, the FFS plan type was associated with increased odds of ACE inhibitor use (OR = 1.16, p = 0.001). Among the covariates, increasing age (OR = 1.01, p = 0.003), male sex (OR = 1.17, p < 0.001) and increasing non-index medication count (OR = 1.22, p < 0.001) were all associated with significantly increased odds of filling prescriptions for ACE inhibitors in study year 2001. Increasing comorbidity score (OR = 0.90, p = 0.004), having an MPR ≥ 80% (OR = 0.91, p = 0.005) and prior use of ACE inhibitors (OR = 0.03, p < 0.001) were associated with significantly decreased odds of filling prescriptions for ACE inhibitors in study year 2001. None of the other covariates were significant predictors of filling prescriptions for ACE inhibitors.

Table 25: Model 2: Logistic regression analysis of ACE inhibitor use in study year 2001 (adjusted for the covariates)

			95% C.I. for OR[1]	
Variable	**p-value**	**OR**	**Lower**	**Upper**
FFS	0.001	1.16	1.07	1.27
PPO	ns	1.07	0.99	1.16
POS	ns	0.99	0.90	1.08
Capitated (referent)	--	--	--	--
Switched Plans	ns	1.13	0.99	1.29
Age	0.003	1.01	1.00	1.01
Sex	< 0.001	1.17	1.10	1.24
Prior Inpatient Stay	ns	1.11	0.96	1.27
Mental Health Condition	ns	1.23	0.94	1.61
Insulin Use	< 0.001	0.86	0.79	0.94
Comorbidity Score	0.004	0.90	0.84	0.97
Non-Index Medication Count	< 0.001	1.22	1.17	1.28
MPR ≥ 80%	0.005	0.91	0.86	0.97
Statin Use, 2000	ns	0.94	0.88	1.01
ACE Inhibitor Use, 2000	< 0.001	0.03	0.03	0.03

[1]OR = Odds Ratio

Results of logistic regression Model 1 for statin use in 2001 are contained in Table 26. FFS (OR = 0.93, p = 0.008), PPO (OR = 0.92, p < 0.001) and POS (0.66, p < 0.001) plan types were each significantly associated with decreased odds of filling prescriptions for statins compared to capitated plans.

Table 26: Model 3: Logistic regression analysis of statin use in study year 2001 (unadjusted for the covariates)

			95% C.I. for OR[1]	
Variable	**p-value**	**OR**	**Lower**	**Upper**
FFS	0.008	0.93	0.89	0.98
PPO	< 0.001	0.92	0.88	0.96
POS	< 0.001	0.66	0.62	0.70
Capitated (referent)	--	--	--	--

[1]OR = Odds Ratio

After adjusting Model 3 using the covariates, individuals in capitated plan types remained significantly more likely to fill prescriptions for statins compared to those in the other three plans types (see Model 4, Table 27). Among the covariates, increasing age (OR = 1.02, $p < 0.001$), male sex (OR = 1.19, $p < 0.001$) and increasing non-index medication count (OR = 1.20, $p < 0.001$) were each associated with increased odds of filling prescriptions for statins. Individuals who switched plan types during the study period, (OR = 0.84, $p = 0.007$), used insulin (OR = 0.86, $p < 0.001$), had an MPR $\geq$ 80% (OR = 0.72, < 0.001) or had previously used either statins (OR = 0.03, $p < 0.001$) or ACE inhibitors (OR = 0.88, $p < 0.001$) were each significantly less likely to fill prescriptions for statins in year 2001. Prior inpatient stay, presence of a mental health condition and comorbidity score were not significant predictors of statin use in 2001.

Table 27: Model 4: Logistic regression analysis of statin use in study year 2001 (adjusted for the covariates)

			95% C.I. for OR[1]	
Variable	**p-value**	**OR**	**Lower**	**Upper**
FFS	< 0.001	0.85	0.78	0.92
PPO	< 0.001	0.81	0.75	0.87
POS	< 0.001	0.66	0.60	0.72
Capitated (referent)	--	--	--	--
Switched Plans	0.007	0.84	0.75	0.96
Age	< 0.001	1.02	1.02	1.03
Sex	< 0.001	1.19	1.23	1.26
Prior Inpatient Stay	ns	0.98	0.86	1.12
Mental Health Condition	ns	1.24	0.96	1.56
Insulin Use	< 0.001	0.86	0.80	0.94
Comorbidity Score	ns	1.00	0.93	1.07
Non-Index Medication Count	< 0.001	1.27	1.21	1.33
MPR ≥ 80%	< 0.001	0.72	0.68	0.77
Statin Use, 2000	< 0.001	0.03	0.026	0.03
ACE Inhibitor Use, 2000	< 0.001	0.88	0.83	0.94

[1]OR = Odds Ratio

5.6.1. Propensity Score Analysis

In the propensity score analysis of ACE inhibitor use in 2001, the significant effect of the FFS plan type observed in the overall dataset was also observed in quintiles 4 and 5 where the odds of enrollment in capitated plan types was highest (Table 28). There were no differences in ACE inhibitor use between the PPO and POS plan types compared to capitated plans. Among the covariates used to adjust the models, switching health care plans had no effect on ACE inhibitor use in either the overall dataset or in any of the quintiles. Although age was associated with significantly increased odds of ACE in the overall dataset, the effect was lost in quintiles 2 though 5 was present in quintile 1. Male sex remained significantly associated with increased odds of ACE inhibitor use in quintiles 3 through 5 but was lost in quintiles 1 and 2. Prior inpatient stay, insulin use and statin use were not associated with ACE inhibitor use in the overall dataset as well as none of the quintiles. Conversely, increasing non-index medication count was significantly associated with ACE inhibitor use in the overall dataset as well as all of the quintiles. Interestingly, prior ACE inhibitor use in 2000 was strongly associated with decreased odds of subsequent ACE inhibitor use in 2001.

In the propensity score analysis for statin use in 2001, the significant effects of FFS and PPO plan types in the overall dataset were also observed quintiles 1 through 3 but not in quintiles 4 and 5 (see Table 29). The POS plan type remained associated with significantly decreased odds of statin use across all five quintiles. Although plan switchers were associated with decreased odds of statin use in the overall dataset, this effect was not observed in any of the quintiles. Male sex, increasing non-index medication count and having MPR $\geq$ 80% were significantly associated with statin use in 2001 in the overall dataset and across all of the quintiles. As seen

with ACE inhibitor use above, prior statin use was strongly associated with decreased odds of subsequent statin use in 2001.

Table 28: Propensity score analysis of ACE inhibitor use by health insurance plan type; all values are Odds Ratios (p-value)

Variable	Overall Dataset	Quintile 1	Quintile 2	Quintile 3	Quintile 4	Quintile 5
FFS	1.16 (0.001)	1.12 (ns)	1.18 (ns)	1.13 (ns)	1.22 (0.043)	1.14 (ns)
PPO	1.07 (ns)	0.98 (ns)	1.11 (ns)	1.02 (ns)	1.16 (ns)	1.17 (ns)
POS	0.99 (ns)	0.94 (ns)	0.91 (ns)	0.90 (ns)	1.01 (ns)	1.16 (ns)
Capitated (ref)	--	--	--	--	--	--
Switched Plans	1.13 (ns)	1.33 (ns)	1.28 (ns)	0.97 (ns)	1.15 (ns)	1.01 (ns)
Age	1.01 (0.003)	0.95 (0.012)	1.00 (ns)	0.99 (ns)	0.99 (ns)	1.01 (ns)
Sex	1.17 (< 0.001)	1.10 (ns)	1.09 (ns)	1.17 (0.022)	1.34 (< 0.001)	1.17 (0.026)
Prior Inpatient Stay	1.11 (ns)	1.09 (ns)	1.11 (ns)	1.24 (ns)	1.05 (ns)	1.14 (ns)
Mental Health Condition	1.23 (ns)	0.81 (ns)	1.16 (ns)	1.87 (ns)	2.36 (0.020)	0.93 (ns)
Insulin Use	0.86 (< 0.001)	0.84 (ns)	0.88 (ns)	1.06 (ns)	1.14 (ns)	0.91(ns)
Comorbidity Score	0.90 (0.004)	--[1]	0.52 (ns)	1.75 (ns)	1.51 (ns)	0.88 (0.019)
Non-Index Medication Count	1.22 (< 0.001)	1.16 (0.007)	1.15 (0.017)	1.23 (< 0.001)	1.22 (0.001)	1.30 (< 0.001)
MPR ≥ 80%	0.91 (0.005)	1.02 (ns)	0.89 (ns)	0.91 (ns)	0.81 (0.003)	0.96 (ns)
Statin Use	0.94 (ns)	0.90 (ns)	0.90 (ns)	1.05 (ns)	0.99 (ns)	0.88 (ns)
ACE Inhibitor Use	0.03 (< 0.001)	0.029 (< 0.001)	0.03 (< 0.001)	0.02 (< 0.001)	0.03 (< 0.001)	0.03 (< 0.001)

[1] Comorbidity score was constant in Quintile 1; all values equal 2

Table 29: Propensity score analysis for statin use by health insurance plan type; all values are Odds Ratios (p-value)

Variable	Overall Dataset	Quintile 1	Quintile 2	Quintile 3	Quintile 4	Quintile 5
FFS	0.85 (< 0.001)	0.78 (0.010)	0.80 (0.014)	0.80 (0.007)	0.91 (ns)	1.01 (ns)
PPO	0.81 (< 0.001)	0.76 (0.001)	0.75 (< 0.001)	0.81 (0.008)	0.93 (ns)	0.90 (ns)
POS	0.66 (< 0.001)	0.54 (< 0.001)	0.81 (0.033)	0.56 (< 0.001)	0.64 (< 0.001)	0.79 (0.014)
Capitated (referent)	--	--	--	--	--	--
Switched Plans	0.84 (0.007)	0.91 (ns)	0.85 (ns)	0.80 (ns)	0.86 (ns)	0.84 (ns)
Age	1.02 (< 0.001)	0.92 (< 0.001)	0.98 (ns)	1.04 (ns)	1.04 (0.039)	1.03 (< 0.001)
Sex	1.19 (< 0.001)	1.19 (0.011)	1.16 (0.022)	1.14 (0.041)	1.15 (0.037)	1.41 (< 0.001)
Prior Inpatient Stay	0.98 (ns)	0.77 (ns)	1.13 (ns)	1.04 (ns)	1.10 (ns)	0.97 (ns)
Mental Health Condition	1.24 (ns)	1.17 (ns)	1.37 (ns)	1.21 (< 0.001)	1.60 (ns)	1.04 (ns)
Insulin Use	0.86 (< 0.001)	0.92 (ns)	1.06 (ns)	0.79 (ns)	0.80 (ns)	1.03 (ns)
Comorbidity Score	1.00 (ns)	--[1]	0.73 (ns)	0.97 (ns)	0.83 (ns)	1.00 (ns)
Non-Index Medication Count	1.27 (< 0.001)	1.29 (< 0.001)	1.16 (0.007)	1.30 (< 0.001)	1.30 (< 0.001)	1.31 (< 0.001)
MPR 80%	0.72 (< 0.001)	0.78 (0.001)	0.68 (< 0.001)	0.74 (< 0.001)	0.67 (< 0.001)	0.75 (< 0.001)
Statin Use	0.023 (< 0.001)	0.03 (< 0.001)	0.03 (< 0.001)	0.03 (< 0.001)	0.02 (< 0.001)	0.03 (< 0.001)
ACE Inhibitor Use	0.88 (< 0.001)	1.08 (ns)	0.83 (0.026)	0.87 (ns)	0.95 (ns)	0.78 (0.001)

[1] Comorbidity score was constant in quintile 1; all values equal 2

6. DISCUSSION

The main effect in this series of analyses was health insurance plan type. The dataset was from the years 2000 – 2001. Although the data are now several years old, it is important to understand that the nature and enrollment characteristics of the insurance plan types has not varied significantly in recent years, as described in Jonas and Kovner, *Health Care Delivery in the United States*, 7th edition, 2002 and it's sequel in the 9th edition, 2008. These volumes provide detailed information on the characteristics of health insurance plan types in the United States. For comparison purposes, the data in Table 30, indicate that the enrollment frequencies among the insurance plan types has been relatively constant over time.

Table 30: Comparison of employer-based health insurance plan enrollment between 1996 and 2006

	Year[1]			
Plan Type	**1996**	**1999**	**2001[2]**	**2006**
Capitated (HMO)	33%	28%	27.4%	22%
FFS	26%	9%	23.5%	4%
PPO	25%	38%	30.6%	62%
POS	16%	25%	18.5%	9%

[1] Values presented for 1996, 1999 and 2006 were adapted from Jonas and Kovner 2002, 7th Ed. and 2008, 9th Ed.
[2] Values for 2001 were from the 2000-2001 MarketScan dataset and are included for comparison purposes

The trend in the growth of enrollment in PPO plans and the reduction of enrollment in traditional FFS plans is evident. Data form the present study supports this trend in that in study years 2000-2001 6.2% of the cohort switched plans. Of these switches, the largest movement of membership was from traditional FFS plans to PPOs as shown in Table 6. Similarly, very few individuals switched from PPO plans. Based on these data, it is believed that until (or unless) there is a major reform in the health care delivery system in the United States, the findings

described in this report accurately reflect the relationships among health insurance plan types today.

6.1. Health Care Resource Utilization

In the analysis of the odds of an ER visit in study year 2001, adjustment for the covariates removed the significant differences observed between the PPO and POS plans compared to the capitated plans. This was not the case for the FFS plans (Table 12). After adjustment for the covariates patients in FFS plans were significantly more likely to experience as ER visit compared to patients in capitated plans. This finding suggests that the hypothesis that members of capitated plans would have decreased odds of an ER visit was confirmed. This is supported by the findings in a randomized controlled study of adult patients with Type 2 diabetes enrolled in an HMO in which a 6-month health care management program was introduced [72]. In this capitated environment, a diabetes self-management intervention was shown to decrease subsequent hospital admissions and outpatient care office visits. Plan types with intermediate levels of restrictiveness, PPO and POS plans, were not significantly different than capitated plans for the odds of an ER visit is year 2001. It is important to keep in mind that the ER visit variable was constructed based on any cause for ER utilization, not strictly for complications due to Type 2 diabetes. Even in this case, the frequency of ER visits was low making inferences between plan types difficult to interpret.

In the propensity score analysis (Table 15), the significance of the FFS plans observed in the overall dataset was not observed in 4 of the 5 quintiles but was observed in quintile 3 only. For quintile 3, the probability that an individual was enrolled in a capitated plan was approximately 45% (data not shown). It is not possible to determine whether this finding was due to chance or due to the fact that the frequency of ER visits was low. In the propensity score analysis, a

reduced number of covariates were used to adjust the models within the quintiles to improve the performance of the logistic regression parameter estimates. In all regression analyses for ER visit, none of the individual covariates were significant predictors of the odds of an ER visit in 2001. Again, it is possible that the low frequency of ER visits overall did not allow an inference for any affects of the covariates on the odds of ER visits in 2001.

In the analysis of the odds of an inpatient stay, adjustment for the covariates removed the significant differences observed between PPO plans and capitated plans. As for ER visits this was not the case for FFS plans, which remained associated with significantly greater odds of an inpatient stay compared to capitated plans Table 14). This finding suggests that the hypothesis that members of capitated plans would have decreased odds of an inpatient stay was also confirmed. Increasing age, comorbidity score and non-index medication count were each associated with increased odds of an inpatient stay in year 2001. This was also observed for patients with MPR $\geq$ 80%. These findings suggested that as working age patients with Type 2 diabetes get older and comorbidities begin to appear, regimen complexity can increase. This trend is consistent with increased resource utilization. Prior inpatient stays, insulin use, statin use and ACE inhibitor use were each associated with decreased odds of an inpatient stay in year 2001. These findings suggested that when working age patients with more advanced Type 2 diabetes plus common comorbidities of hypertension and dyslipidemia encountered the health care system, either on an inpatient or outpatient basis, the result was reduced resource utilization in year 2001. Switching health care plan types, sex and the presence of a mental health condition were not associated with the odds of an inpatient stay.

Unlike the frequency of ER visits, the frequency of inpatient stays in the dataset was much higher (Table 5), therefore it was possible to include the same set of covariates in the regression

analyses of the propensity score analysis as for the overall dataset. In the propensity score analysis (Table 16), the significance associated with the FFS plan type observed in the overall dataset was not observed in any of the quintiles. The trends observed across the quintiles were directionally consistent compared to the overall dataset. It has been shown that there were no differences among health insurance plan types (HMO, PPO, POS and indemnity plans) for accepted, general diabetes care, including utilization as measured by outpatient office visits [69]. The consistently reduced likelihood of an ER visit or an inpatient stay for diabetics in capitated plans is consistent with the prevailing opinion that capitated plans seek to avoid hospital admissions, when possible. As with ER visits, these data support previous reports that utilization rates are higher in traditional FFS plans compared to managed care plans. Until the content and quality of claims data approaches that of a randomized clinical trial, including some kind of linkage to clinical data, a well designed propensity score analysis offers a reality check for regression analyses that cannot correct for selection biases.

Prior resource utilization, insulin use, statin use and ACE inhibitor use were all associated with decreased odds of an inpatient stay. These findings are consistent with the current clinical practice guidelines in that patients with Type 2 diabetes who encountered health care on an inpatient basis, are stable on their insulin treatment regimen and fill prescriptions for statins and ACE inhibitors, the standard of care, could be expected to have reduced odds on an inpatient stay in study year 2001. Interestingly, having a "good" MPR for oral anti-diabetic medications was associated with increased odds of an inpatient stay. These trends were consistent across the quintiles. The significant effect of increasing non-index medication count observed in the overall dataset was observed only in quintile 5 of the propensity score analysis where the odds of being a member of a capitated plan were highest. One interpretation of this finding could be that

as regimen complexity increases, patients with Type 2 diabetes may be less compliant with their regimen leading to more episodes that require inpatient care. However, this interpretation must be viewed with caution because the inpatient stay variable reflects all-cause hospitalization, not acute diabetes specific complications.

In the overall dataset, both statin and ACE inhibitor use were associated with decreased odds of an inpatient stay in year 2001. However, in quintile 5 where the odds of patient membership in a capitated plan type were highest, the association was no longer significant suggesting that the individuals in quintile 5 may have been more likely to have been treated according to current clinical practice guidelines.

6.2. Medication Possession Ratios (MPR)

Whether or not the relationship between MPR and health insurance plan type was adjusted for the covariates, members of capitated plans were significantly more likely to have MPR > 80%. Members if FFS, PPO or POS plan types were found to be approximately 25% to 30% less likely to have MPR > 80%. In patients with Type 2 diabetes, MPR can be considered as a surrogate measure of the level of glycemic control [11]. The MPR can also be considered as a measure of patient access to and acquisition of prescription drugs [42]. It might be expected that with FFS plans physicians would provide services of high volume and low cost to increase income, while under capitated plans they would focus on prevention and disease management to minimize future costs [17]. In this study there were clear and significant differences between health insurance plan types and the proportion of patients with MPR > 80% with capitated plans consistently indicating better medication possession behavior. This finding is consistent with a retrospective study of the impact of managed care on chronic medication usage, where members of managed care plans were more likely to persist in their use of medications [131]. This finding also leads to rejection of the null hypothesis that there are no differences in medication possession in Type 2 diabetes based on health insurance plan types. The alternative hypothesis that capitated plans tend to be restrictive about paying for provider services outside of the accepted list of providers in the network and focus on preventive measures in chronic diseases such as Type 2 diabetes would have better odds of enrollees having good medication possession behavior appears to be correct.

The propensity score analysis was based on the predicted probability that patients enrolled in capitated plans. Quintile 1 represented the portion of the cohort with the lowest probability of enrollment in a capitated plan and quintile 5 represented the highest probability of enrollment in

a capitated plan. The observation that POS plans were not significantly different than capitated plans in quintiles 1 and 2 could be the result of random chance since the PPO plan types remained significantly different than capitated plans. Alternatively, the POS plans in the MarketScan dataset, which are intermediate in terms of restrictiveness, may have been similar to capitated plans regarding coverage for and access to prescription drugs. In quintile 5, the FFS plan type was not significantly different that the capitated plans (Table 19) for having MPR > 80%. The odds ratio was directionally the same as in quintiles 1 – 4 (OR = 0.01) but did not reach statistical significance. Further analysis of the data in quintile 5 indicated that approximately 45% of patients in FFS plans had poor MPR compared to 40% in for those in capitated plans. It is possible that in this case, statistical power to detect a difference between plan types was lost; however, the FFS plan type in quintile 5 did follow the trend for poorer MPR.

Among the covariates use to adjust the models of MPR, non-index medication count, statin use and ACE inhibitor use were all associated with decreased odds of having MPR > 80%. Although blood pressure maintenance and control of dyslipidemia are important aspects of the standard of care, it is possible that these variables reflect the impact of more complex regimens on patient medication possession behavior beyond the oral treatment regimen for Type 2 diabetes. Patients who switched health insurance plans in the study period consistently had increased odds of having MPR > 80%. Although reasons for switching plans were not available, it is possible that this subset of the cohort was motivated to change plans to improve access to care. Analysis of the data for those who switched plans reveals that most of the switches occurring in 2000-2001 could attributed to the rapid growth of the PPO market in this timeframe with patients leaving

traditional FFS plans and enrolling in emerging discounted FFS arrangements, such as PPO and non-capitated POS plans.

In the sensitivity analysis, capitated plans consistently had lower rates of poor MPR. This trend persisted regardless of the cut-off value for the boundary between "good" and "poor" MPR (Table 21). Varying the MPR cut-off value above and below 80% revealed that those who switched plans also consistently had better odds of having good medication possession behavior. Also, at the lower cut-off values (50% and 70%) ACE inhibitor use was associated with decreased odds of having MPR > 80%.

Plans with capitation arrangements were significantly more likely to have MPR values ≥ 80% [39] compared to PPO plans which is consistent with the suggestion that capitated plans are associated with more preventive measures. Improved medication compliance is clearly warranted and has been the subject of research projects for some time [132]. Also, because MPR can vary when the number of prescribed medications is high or when mental illness is present or when prescribed medications have troublesome side effects or when treatment regimens are complex regimen simplification and behavioral interventions may offer improvements in medication adherence.

6.3. Processes of Care – ACE Inhibitor and Statin Use

The guidelines for control of hypertension in patients with Type 2 diabetes have been defined in the literature for some time. Although different classes of antihypertensive drugs have been evaluated in clinical trials, the ACE inhibitors were identified as first line therapy in the study period [12, 119, 133, 134]. The goal of treatment was and continues to be blood pressure of 130/80 or less [60]. The data for the likelihood of ACE inhibitor use in year 2001 suggested that

after adjustment for the covariates, FFS plans were associated with increased odds of ACE inhibitor use; however, after applying propensity scores to the dataset to further control for selection bias, this observation was no longer seen. Assuming the validity of the propensity score model that was used in the analysis, the hypothesis that there were no differences in ACE inhibitor use between capitated and FFS plans should be accepted. This suggests that in the study period the clinical benefits of ACE inhibitors were widely accepted by health care providers, whether the motivation stemmed from adherence to clinical practice guidelines in place at the time or from the increased resource utilization that was associated with FFS arrangements [14, 17]. In either case, this study suggests that ACE inhibitor use was relatively uniform among the different health insurance plan types. This conclusion is supported by the observation that patients who switched plan types in the study period were as likely to use ACE inhibitors as those who did not switch plans. Similar studies comparing health insurance plan types are limited. In a study of patients with Type 2 diabetes over the age of 18 years enrolled in a capitated HMO in the mid-western United States, adherence to ACE inhibitor therapy was good (92.7%) with no significant association with systolic blood pressure [135]. In another study that analyzed diabetes preventive assessments covered under 20 different health insurance plans (7 HMOs, 7 PPOs, 5 POS and 1 indemnity plan) from two Fortune 500 companies and the Federal Employees Health Benefits Plan found that HMO and PPO plan types had a higher frequency of assessment coverage [69]. In the examination of the association between physician organizational model and diabetes processes of care, there were no significant differences between managed care models in terms of systolic blood pressure control [36].

The data for statin use suggest a different scenario for control of dyslipidemia. Like the ACE inhibitors, guidelines for the treatment of dyslipidemia in patients with Type 2 diabetes have been established for a long time [12, 136]. Treatment goals are based on the level of risk of coronary heart disease. In the study period treatment guidelines stated that diabetics were at high, borderline or low levels of risk when LDL-cholesterol levels were $\geq$ 130 mg/dL, 100-129 mg/dL or < 100 mg/dL [133]. However, unlike the ACE inhibitors, after adjusting for the covariates, patients in capitated plans were significantly more likely to fill prescriptions for statins than patients in either FFS, PPO or POS plan types. In the propensity score analysis for statin use, the greater likelihood of statin use by patients in capitated plans remained in all of the quintiles, except in quintiles 4 and 5 for FFS and PPO plans. In the latter case, the only difference between the plan types remained between POS and capitated plans. It is possible that capitated plans either had lower out-of-pocket costs for lipid management or this plan type exhibited earlier adoption of statin use in the years following the diffusion of the landmark clinical trials, WOSCOPS [137] and SSSS [138] into clinical practice guidelines [139]. POS plans have been characterized as having more choices in providers by allowing selection of providers outside of the network but at a higher cost to the patient [140], which might explain the trend toward low odds of statin use in this plan type. The FFS and PPO plans had somewhat higher odds ratios but were still significantly lower than for capitated plans. Interestingly, in the overall dataset switching insurance plan types was associated with significantly decreased odds of statin use; however, this effect was lost after adjustment for selection bias in the propensity score analysis (Table 8).

Prior healthcare resource utilization, as represented by a prior in-patient stay in year 2000, was not a significant predictor in the adjusted model for ACE inhibitor use. Neither the presence of a mental health condition nor increasing non-index medication count was associated with ACE inhibitor and statin use in 2001. As expected in the working age population of patients with Type 2 diabetes who also have employer based private health insurance, comorbidity score was not a significant predictor of the odds of either ACE inhibitor or statin use in 2001.

6.4. Limitations

This study had limitations. The MarketScan dataset may not be generalizable to all parts of the United States because the employers contributing to claims data are predominantly located in the southern states and less concentrated in western states. The MarketScan dataset also has a greater proportion of females compared to the general population. Healthcare plans in other parts of the United States, particularly the western states may operate differently. Likewise, data from public forms of health insurance, Medicare and Medicaid, were not included in the MarketScan dataset, therefore the results reported here may not be applicable to these segments of the health care system. The study period was years 2000-2001. The results obtained from this time period may not be applicable today. Given the rapidity and extent of the evolution of the health care system in the US, these data may not reflect the current state of health insurance in the United States, and especially so if the United States adopts public insurance legislation that competes with or eliminates the private health insurance sector.[31, 141].

The ICD-9-CM code algorithm used to identify patients with Type 2 diabetes may have captured some Type 1 diabetics depending on the accuracy of the billing process. This is not expected to be a significant source of error given the high specificity and sensitivity of the method used [116]. The MarketScan dataset includes 7 insurance plan types that were consolidated into 4

categories. It is not clear to what extent the consolidation affected the results; however, the pattern of consolidation has been documented in the literature [117].

The MarketScan dataset includes provisions to capture data on 7 insurance plan types. Of these, two plan types in the study period had frequencies of zero. The remaining 5 plan types were consolidated into 4 categories ranging from most (capitated) to least (traditional FFS) restrictive in terms of accessing out-of-network providers. It is not clear to what extent the consolidation affected the results; however, this pattern of consolidation has been documented previously in the literature [117]. Within each of the 4 categories, multiple plans of a given type were assumed to have similar affects on the dependent variables. This could influence the results based on the fact that the characteristics of physician practices are variable. Variability could arise from the number of physicians in the practice, most practices are not exclusively tied to FFS or capitation arrangements but generally have mixed forms of payment and differing incentives may be used within a practice based on productivity, quality of care or patient satisfaction measures. It is not clear to what extent the consolidation affected the results; however, the pattern of consolidation was documented in the literature and the only consolidation done was to group together the capitated plans since there were no occurrences of either Basic/Major Medical or EPO plans.

In the analysis of health care resource utilization, there was no evaluation of costs. Health insurance is not free. There are provisions for premiums, copayments, deductibles and coinsurance in the MarketScan dataset. Additional research is needed to link the findings in the present study to out-of-pocket costs to patients. Further research should be done to determine the affect of direct out of pocket costs on ACE inhibitor and statin use in patients with Type 2 diabetes.

As indicated above, both ER visits and inpatient stays were identified in the dataset on an all-cause basis, not whether the utilization was due to complications of diabetes. The low frequency of ER visits, especially in study year 2000 prevented use of this predictor variable in some of the logistic regression analyses.

The analysis of ACE inhibitor and statin use did not distinguish between specific drugs within these therapeutic classes. In the study period, in addition to ACE inhibitors, angiotensin II receptor antagonists (ARBs) were also available as antihypertensive medications that were commonly used in patients with diabetes. Although in the study period ARBs were mentioned in the clinical practice guidelines, the ACE inhibitors were recognized as first line therapy [12, 119]. In the most recent clinical practice guidelines either class of antihypertensive could be used as first line therapy [136]. Further research could be done to examine the differences in drug use by class. Also, for both ACE inhibitors and statins, medication possession ratios (MPR) were not computed so it is only possible to know that prescriptions were filled at least once, not whether medication possession behavior was adequate. Further research may be warranted to examine the effects of different classes of drugs and drugs within classes for control of hypertension and dyslipidemia. Medication possession rates were not evaluated for any prescription drugs other than the oral antihyperglycemic products available in the study period [70].

In terms of additional processes of care, additional variables could have been included, such as evidence of HbA1c testing, urinalysis for the presence of proteinuria and whether patients underwent ophthalmic examinations. Further research is needed to evaluate a more comprehensive range of processes of care for patients with Type 2 diabetes.

The literature describes three methods in which selection bias may be minimized in observational studies [104, 106] using propensity scores. These methods are: stratification, matching, and covariate adjustment. There is no preferred method [103]; however, stratification was used in the present study. The results of this study may have been different had an alternative method been used. The theoretical framework used to derive the variables in the propensity score analysis was based on the TRIAD study [142]. TRIAD was a multicenter prospective cohort study in diverse population of patients with diabetes who were over 18 years of age. TRIAD compared managed care structure to processes of care among 6 study sites and 10 insurance plans, including: staff, network and IPA HMO models, POS plans and PPO plans. Numerous studies have been published based on TRIAD. The literature based on the TRIAD study was reviewed with respect to published studies that included variables for resource utilization, medication adherence and receipt of appropriate processes of care to develop a set of predictor variables to include in the propensity score model. The following variables were selected for inclusion in the propensity score model because the data suggested there could some influence on health care plan type selection or that potential confounding may exist among the variables: ACE inhibitor and insulin use [112]; insulin use; age and comorbidity burden [113]; and treatment intensification to maintain glycemic control [115]. Because propensity score analyses are dependent on the variables used to compute the scores, it is critical to base the process on a rationale theoretical framework. The TRIAD study was focused on managed care and utilization of health care resources were considered; however, the selection of the set of variables could have varied from the five variables used in this study. It is reasonable to expect that the combination of age, comorbidity score, insulin use, ACE inhibitor use and regimen

complexity represent potentially confounding variables that should be accounted for in the analyses.

7. CONCLUSIONS AND RECOMMENDATIONS

7.1. Resource Utilization

The results of this study suggested that the well documented higher utilization rates for less restrictive FFS plans compared to more restrictive capitated plans may not be as robust as previously reported. Although the data suggested that members in FFS plans had increased odds of an ER visit or an inpatient stay, when the dataset was stratified into quintiles in which patients with Type 2 diabetes had similar likelihood of being in a capitated plan type, or not, no differences among any of the plan types were observed. Based on the propensity score analysis, the hypothesis that members of capitated plans would have decreased resource utilization was rejected. There were no differences in resource utilization among the plan types.

PPO and POS plan types with intermediate levels of restrictiveness to access to out-of-network care were not significantly different than capitated plans based on odds of either ER visits or inpatient stays.

Although the regression models were adjusted for patients who switched plans during the study period and for the presence of mental health conditions, neither of these covariates were associated with increased resource utilization.

7.2. Medication Possession Ratios (MPR)

There were clear and significant differences between health insurance plan types and the proportion of patients with MPR $\geq$ 80% with capitated plans consistently indicating better medication possession behavior.

The propensity score analysis confirmed that member of both FFS and PPO plan types had decreased odds of having an MPR $\geq$ 80% compared to capitated plans. MPR for members of POS plan types were not significantly different than capitated in quintiles 1 and 2, where the odds of enrollment in capitated plans were lowest.

In the sensitivity analysis, there was a consistent trend within all four plan types for the proportion of patients to increase as the cut-off ranged from 50% to 100%.

Patients who switched plans during the study period were associated with increased odds of having an MPR $\geq$ 80%. This finding was observed in all quintiles of the propensity score analysis.

The presence of a mental health condition, insulin use and comorbidity score were not predictors of the odds of having an MPR $\geq$ 80% in any of the analyses.

7.3. Processes of Care – ACE Inhibitor and Statin Use in Year 2001

In the main analysis of the overall dataset, the hypothesis that no differences in ACE inhibitor use in year 2001 would be observed between FFS and capitated plans was not confirmed. Members in FFS plans were more likely to use ACE inhibitors than members in capitated plans; however, a statistically significant difference among the plan types was not observed in the propensity score analysis. The effect was lost after adjusting for selection bias. There was no difference between either PPO or POS plans compared to capitated plans in any of the analyses.

Switching health insurance plan types during the study period was not associated with ACE inhibitor use in year 2001.

In the main analysis of the overall dataset, the hypothesis that no differences in statin use in year 2001 would be observed between FFS and capitated plans was confirmed in the main analysis on

the overall dataset as well as in the propensity score analysis. Patients enrolled in capitated plans were significantly more likely to use statins in year 2001 compared to either FFS, PPO or POS plan types in all analyses, except in quintiles 4 and 5 for the FFS and PPO plans.

In the main analysis on the overall dataset of statin use in year 2001, both switching health insurance plan types and insulin use were significant predictors of reduced statin use; however, this observation was lost in the propensity score analysis. After correction for selection bias, neither switching health insurance plan types nor insulin use were predictors of statin use.

Regimen complexity was associated with increased statin use in 2001 in all analyses. Similarly, having MPR $\geq$ 80 % was associated with decreased statin use in 2001 in all analyses.

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EFFECTS OF HEALTH INSURANCE PLAN TYPE ON HEALTH CARE RESOURCE UTILIZATION IN ADULT WORKING AGE PATIENTS WITH TYPE 2 DIABETES MELLITUS

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ABSTRACT

The objective of this study was to evaluate the main effect of health insurance plan type on health resource utilization (emergency room (ER) visit or hospital admission) in privately insured patients with Type 2 diabetes between the ages of 18 to 64 years. The outcomes of interest were the odds of an emergency room visit or a hospital admission associated in patients with Type 2 diabetes. The data source was the 2000-2001 MarketScan database, which is comprised of administrative claims data for over 2.5 million privately insured individuals in the United States. The odds of an emergency room visit or hospital admission were evaluated using multiple logistic regression models specified to control for demographic and clinical characteristics of the target patient population. A propensity score analysis using the stratification approach was also done to further control for selection bias. Patients enrolled in FFS plans were significantly more likely to experience an ER visit or an inpatient stay compared to patients in capitated plans (odds ratio for ER visit: 1.64, $p<0.05$; odds ratio for an inpatient stay: 1.11, $p<0.05$). The results of this study confirm that utilization rates are higher in FFS plans; however, the strength of the association was not as robust when the regression models were adjusted for propensity score. Capitated plans seek to reduce resource utilization.

INTRODUCTION

Increasing prevalence of Type 2 diabetes mellitus in the US and around the world presents a major resource utilization and cost burden on the healthcare system [1]. Compared to patients without diabetes, patients with diabetes are more likely to be absent from work and to have physical limitations on the job and thus be less productive [2]. Likewise, patients with diabetes are 2 to 3 times more likely than non-diabetics to report loss of employment due to disability or poor health status, and are approximately 4 times more likely to report limitations in the work place [2]. As patients with diabetes age and accumulate additional co-morbidities, the level of their resource utilization and associated costs of care increase [3], [4]. Prevention and proper ambulatory care management of diabetes patients should help reduce their consumption of heath care resources resulting in positive social and economic benefits for both employees and employers. Having health insurance coverage, access to health care delivery and prescription drug coverage may reduce health care resource utilization associated with Type 2 diabetes by minimizing relatively expensive emergency encounters and potential inpatient stays due to acute episodes of complications due to Type 2 diabetes [5, 6]. Avoiding the more severe episodes resulting from lack of glycemic control is important from a resource utilization perspective [7].

From the perspective of the patient, a younger, well controlled diabetic may opt to enroll in widely available managed care insurance plan types, such as, capitated health maintenance organizations (HMOs) or a Preferred Provider Organization (PPO) to access readily available primary care. Although both of these plan types are considered managed care, they differ in how physicians are compensated. Patients with more advanced diabetes who experience complications may opt for an insurance plan type that allows health care delivery by a physician practice of choice where more treatment options exist without referral rather than having to

select from a pre-specified list of providers [8, 9]. Under capitation arrangements, per member per month fees are pre-paid to the physician practice by the insurer. The financial risk is held by the provider [10, 11], [12, 13]. Under capitation, physicians tend to increase their patient panel size (number of patients using a certain practice for health care) and to decrease the amount of time spent with each patient during an encounter [13, 14]. Practices delivering healthcare predominantly from capitated contracts were positively correlated with physician compensation based upon quality of care ($p = 0.02$) [15]. If true, these features of capitation arrangements would suggest differences in the amount, type and quality of care delivered to diabetic patients.

Much of the current literature indicates that, in general FFS healthcare plan types are associated with increased resource utilization compared to capitated plan types [11]. Both PPOs and traditional indemnity insurance plans are FFS arrangements. PPOs are managed care plans where the prices of services are negotiated with payers, generally at a discounted rate per service. The traditional plans operate according to market conditions and prices are set by the practice. Under FFS arrangements the financial risk is held by the payer, that is, the insurance carrier. FFS is generally associated with provision of more care, more out-patient office visits, and more procedures.

Patients with Type 2 diabetes select healthcare plans based on the benefits garnered under the plan, as well as, their perceived level of medical care need. At the same time, physicians are paid differently under different types of healthcare plans and their treatment patterns may differ, accordingly [10]. These factors work simultaneously. Selection of a particular insurance plan type by patients and medical practice preferences on the part of physicians may represent confounding factors in analyses of health care resource utilization based on administrative claims data. Unfortunately, observational studies based on insurance claims data differ from

randomized clinical trials in that it not possible to balance the baseline characteristics of the cohort by randomization prior to attempting to estimate the effect of an intervention of interest [16-18]. In observational studies patient characteristics are likely to vary in different groups in ways related to patient clinical status, health care taking behavior and the physician practice patterns [17]. Biases may exist in the claims data that must be accounted for in the analysis.

The objective of this study is to determine whether there are differences among private health insurance plan types in terms of health care resource utilization in privately insured patients with Type 2 diabetes between the ages of 18 to 64 years. Although many studies have been reported that describe the effects of health insurance plans on healthcare resource utilization in patients with Type 2 diabetes, limited data are available when out-patient and in-patient encounter claims, pharmacy claims and benefit plan design features are available together in the same data set. Similarly, to our knowledge use of a propensity score analysis of the effect of health insurance plan type in this Type 2 diabetic population to control for selection bias has not been reported. This study extends the literature by examining the affects of health insurance type on healthcare resource utilization, including ER visits and hospitalization in patients with Type 2 diabetes.

After controlling for the covariates, the objective of this study was to determine whether health care resource utilization differed by health insurance plan type in which adult privately insured patients with Type 2 diabetes were enrolled. FFS plans are generally believed to be associated with delivery of more services than capitated plans. Capitated plans tend to be very restrictive about paying for provider services outside of the accepted list of providers in the network would have lower odds of enrollees making an ER visit or experiencing an inpatient stay compared to members of traditional FFS plans that are based on revenue resulting from increased service

utilization. Likewise, capitated plans are generally understood to focus on preventive services to reduce costly episodes of acute care in the future, and often include prescription drug coverage. The hypothesis tested was that compared to less restrictive plan types, members of capitated plans would have increased odds of experiencing an ER visit or inpatient stay.

A theoretical framework used to evaluate access to healthcare, the Behavioral Model developed in the 1970's [19-21] was used to organize the variables in this study.

METHODS

Data Source

The 2000-2001 MarketScan Commercial Claims and Encounters administrative claims database (available from MedStat; Ann Arbor, MI) was used in this retrospective study of adult patients with Type 2 diabetes. This 2-year database contains inpatient, outpatient and pharmacy insurance claims information on approximately 2.5 million covered lives in the United States. Patients of working age between 18 and 64 years were included in the study cohort. The individual patient was the unit of analysis. To be eligible for inclusion in the analytic file, patients must have been continuously enrolled in their health insurance plan throughout the study period.

Population

A patient's index date is the first date in the claims data at which the inclusion criteria were met for a diagnosis of Type 2 diabetes. The Index Date must have occurred in the first half of the year 2000. Patients were excluded if they had an inpatient admission prior to the index date of the study or were pregnant or admitted for child birth. Patients with Type 2 diabetes were identified in the dataset according to both outpatient and inpatient claims for reimbursement using the methodology reported by O'Connor [22]. A patient was considered to be diagnosed with Type 2 diabetes if the claims record included at least one of the three following criteria: at least one inpatient hospitalization with a diagnosis of diabetes; two outpatient encounters with a primary ICD-9-CM diagnosis code specific for diabetes; or a prescription for an anti-hyperglycemic medication in 2000 – 2001. A primary diagnosis of diabetes was defined as the ICD-9-CM code 250.x. Microvascular complications of diabetes included ICD-9-CM codes 250.5 (renal), 362.0x (ophthalmic), 366.41 (ophthalmic), 250.6 (neurological) and 357.2

(neurological). This method has demonstrated a sensitivity of 0.91 and a specificity of 0.99 for the identification of patients with Type 2 diabetes in an HMO claims database [22].

Main Effects

In the analyses presented below, health insurance plan type was the main effect of interest. Possession of health insurance coverage is an enabling factor according to the Behavioral Model of access to health care. The MarketScan dataset includes provisions to collect variables for seven (7) different health insurance plan types: Traditional FFS plans Basic/Major Medical and Comprehensive policies, and Managed Care plans: EPOs, HMOs, POS (with either capitation or FFS physician payment arrangements) and PPOs. With the potential availability of 7 different plan types, it was necessary to consider appropriate ways to consolidate the plan types into fewer categories, as has been done in other studies using the MarketScan dataset [23]. Categories were created to reflect decreasing levels of restrictiveness on seeking care from specialists or other out-of network providers, where capitated plans would be expected to be most restrictive and traditional FFS plans would be least restrictive. PPO and non-capitated POS plans would be intermediate with respect to restrictiveness. The four consolidated insurance plan type categories were:

1 HMO plans (capitated) and POS plans (capitated/partially capitated) and;

2 - Non-capitated POS plans (POS);

3 Preferred Provider Organizations (PPO) plans;

4 - Traditional FFS arrangements: Basic/Major Medical and Comprehensive plans (FFS)

In the analyses below, the plan types were referred to as "capitated", "POS", "PPO" and "FFS" to reflect decreasing level of restrictiveness for accessing out-of-plan health care service use.

Dependent Variables

Parameters used to estimate the relationship between health care resource utilization and health insurance plan type were the odds of ER visits and hospital admissions in the cohort of patients with Type 2 diabetes that occurred in the year 2001. Resource utilization was considered a need-based factor according to the Behavioral Model of access to health care. Categorical variables were constructed for the resource utilization variables as part of the process of identifying patients with Type 2 diabetes in the study cohort.

Covariates

A series of covariates was used to adjust for potential biases and confounders in the analyses. This set of variables was referred to as "the covariates" in the analyses presented below.

Models were adjusted for demographic variables, age and sex. Age was used as a continuous variable.

The MarketScan dataset covers years 2000-2001. To account for the possibility that individuals who were eligible for entry into the analytic file in year 2000 and may remain in the dataset but switched to another plan type during the study period, a categorical variable was created to indicate whether individuals remained in their existing plan or switched to another plan type. This allowed adjustment for switching plan types while including these additional data in the analysis.

A categorical variable was created to indicate prior resource utilization according to whether patients experienced either an ER visit or inpatient stay, or not [24] in study year 2000. This variable was created in the process of identifying patients with Type 2 diabetes and was used to adjust models of the effect of health insurance plan type for prior health care resource utilization.

The presence of comorbidities reflects the concurrent manifestation of two or more diseases that are etiologically independent and not causally linked to the index disease of interest [25]. It is important to note that complications, e.g., presence of ketoacidosis in patients with diabetes, are not considered co-morbidities. The presence of increasing numbers of co-morbidities with various levels of severity can be viewed as a partial measure of the underlying health status of individuals in a population [26, 27]. Unlike randomized clinical trials it is not possible to control for differences in patient baseline characteristics by randomization. The goal of adjusting statistical analyses for the presence of baseline co-morbidities in health services research is to minimize the risk of confounding and to be able to interpret inferences with greater reliability and accuracy [26]. Although review of the recent literature suggests that the Charlson Co-morbidity Index [28], as adapted by Deyo [29] has been the most frequently used measure of co-morbidity in studies of patients with diabetes [30-33]; the D'Hoore modification was used in the present study based on its simplicity [34-37]. This co-morbidity score is based on only the first three digits of the ICD-9 codes in the claims dataset. Therefore the D'Hoore modification captures all patients with diabetes but cannot distinguish between complicated versus uncomplicated diabetes. In the present study it was not essential to make this distinction, and the D'Hoore modification has similar characteristics compared to other adaptations of the Charlson score [37]. Likewise, the literature does not recommend use of a particular measure of co-morbidity when administrative claims data are used even though many studies have been conducted in patients with diabetes. Because the Charlson co-morbidity index includes diabetes which has a weight of 2 in this scoring system, all patients in the final analytic file were assigned a default co-morbidity weight of at least 2 [38]. Higher scores are correlated with increased risk of 1-year mortality. The co-morbidity score was a continuous variable computed for study year

2000. Co-morbidity burden was considered a need based factor in the Behavioral Model of access to health care.

Oral anti-diabetic medications were identified in the MarketScan dataset using product NDC numbers for products that were commercially available in the first six months of the study period [39]. Index-MPR values were determined for each individual in the cohort in the first 6 months of study year 2000 by first computing a continuous variable based on oral anti-diabetic medications included in the first 6 months of the study period, where the MPR is the sum of days of supply of a particular oral anti-diabetic medication divided by the number of days between the first and last prescription fill dates plus the number of days for the last refill:

MPR = Σ(days supply)/#days between 1st & last refill + days supply for last refill

This continuous variable was then dichotomized according to the definition of "good" medication possession, i.e., whether the MPR was greater than or equal (good) to 0.8, or not (poor). If more than one medication was found for a single patient, separate MPR values were computed for each active ingredient, then averaged for those patients on multiple medications. MPR values were computed only for oral anti-diabetic medications, not for ACE inhibitors, statins or insulin. Computing accurate MPR values for insulin use was not possible using administrative data because the variability in daily insulin regimens was not captured in the administrative dataset [40-42].

To adjust for the possibility that oral medication regimens for glycemic control could be changed or intensified in the remaining 18 months of the study period, the actual count of all non-index medications prescribed for treatment of Type 2 diabetes was determined after the index MPR was computed [43]. This variable was constructed as a simple count of the number of new drugs added to or switched from the index regimen. Non-index medication counts were aggregated

into values of 0 (no new medications for diabetes added), 1 (one medication added), or ≥ 2 (two or more medications added). The counts were used in the main statistical models of the effect of insurance plan type as a continuous variable.

Diabetic patients diagnosed with mental health conditions, especially depression, have been shown to receive more healthcare services on a cumulative basis than diabetics without mental disorders but are less likely to receive complete diabetes-specific care [44]. The proportion of patients with poorer glycemic control increases with the presence of concurrent mental health conditions [45]. Likewise, patients with mental health conditions may be less able to adhere to diabetes self-management behaviors, such as, diet, medication compliance and keeping out-patient office visit appointments. [32]. Although a significant proportion of patients, i.e., >2% with mental health conditions is not anticipated to be found in the population represented in the MarketScan database, a categorical indicator variable was constructed for the analyses to adjust for whether a patient with Type 2 diabetes was also diagnosed with a mental health condition [44-46]. For this study, patients will be considered to have a mental health condition, if any of the following ICD-9-CM codes are present in any of the diagnosis fields (dx1 – dx15) in the MarketScan dataset [47]:

Anxiety disorder: 293.84, 293.89, 300.00-300.09, 300.2-300.30, 300.90, 308.30, 309.81

Substance abuse disorder: 291-292.90, 303-305

Although it was not possible to determine the exact insulin regimen that diabetics used during the study period, a categorical variable was constructed to adjust the models for insulin use, or not. This variable was used to control for disease progression and regimen complexity [42].

As in study year 2001 for the processes of care dependent variables described above, use of ACE inhibitors and statins in study year 2000 also represented the standard of care of patients with Type 2 diabetes [48]. To adjust the logistic regression models for treatment of dyslipidemia and hypertension in 2000, categorical variables were constructed to reflect whether patients were receiving prescriptions for statins and ACE inhibitors as specified in the 2000 treatment practice guidelines [49]. Prescriptions for statins and ACE inhibitors were identified in pharmacy records contained in the MarketScan dataset using the National Drug Codes (NDC numbers) for these medications that were commercially available in the study period. MPR values were not computed for these therapies.

Propensity Score Analysis to Control for Selection Bias

Each of the models specified below for health care resource utilization were also evaluated using a propensity score analysis. In the propensity score analysis, a separate unique logistic regression model was developed based on published data from the TRIAD study [50]. Propensity scores were derived from a logistic regression model of the odds of choosing between health care plan types based on how restrictive plans are with respect to seeking care from out-of-net-work providers. The four plan type categories, non-capitated, POS, PPO and FFS were recoded into two groups – the most restrictive plan types - (HMO and capitated POS plans) and the least restrictive plan types – (traditional FFS plans, PPO and non-capitated POS plans). The propensity scores were patient level probabilities that an individual selected a particular insurance plan type given their health status at the time. The variables derived from the TRIAD study for inclusion in the propensity score model were: age, comorbidity score, insulin use, ACE inhibitor use and regimen complexity. These variables represent factors that could influence selection of a particular health insurance plan type and confound the analyses. For the

propensity score analysis, non-index medication count was used as a categorical variable where 0 indicated no additional medications for glycemic control were added to a regimen, and 1 indicated that one or more new classes of drugs were added to a regimen.

The predicted probabilities from the regression model (i.e., the propensity scores) were then used to stratify the dataset into quintiles. Quintile 1 represents individuals with the lowest propensity (probability) of being enrolled in more restrictive plan types (i.e., more likely to be in a FFS plan type). Quintile 5 represents individuals with the highest propensity (probability) of being enrolled in more restrictive plan types (i.e., more likely to be in a capitated plan type). The effect of health insurance plan type on each of the dependent variables was compared between the overall dataset and within each quintile of the dataset adjusted for individual propensity scores. The distribution of propensity scores within each quintile are anticipated to substantially overlap within the re-coded groups ranging from lowest to highest levels of restrictiveness to access health care form out-of-network providers.

Analyses and Model Specification

Multiple logistic regression models were used to estimate the odds of an ER visit or an inpatient stay according to insurance plan type, the main effect of interest. For each dependent variable, the models were adjusted for insurance plan type with and without further adjustment for the covariates. Four equations were specified:

Model 1 – Odds of ER visit in year 2001; adjusted for plan type only

Model 2 – Odds of ER visit in year 2001; adjusted for plan type and the covariates

Model 3 – Odds of admission in year 2001; adjusted for plan type only

Model 4 – Odds of admission in year 2001; adjusted for plan type and the covariates

All of the logistic regression models were analyzed using SPSS version 17.0. The variables were constructed using SAS version 9.1. The capitated plan type was referent in all regression analyses of the effect of health insurance plan type.

RESULTS

Characteristics of the Study Cohort

The characteristics of the study cohort are contained in Table 1. As expected with the inclusion criterion that individuals must be enrolled continuously in their health insurance plan type throughout the study period, fewer individuals were observed in year 2001 compared to year 2000. The reasons for individuals to leave their plan at the time of eligibility for inclusion in the study cohort cannot be discerned quantitatively; however, it was possible to control for individuals who remained in the dataset but who switched plans. Approximately 6% of patients with Type 2 diabetes (n = 3174) switched plan types between 2000 and 2001. The average age of the cohort was 52.9 years and was 53.4% male. The frequency of inpatient stays was 14% in study year 2001 compared to 7.5% in study year 2000. The observed frequency of ER visits was very low in both study years with a total of only 168 visits documented in 2001. The frequency of diagnosis for mental health conditions was 1.6%. The proportion of individuals using insulin was 29.3%. The frequency of both statin and ACE inhibitor use was 26.4% and 28.6%, respectively. Although the MarketScan data base was designed to capture data from up to seven different health insurance plan types, in the 2000-2001 dataset used for this study there were no occurrences of either the Basic/Major Medical or EPO plan types. Because the frequency of the HMO plan type was relatively low (4.5% of the study cohort were HMO members), the capitated plan types (HMOs and capitated POS plans) were consolidated into a single category as indicated by the Capitated plan type shown in Table 1. Consolidation of the capitated plan types resulted in four categories that were used in the main analyses of the effects of health insurance plan type on each of the dependent variables. The proportion of individuals in the consolidated

plans represented 27.4% of the study cohort. The PPO plan type included 30.6% of the study cohort. The proportion of individuals in the FFS and POS plan types was 23.5% and 18.5%, respectively. The capitated plan type category was referent in the statistical analyses below.

The mean comorbidity score was 2.13. All individuals in the sample had a minimum score of 2 as a result of having Type 2 diabetes. Other than having Type 2 diabetes, the comorbidity burden was relatively low in the study cohort. The overall mean MPR was 0.824 (82.4%). The proportion of the study cohort with MPR $\geq$ 80% was 67.0%. These data suggest that the on average MPR was considered good. Non-index medication count was used to adjust for the existence of more complicated treatment regimens. Values for non-index medication count ranged from 0 to 5 in the dataset; however, the frequencies for the addition of 3, 4 and 5 new medications to any treatment regimens were very low. Therefore frequencies greater than 2 were aggregated to values of 0, 1 and $\geq$ 2 for use in the analyses. Non-index medication count was used as a continuous variable in the main analyses of the effect of insurance plan type. In the propensity score analysis, non-index medication count was dichotomized into two categories where values of 0 and 1 referred to no additional medications added (0) and one or more new medications added (1) as an estimate of regimen complexity. Only 7.0% of the study cohort was taking one or more non-index oral medications for Type 2 diabetes. The variable for the propensity score was computed as the predicted probability of whether an individual was enrolled in more restrictive plans (i.e., capitated plans) or less restrictive plans (i.e., FFS plans). On average, the propensity score was 0.459. In other words, the likelihood that an individual was enrolled in a more restrictive plan type was approximately a 45.9%. The propensity score ranged from 0.313 to 0.978.

Table 1: Characteristics of the study cohort

Variable	Year 2000	Year 2001
Age in years, mean (SD)	**52.9** (9.2)	
Sex (% male)	**53.4%**	
In-Patient Stay (% with ≥ 1 overnight stays)	**7.5%** (4686/62243)	**14.0%** (7298/52250)
ER Visit (% with ≥ 1 ER visits)	**0.04%** (27/61257)	**0.3%** (168/51131)
Mental Health Condition (%)	**1.6%** (994/62243)	
Insulin Use (%)	**29.3%** (18209/62243)	
Statin Use (%)	**26.4%** (16407/62243)	
ACE Inhibitor Use (%)	**28.6%** (17822/62243)	
Insurance Plan Type Category		
Capitated (referent)	**27.4%** (17032/62212)	
POS	**18.5%** (11496/62212)	
PPO	**30.6%** (19063/62212)	
FFS	**23.5%** (14621/62212)	
Switched Plans (%)	**6.2%** (3174/51446)	
Co-morbidity Score, mean (SD)	**2.13** (0.57)	
Medication Possession Ratio		
Overall Mean MPR (SD)	**0.824** (0.205)	
Index MPR ≥ 80%	**67.0%** (28587/42689)	
Non-Index Medication Count (%)		
0	**62.5%** (26883/42966)	
1	**30.5%** (13088/42966)	
≥ 2	**7.0%** (2995/42966)	
Regimen Complexity[1]		
No new oral medications added	**62.6%** (26883/42966)	
≥ 1 new medications added	**37.4%** (16083/42966)	
Propensity Score (Range)		
(n = 42966)	**0.459** (0.313-0.978)	
Quintile 1 (n)	9068	
Quintile 2 (n)	8414	
Quintile 3 (n)	8518	
Quintile 4 (n)	8558	
Quintile 5 (n)	8408	

[1] Regimen complexity was defined as whether subjects in the cohort had at least 1 new oral medication added to their non-index medication regimen

The frequencies of each dependent variable (study year 2001) by insurance plan type are contained in Table 2. These data indicate that there were significant differences between health insurance plan type and the primary outcomes of this study, and confirms that the frequency of emergency room visits in the study period was low. The POS insurance plan type had the lowest frequencies and proportions of each dependent variable.

Table 2: Frequency and proportion of individuals for each dependent variable by health insurance plan type

Dependent variable [1]	FFS	Capitated	POS	PPO	Total	p-value[2]
ER Visit, 2001	60 (0.5%)	53 (0.4%)	18 (0.2%)	37 (0.2%)	168	<0.001
In-Patient Stay, 2001	1791 (14.7%)	1940 (13.4%)	1237 (13.2%)	2325 (14.4%)	7298	0.001

[1] Dependent variables are for year 2001, except for the MPR analysis which was cross-sectional over the two year study period

[2] Chi-Square statistics for differences between plan types

The results of logistic regression analysis of ER visits in study year 2001, unadjusted for the covariates (Model 1) are contained in Table 3. These data indicated that there was no significant difference between the odds of an ER visit for individuals in FFS plans compared to capitated plans; whereas, individuals in both PPO and POS plans were significantly less likely to experience an ER visit (OR = 0.62, p = 0.027 and OR = 0.52, p = 0.019, respectively).

The covariates were then used to adjust Model 1. The results obtained from the adjusted model (Model 2) are shown in Table 4 below. After adjusting for the covariates, the data indicated that the significant differences observed between PPO and POS plans compared to capitated plans were no longer significant. However, after adjustment individuals in FFS plans were 64% more likely to experience an ER visit in 2001 (OR = 1.64, p = 0.043) compared to individuals in capitated plans. None of the covariates were significant predictors of the odds of an ER visit.

Table 3: **Model 1: Logistic regression analysis of ER visit in study year 2001 (adjusted for plan type only); values are Odds Ratios (OR)**

			95% C.I. for OR[1]	
Plan Type	**p-value**	**OR**	**Lower**	**Upper**
FFS	0.118	1.34	0.93	1.95
PPO	0.027	0.62	0.41	0.95
POS	0.019	0.52	0.31	0.90
Capitated (referent)	--	--	--	--
Constant	0.000	0.002	--	--

[1] OR = Odds Ratio

Table 4: **Model 2: Logistic regression analysis of ER visits in study year 2001 by plan type (adjusted for both insurance plan type and the covariates); values are Odds Ratios (OR)**

			95% C.I. for OR[1]	
Variable	**p-value**	**OR**	**Lower**	**Upper**
FFS	0.043	1.64	1.02	2.65
PPO	0.240	0.73	0.43	1 24
POS	0.055	0 50	0.24	1.01
Capitated (referent)	--	--	--	--
Switched Plans	0.073	2.91	0.91	9.31
Age (years)	0.075	0.98	0.95	1.00
Sex	0.524	0.88	0.60	1.30
Prior Inpatient Stay (2000)	0.637	0.82	0.37	1.85
Mental Health Condition	0.280	0.53	0.16	1.69
Comorbidity Score	0.976	0.99	0.65	1.52
Insulin Use	0.239	0.75	0.46	1.21
MPR ≥ 80%	0.424	0.84	0.55	1.28
Non-index Medication Count	0.434	1.12	0 84	1.50
Statin Use	0.080	0.70	0.47	1.04
ACE Inhibitor Use	0.804	1.06	0.69	1.60
Constant	0.001	0.01	--	--

[1] OR = Odds Ratio

The results of logistic regression analysis of inpatient stays in study year 2001, unadjusted for the covariates (Model 3) are contained in Table 5. These data indicated that individuals in both FFS and PPO plans were significantly more likely to experience an inpatient stay compared to those in capitated plans (OR = 1.11, p = 0.002 and OR = 1.08, p = 0.015, respectively). There was no significant difference between POS and capitated plans in the model adjusted for plan type only.

The covariates were then used to adjust Model 3. The results obtained from the adjusted model (Model 4) are shown in Table 6. After adjusting for the covariates, the data indicated that the significant difference observed between FFS and capitated plans remained significantly different (OR = 1.11, p = 0.022). Among the covariates used to adjust the model, increasing age (OR = 1.02, $p < 0.001$), higher co-morbidity score (OR = 1.37, $p < 0.001$), MPR greater than 80% (OR = 1.25, $p < 0.001$) and increasing non-index medication count (OR = 1.10, $p < 0.001$) were each associated with significantly increased odds of an inpatient stay in study year 2001. Prior inpatient stay (OR = 0.43, $p < 0.001$), insulin use (OR = 0.58, $p < 0.001$), statin use (OR = 0.93, p = 0.028) and ACE inhibitor use (OR = 0.85, $p < 0.001$) were each associated with decreased odds of an inpatient stay in study year 2001.

Table 5: Model 3: Logistic regression analysis of inpatient stays in study year 2001; values are Odds Ratios (OR)

			95% C.I. for OR[1]	
Plan Type	**p-value**	**OR**	**Lower**	**Upper**
FFS	0.002	1.11	1.04	1.19
PPO	0.015	1.08	1.02	1.16
POS	0.660	0.98	0.91	1.06
Capitated (ref)	--	--	--	--
Constant	0.000	0.16	--	--

[1] OR = Odds Ratio

Table 6: Model 4: Logistic regression analysis of inpatient stays in study year 2001 by insurance plan type (adjusted for insurance plan type and the covariates); values are Odds Ratios (OR)

			95% C.I. for OR[1]	
Variable	**p-value**	**OR**	**Lower**	**Upper**
FFS	0 022	1 11	1.02	1.22
PPO	0 143	1 06	0 98	1 16
POS	0 350	0 95	0 87	1 05
Capitated (referent)	--	--	--	--
Switched Plans	0 724	1 03	0 89	1 18
Age (years)	0 000	1 02	1 02	1 03
Sex	0 058	0 94	0 88	1 00
Prior ER Visit	0 512	0 62	0 15	2 59
Prior Inpatient Stay (2000)	0 000	0 43	0 39	0 49
Mental Health Condition	0 143	0 84	0 66	1 06
Comorbidity Score	0 000	1 37	1 29	1 45
Insulin Use	0 000	0 58	0 54	0 63
MPR ≥ 80%	0 000	1 25	1 17	1 33
Non-index Medication Count	0 000	1 10	1 05	1 16
Statin Use	0 028	0 93	0 87	0 99
ACE Inhibitor Use	0 000	0 85	0 79	0 91
Constant	0 009	0 14	--	--

[1] OR = Odds Ratios

Table 7 contains a summary by quintile for ER visits in year 2000 in the propensity score analysis for this dependent variable. Because the frequency of several of the covariates was low, the logistic regression analyses within the quintiles were done without inclusion of plan switchers, prior inpatient stays and presence of a mental health condition. In addition, in quintile 1 all comorbidity scores were constant at a Charlson Score of 2 indicating that this subset of

individuals had only Type 2 diabetes and no record of other chronic diseases that comprise the score. As in the overall dataset the FFS plan type was associated with increased odds of an ER visit only in quintile 3 (OR = 4.01, p = 0.036). Likewise, none of the covariates were predictors of the odds of an ER visit in any of the quintiles.

Table 8 contains a summary by quintile for inpatient stay in year 2001 in the propensity score analysis for this dependent variable. The increased odds of experiencing and inpatient stay for individuals for FFS plans were not observed in the propensity score analysis. In fact, there were no differences between the plans types with respect to inpatient stays in year 2001 after the dataset was stratified into quintiles. Among the covariates used to adjust the models, prior inpatient stay, insulin use and MPR $\geq$ 80% were each significantly associated with the odds of an inpatient stay in study year 2001 across the propensity score quintiles. Patients experiencing prior utilization in the form of inpatient stays were significantly less likely to experience an additional subsequent inpatient stay in study year 2001. The odds of experiencing an inpatient stay in study year 2001 when an inpatient stay occurred in year 2000 was on average 56% lower than when there was no prior inpatient stay. This compares favorably to the odds of an inpatient stay in the entire cohort where the odds ratio was OR = 0.43 ($p < 0.001$). A similar relationship was observed for insulin use where the odds of a inpatient stay were approximately 40 % lower for insulin users, whether in the overall study cohort or on average across the quintiles. Conversely, in this analysis the odds of an inpatient stay increased by approximately 25% when the MPR was greater than 80%. Increasing age was associated with slightly increased odds of an inpatient stay only in quintile 5 (OR = 1.03, $p < 0.001$). Male sex was associated with decreased odds of an inpatient stay (OR = 0.65, $p < 0.001$).

Table 7: Odds ratios for ER visit in study year 2001 by insurance plan type in the overall dataset and within each quintile of the propensity score; all values are Odds Ratios (p-value)

Variable	Overall Dataset	Quintile 1	Quintile 2	Quintile 3	Quintile 4	Quintile 5
FFS	**1.64 (p=0.043)**	0 98 (ns)	1 14 (ns)	**4.01 (p=0.036)**	1 30 (ns)	1 44 (ns)
PPO	0 73 (ns)	0 77 (ns)	0 66 (ns)	1 96 (ns)	0 25 (ns)	0 79 (ns)
POS	0 50 (ns)	0 49 (ns)	0 90 (ns)	0 58 (ns)	0 33 (ns)	0 30 (ns)
Capitated (referent)	--	--	--	--	--	--
Switched Plans[1]	2 91 (ns)	--	--	--	--	--
Age	0 98 (ns)	0 89 (ns)	0 88 (ns)	0 89 (ns)	0 87 (ns)	0 99 (ns)
Sex	0 88 (ns)	1 51 (ns)	1 01 (ns)	0 88 (ns)	0 63 (ns)	0 75 (ns)
Prior ER Visit[1]	--	--	--	--	--	--
Prior Inpatient Stay[1]	0 82 (ns)	--	--	--	--	--
Mental Health Condition[1]	0 53 (ns)	--	--	--	--	--
Comorbidity Score	0 99 (ns)	--[2]	1 00 (ns)	7 95 (ns)	2 48 (ns)	0 99 (ns)
Insulin Use	0 75 (ns)	0 87 (ns)	1 51 (ns)	0 98 (ns)	1 18 (ns)	0 78 (ns)
MPR 80%	0 84 (ns)	1 51 (ns)	0 49 (ns)	0 61 (ns)	1 02 (ns)	1 01 (ns)
Non-Index Medication Count	1 12 (ns)	0 73 (ns)	0 90 (ns)	1 55 (ns)	0 88 (ns)	1 21 (ns)
Statin Use	0 70 (ns)	0 42 (ns)	0 78 (ns)	0 83 (ns)	0 88 (ns)	0 56 (ns)
ACE Inhibitor Use	1 06 (ns)	1 19 (ns)	0 99 (ns)	1 30 (ns)	0 54 (ns)	1 12 (ns)

[1] Model adjustment for prior ER visit in year 2000, prior inpatient stay in year 2000, presence of a mental health condition and plan switchers were not used to adjust the models for ER visit in year 2001 due to the low frequency of this dependent variable

[2] Comorbidity score was constant in Quintile 1, all values equal 2

Table 8: Odds ratios for inpatient stay in study year 2001 by insurance plan type in the overall dataset and within each quintile of the propensity score; all values are Odds Ratios (p-value)

Variable	Overall Dataset	Quintile 1	Quintile 2	Quintile 3	Quintile 4	Quintile 5
FFS	**1.11 (p=0.022)**	1.10 (ns)	1.06 (ns)	1.18 (ns)	1.13 (ns)	1.00 (ns)
PPO	1.06 (ns)	0.93 (ns)	1.09 (ns)	1.12 (ns)	1.08 (ns)	1.13 (ns)
POS	0.95 (ns)	0.79 (ns)	1.00 (ns)	1.00 (ns)	0.95 (ns)	0.95 (ns)
Capitated (referent)	--	--	--	--	--	--
Switched Plans	1.03 (ns)	1.19 (ns)	0.96 (ns)	1.11 (ns)	0.88 (ns)	1.08 (ns)
Age	**1.02 (p<0.001)**	0.99 (ns)	0.99 (ns)	1.05 (ns)	1.01 (ns)	**1.03 (p<0.001)**
Sex	0.94 (ns)	1.02 (ns)	1.07 (ns)	0.90(ns)	1.05 (ns)	**0.65 (p<0.001)**
Prior ER Visit[1]	0.62 (ns)	--	--	--	--	--
Prior Inpatient Stay	**0.43 (p<0.001)**	**0.49 (p<0.001)**	**0.38 (p<0.001)**	**0.47 (p<0.001)**	**0.44 (p<0.001)**	**0.42 (p<0.001)**
Mental Health Condition	0.84 (ns)	0.75 (ns)	0.65 (ns)	0.81 (ns)	0.94 (ns)	0.88 (ns)
Comorbidity Score	**1.37 (p<0.001)**	--[2]	2.41 (ns)	1.45 (ns)	**1.77 (p=0.044)**	**1.26 (p<0.001)**
Insulin Use	**0.58 (p<0.001)**	**0.60 (p<0.001)**	0.79 (ns)	**0.51 (p = 0.001)**	**0.60 (p=0.005)**	**0.55 (p<0.001)**
MPR 80%	**1.25 (p<0.001)**	1.12 (ns)	**1.18 (p=0.022)**	**1.37 (p<0.001)**	**1.29 (p=0.001)**	**1.28 (p=0.001)**
Non-Index Medication Count	**1.10 (p<0.001)**	1.20 (ns)	1.00 (ns)	1.07 (ns)	1.08 (ns)	**1.16 (p=0.008)**
Statin Use	**0.93 (p=0.028)**	**0.98 (p=0.05)**	1.08 (ns)	**0.81 (p=0.008)**	0.88 (ns)	0.85 (ns)
ACE Inhibitor Use	**0.85 (p<0.001)**	0.86 (ns)	**0.79 (p<0.005)**	**0.83 (p=0.039)**	**0.81 (p=0.014)**	0.94 (ns)

[1] Prior ER Visit in year 2000 was not used in the propensity score analysis due to low frequency of this covariate

[2] Comorbidity score was constant in Quintile 1; all values equal 2

DISCUSSION

In the analysis of the odds of an ER visit in study year 2001, adjustment for the covariates removed the significant differences observed between the PPO and POS plans compared to the capitated plans. This was not the case for the FFS plans (Table 4). After adjustment for the covariates patients in FFS plans were significantly more likely to experience as ER visit compared to patients in capitated plans. This finding suggests that the hypothesis that members of capitated plans would have decreased odds of an ER visit was confirmed. This is supported by the findings in a randomized controlled study of adult patients with Type 2 diabetes enrolled in an HMO in which a 6-month health care management program was introduced {Sadur, 1999 #75}. In this capitated environment, a diabetes self-management intervention was shown to decrease subsequent hospital admissions and outpatient care office visits. Plan types with intermediate levels of restrictiveness, PPO and POS plans, were not significantly different than capitated plans for the odds of an ER visit is year 2001. It is important to keep in mind that the ER visit variable was constructed based on any cause for ER utilization, not strictly for complications due to Type 2 diabetes. Even in this case, the frequency of ER visits was low making inferences between plan types difficult to interpret.

In the propensity score analysis (Table 7), the significance of the FFS plans observed in the overall dataset was not observed in 4 of the 5 quintiles but was observed in quintile 3 only. For quintile 3, the probability that an individual was enrolled in a capitated plan was approximately 45% (data not shown). It is not possible to determine whether this finding was due to chance or due to the fact that the frequency of ER visits was low. In the propensity score analysis, a reduced number of covariates were used to adjust the models within the quintiles to improve the performance of the logistic regression parameter estimates. In all regression analyses for ER

visit, none of the individual covariates were significant predictors of the odds of an ER visit in 2001. Again, it is possible that the low frequency of ER visits overall did not allow an inference for any affects of the covariates on the odds of ER visits in 2001.

In the analysis of the odds of an inpatient stay, adjustment for the covariates removed the significant differences observed between PPO plans and capitated plans. As for ER visits this was not the case for FFS plans, which remained associated with significantly greater odds of an inpatient stay compared to capitated plans (Table 6). This finding suggests that the hypothesis that members of capitated plans would have decreased odds of an inpatient stay was also confirmed. Increasing age, comorbidity score and non-index medication count were each associated with increased odds of an inpatient stay in year 2001. This was also observed for patients with MPR $\geq$ 80%. These findings suggested that as working age patients with Type 2 diabetes get older and comorbidities begin to appear, regimen complexity can increase. This trend is consistent with increased resource utilization. Prior inpatient stays, insulin use, statin use and ACE inhibitor use were each associated with decreased odds of an inpatient stay in year 2001. These findings suggested that when working age patients with more advanced Type 2 diabetes plus common comorbidities of hypertension and dyslipidemia encountered the health care system, either on an inpatient or outpatient basis, the result was reduced resource utilization in year 2001. Switching health care plan types, sex and the presence of a mental health condition were not associated with the odds of an inpatient stay.

Unlike the frequency of ER visits, the frequency of inpatient stays in the dataset was much higher (Table 1), therefore it was possible to include the same set of covariates in the regression analyses of the propensity score analysis as for the overall dataset. In the propensity score analysis (Table 8), the significance associated with the FFS plan type observed in the overall

dataset was not observed in any of the quintiles. The trends observed across the quintiles were directionally consistent compared to the overall dataset. It has been shown that there were no differences among health insurance plan types (HMO, PPO, POS and indemnity plans) for accepted, general diabetes care, including utilization as measured by outpatient office visits {Cooksey, 2003 #538}. The consistently reduced likelihood of an ER visit or an inpatient stay for diabetics in capitated plans is consistent with the prevailing opinion that capitated plans seek to avoid hospital admissions, when possible. As with ER visits, these data support previous reports that utilization rates are higher in traditional FFS plans compared to managed care plans. Until the content and quality of claims data approaches that of a randomized clinical trial, including some kind of linkage to clinical data, a well designed propensity score analysis offers a reality check for regression analyses that cannot correct for selection biases.

Prior resource utilization, insulin use, statin use and ACE inhibitor use were all associated with decreased odds of an inpatient stay. These findings are consistent with the current clinical practice guidelines in that patients with Type 2 diabetes who encountered health care on an inpatient basis, are stable on their insulin treatment regimen and fill prescriptions for statins and ACE inhibitors, the standard of care, could be expected to have reduced odds on an inpatient stay in study year 2001. Interestingly, having a "good" MPR for oral anti-diabetic medications was associated with increased odds of an inpatient stay. These trends were consistent across the quintiles. The significant effect of increasing non-index medication count observed in the overall dataset was observed only in quintile 5 of the propensity score analysis where the odds of being a member of a capitated plan were highest. One interpretation of this finding could be that as regimen complexity increases, patients with Type 2 diabetes may be less compliant with their regimen leading to more episodes that require inpatient care. However, this interpretation must

be viewed with caution because the inpatient stay variable reflects all-cause hospitalization, not acute diabetes specific complications.

In the overall dataset, both statin and ACE inhibitor use were associated with decreased odds of an inpatient stay in year 2001. However, in quintile 5 where the odds of patient membership in a capitated plan type were highest, the association was no longer significant suggesting that the individuals in quintile 5 may have been more likely to have been treated according to current clinical practice guidelines.

This study had limitations. The MarketScan dataset may not be generalizable to all parts of the United States because the employers contributing to claims data are predominantly located in the southern states and less concentrated in western states. The MarketScan dataset also has a greater proportion of females compared to the general population. Healthcare plans in other parts of the United States, particularly the western states may operate differently. Likewise, data from public forms of health insurance, Medicare and Medicaid, were not included in the MarketScan dataset, therefore the results reported here may not be applicable to these segments of the health care system. The study period was years 2000-2001. The results obtained from this time period may not be applicable today. Given the rapidity and extent of the evolution of the health care system in the US, these data may not reflect the current state of health insurance in the United States, and especially so if the United States adopts public insurance legislation that competes with or eliminates the private health insurance sector.[55, 56].

The ICD-9-CM code algorithm used to identify patients with Type 2 diabetes may have captured some Type 1 diabetics depending on the accuracy of the billing process. This is not expected to be a significant source of error given the high specificity and sensitivity of the method used [22].

The MarketScan dataset includes provisions to capture data on 7 insurance plan types. Of these, two plan types in the study period had frequencies of zero. The remaining 5 plan types were consolidated into 4 categories ranging from most (capitated) to least (traditional FFS) restrictive in terms of accessing out-of-network providers. It is not clear to what extent the consolidation affected the results; however, this pattern of consolidation has been documented previously in the literature [23] and the only consolidation done was to group together the capitated plans since there were no occurrences of either Basic/Major Medical or EPO plans. Within each of the 4 categories, multiple plans of a given type were assumed to have similar affects on the dependent variables. This could influence the results based on the fact that the characteristics of physician practices are variable. Variability could arise from the number of physicians in the practice, most practices are not exclusively tied to FFS or capitation arrangements but generally have mixed forms of payment and differing incentives may be used within a practice based on productivity, quality of care or patient satisfaction measures.

In the analysis of health care resource utilization, there was no evaluation of costs. Health insurance is not free. There are provisions for premiums, copayments, deductibles and coinsurance in all policies in the MarketScan dataset. Additional research is needed to link the findings in the present study to out-of-pocket costs to patients. As indicated above, both ER visits and inpatient stays were identified in the dataset on an all-cause basis, not whether the utilization was due to complications of diabetes. The low frequency of ER visits, especially in study year 2000 prevented use of this predictor variable in some of the logistic regression analyses.

The literature describes three methods in which selection bias may be minimized in observational studies [17, 51] using propensity scores. These methods are: stratification,

matching, and covariate adjustment. There is no preferred method [16]; however, stratification was used in the present study. The results of this study may have been different had an alternative method been used. The theoretical framework used to derive the variables in the propensity score analysis was based on the TRIAD study [52]. TRIAD was a multicenter prospective cohort study in diverse population of patients with diabetes who were over 18 years of age. TRIAD compared managed care structure to processes of care among 6 study sites and 10 insurance plans, including: staff, network and IPA HMO models, POS plans and PPO plans. Numerous studies have been published based on TRIAD. The literature based on the TRIAD study was reviewed with respect to published studies that included variables for resource utilization, medication adherence and receipt of appropriate processes of care to develop a set of predictor variables to include in the propensity score model. The following variables were selected for inclusion in the propensity score model because the data suggested there could some influence on health care plan type selection or that potential confounding may exist among the variables: ACE inhibitor and insulin use [53]; insulin use ; age and comorbidity burden [54]; and treatment intensification to maintain glycemic control [43]. Because propensity score analyses are dependent on the variables used to compute the scores, it is critical to base the process on a rationale theoretical framework. The TRIAD study was focused on manage care and utilization of health care resources were considered; however, the selection of the set of variables could have varied from the five variables used in this study. It is reasonable to expect that the combination of age, comorbidity score, insulin use, ACE inhibitor use and regimen complexity represent potentially confounding variables that should be accounted for in the analyses.

CONCLUSIONS

The results of this study suggested that the well documented higher utilization rates for less restrictive FFS plans compared to more restrictive capitated plans may not be as robust as previously reported. Although the data suggested that members in FFS plans had increased odds of an ER visit or an inpatient stay, when the dataset was stratified into quintiles in which patients with Type 2 diabetes had similar likelihood of being in a capitated plan type, or not, no differences among any of the plan types were observed. Based on the propensity score analysis, the hypothesis that members of capitated plans would have decreased resource utilization was rejected. There were no differences in resource utilization among the plan types.

PPO and POS plan types with intermediate levels of restrictiveness to access to out-of-network care were not significantly different than capitated plans based on odds of either ER visits or inpatient stays.

Although the regression models were adjusted for patients who switched plans during the study period and for the presence of mental health conditions, neither of these covariates were associated with increased resource utilization.

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APPENDIX 2: PAPER #2

ASSOCIATION BETWEEN HEALTH INSURANCE PLAN TYPE AND MEDICATION POSSESSION RATIOS IN ADULT WORKING AGE PATIENTS WITH TYPE 2 DIABETES MELLITUS

ASSOCIATION BETWEEN HEALTH INSURANCE PLAN TYPE AND MEDICATION POSSESSION RATIOS IN ADULT WORKING AGE PATIENTS WITH TYPE 2 DIABETES MELLITUS

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ABSTRACT

The objective of this research project was to evaluate the effect of health insurance plan type on anti-diabetic medication adherence as measured by medication possession ratios (MPR>0.80: good MPR) for oral medications. The data source for this research project was the 2000-2001 MarketScan dataset, which is comprised of administrative claims data for over 2.5 million privately insured individuals in the United States. MPR was defined as the sum of days supply each anti-diabetic medication divided by the number of days between the first and last prescription fill dates plus the number of days for the last refill. The odds of having a good MPR for oral anti-diabetic medications were evaluated using multiple logistic regression models controlled for insurance plan type plus demographic and clinical characteristics of the target patient population. A propensity score analysis was done using a stratification approach to further control for selection bias. The proportion of patients with MPR ≥80% was 68.2%. Patients in capitated plans were more likely to have good MPR compared to FFS, PPO and POS plan types (odds ratios: 0.75, $p<0.001$; 0.81, $p<0.001$; 0.81, $p<0.001$, respectively). This relationship remained in all quintiles of the propensity score analysis.

INTRODUCTION

Prevention of the expensive, episodic short-term and chronic long-term complications associated with Type 2 diabetes has been the basis for clinical practice recommendations published by the American Diabetes Association (ADA) for years [1-6]. Maintaining glycemic control to minimize the occurrence of microvascular complications that are associated with clinically significant morbidity and mortality is the central goal of the recommendations [7, 8]. Microvascular complications include retinopathy (loss of vision), nephropathy (end stage renal disease) and neuropathy (peripheral numbing or loss of the sense of touch). Glycemic control is accomplished through both appropriate self-management and in the delivery of appropriate processes of diabetes care by healthcare providers. Glycemia, measured as either plasma concentrations of glycosylated hemoglobin (% HbA1c) or fasting blood glucose (mg/dL), is considered to be controlled when these parameters are continually maintained at <7% or <126 mg/dL, respectively [1, 5].

Treatment regimens should strive to maintain glycemia at or near normal without inducing hypoglycemia [9]. Interventions to improve glycemic control are intended to preserve or improve β-cell function, reduce glucose production in the liver and improve peripheral tissue uptake of glucose. Diligence is required because over time it is known that currently available treatment options, while providing appropriate initial glycemic control, will eventually fail as the disease progresses [10]. Measures of glycemia drift upward and β-cell function declines [11-13]. Based on differing mechanisms of action, different treatments have different effects on β-cell function.

The amount of time patients spend out of adequate glycemic control is cumulative with deleterious effects on the body [10]. In fact, the likelihood that a patient whose diabetes has progressed to an HbA1c level > 8% will return to <7% is only 0.2 (20%) [10]. Unfortunately, studies have shown that on average physicians tend to allow a lack of glycemic control to persist before taking action to change the treatment regimen and restore adequate glycemic control [10].

Maintaining glycemic control is accomplished by patients routinely accessing health care resources in conjunction with providers delivering appropriate processes of care during each encounter. Both of these aspects, patients seeking care and providers delivering care, are facilitated by the features of health care insurance plans. Benefit plan designs differ in terms of accessibility and out-of-pocket costs to patients with diabetes and the method by which providers are compensated for services rendered. These factors operate simultaneously. It is possible that different benefit plan designs are associated with increasing rates of failure to maintain adequate glycemic control as a result of patient- and provider-related factors. Different methods of delivering processes of care may lead to different outcomes.

Medication adherence is the extent to which patients follow the recommendations of their health care provider [14, 15]. Medication possession can be considered as a surrogate measure of the level of glycemic control experienced by each patient [16]. Medication possession [17] is also considered to be a measure of patient access to and acquisition of prescription drugs for certain conditions. These measures assume that a prescription filled is a prescription ingested [18]. For patients with diabetes, reduced adherence to prescription drug therapy may result in worsening conditions and lead to increased out-patient office visits, use of emergency room services, hospital admission and cost [17]. Although limited data for HbA1c are generally available in retrospective cohort studies, it has been shown that non-adherence (<80%) is associated with

higher HbA1c [14, 19]. Patients with adherence rates ≥80% are considered to be complaint with healthcare provider recommendations. Over time most patients do not comply with their prescribed medication regimen, especially younger patients with fewer co-morbidities, who may be less symptomatic than older patients or patients who have had the longer [19].

Little is known about the affects of different types of private insurance plans on medication possession in privately insured, working age adults with Type 2 diabetes. Limited research has been done when health insurance plan type, out-patient and in-patient claims, pharmacy claims and benefit plan design data are available in the same data set. This study extends the literature by examining the affects of health insurance type (FFS, POS, PPO or capitated) on medication possession ratios (MPR) for oral anti-diabetic medications in working age adults with Type 2 diabetes.

After controlling for the covariates, the objective of this study was to determine whether medication possession rates differed by health insurance plan type in which adult privately insured patients with Type 2 diabetes were enrolled. FFS plans are generally believed to be associated with delivery of more services than capitated plans. Capitated plans tend to be very restrictive about paying for provider services outside of the accepted list of providers in the network compared to members of less restrictive traditional FFS plans that are based on revenue resulting from increased service utilization. Likewise, capitated plans are generally understood to focus on preventive services to reduce costly episodes of acute care in the future, and often include prescription drug coverage. The hypothesis tested was that compared to less restrictive plan types, members of capitated plans would have increased odds of having good medication possession behavior.

METHODS

Data Source

The 2000-2001 MarketScan Commercial Claims and Encounters administrative claims database (available from MedStat; Ann Arbor, MI) was used in this retrospective study of adult patients with Type 2 diabetes. This 2-year database contains inpatient, outpatient and pharmacy insurance claims information on approximately 2.5 million covered lives in the United States. Patients of working age between 18 and 64 years were included in the study cohort. The individual patient was the unit of analysis. To be eligible for inclusion in the analytic file, patients must have been continuously enrolled in their health insurance plan throughout the study period.

Population

A patient's index date is the first date in the claims data at which the inclusion criteria were met for a diagnosis of Type 2 diabetes. The Index Date must have occurred in the first half of the year 2000. Patients were excluded if they had an inpatient admission prior to the index date of the study or were pregnant or admitted for child birth. Patients with Type 2 diabetes were identified in the dataset according to both outpatient and inpatient claims for reimbursement using the methodology reported by O'Connor [20]. A patient was considered to be diagnosed with Type 2 diabetes if the claims record included at least one of the three following criteria: at least one inpatient hospitalization with a diagnosis of diabetes; two outpatient encounters with a primary ICD-9-CM diagnosis code specific for diabetes; or a prescription for an anti-hyperglycemic medication in 2000 – 2001. A primary diagnosis of diabetes was defined as the ICD-9-CM code 250.x. Microvascular complications of diabetes included ICD-9-CM codes

250.5 (renal), 362.0x (ophthalmic), 366.41 (ophthalmic), 250.6 (neurological) and 357.2 (neurological). This method has demonstrated a sensitivity of 0.91 and a specificity of 0.99 for the identification of patients with Type 2 diabetes in an HMO claims database [20].

Main Effects

In the analyses presented below, health insurance plan type was the main effect of interest. Possession of health insurance coverage is an enabling factor according to the Behavioral Model of access to health care. The MarketScan dataset includes provisions to collect variables for seven (7) different health insurance plan types: Traditional FFS plans - Basic/Major Medical and Comprehensive policies, and Managed Care plans: EPOs, HMOs, POS (with either capitation or FFS physician payment arrangements) and PPOs. With the potential availability of 7 different plan types, it was necessary to consider appropriate ways to consolidate the plan types into fewer categories, as has been done in other studies using the MarketScan dataset [21]. Categories were created to reflect decreasing levels of restrictiveness on seeking care from specialists or other out-of network providers, where capitated plans would be expected to be most restrictive and traditional FFS plans would be least restrictive. PPO and non-capitated POS plans would be intermediate with respect to restrictiveness. As hypothesized, the expectation was that capitated plans would indicate decreased odds of an ER visit or an inpatient stay compared to less restrictive FFS plan types. Likewise, based on their preventive health care strategies, capitated plans were anticipated to reflect increased odds of good medication possession and current processes of care as estimated by use of ACE inhibitors and statins. The four consolidated insurance plan type categories were:

1 - HMO plans (capitated) and POS plans (capitated/partially capitated) and;

2 - Non-capitated POS plans (POS);

3 - Preferred Provider Organizations (PPO) plans;

4 Traditional FFS arrangements: Basic/Major Medical and Comprehensive plans (FFS)

In the analyses below, the plan types were referred to as "capitated", "POS", "PPO" and "FFS" to reflect decreasing level of restrictiveness for accessing out-of-plan health care service use.

Dependent Variable

The dependent variable in this study was odds that patients with Type 2 diabetes had "good" medication possession behavior with respect to oral antihyperglycemic medications. Medication possession is considered an enabling factor according to the Behavioral Model of access to health care. Medication possession [17] is a measure of patient access to and acquisition of prescription drugs for certain conditions. In this study, medication possession was evaluated in a cross-sectional analysis of the entire 2-year study period because the observation of prescription filling behavior requires at least 6-9 months of longitudinal claims data [16, 22]. Oral anti-diabetic medications were identified in the MarketScan dataset using product NDC numbers for products that were commercially available in the first six months of the study period [23]. Medication possession ratios (MPR) were generated by first computing a continuous variable based on oral anti-diabetic medications included in the dataset, where the MPR is the sum of days of supply of a particular oral anti-diabetic medication divided by the number of days between the first and last prescription fill dates plus the number of days for the last refill:

MPR = Σ(days supply)/#days between 1st & last refill + days supply for last refill

This continuous variable was then dichotomized according to the definition of "good" medication possession, i.e., whether the MPR was greater than or equal (good) to 0.8, or not

(poor). If more than one medication was found for a single patient, separate MPR values were computed for each active ingredient, then averaged for those patients on multiple medications. This was the index MPR for oral antihyperglycemic medication. MPR values were computed only for oral anti-diabetic medications, not for ACE inhibitors, statins or insulin. Computing accurate MPR values for insulin use was not possible using administrative data because the variability in daily insulin regimens was not captured in the administrative dataset [16, 24, 25].

Because it is not possible to know with certainty that patients actually take their medication despite a high MPR, a sensitivity analysis was done using different cut-off values to define "good" medication possession behavior and to further evaluate the influence of plan type on medication possession. This was done by dichotomizing the continuous MPR variable the additional cut-off values: ≥ 0.5, ≥ 0.7, ≥ 0.9, and 1.0. Models 1 and 2 specified for MPR were then repeated at each new cut-off for the definition of "good" Models were used to examine the effect by plan type at each level of "good" for the definition of medication possession.

Covariates

A series of covariates was used to adjust for potential biases and confounders in the analyses. This set of variables was referred to as "the covariates" in the analyses presented below.

Models were adjusted for demographic variables, age and sex. Age was used as a continuous variable.

The MarketScan dataset covers years 2000-2001. To account for the possibility that individuals who were eligible for entry into the analytic file in year 2000 and may remain in the dataset but switched to another plan type during the study period, a categorical variable was created to indicate whether individuals remained in their existing plan or switched to another plan type. A

categorical variable was created to indicate prior resource utilization according to whether patients experienced either an ER visit or inpatient stay, or not in study year 2000 [26]. This variable was created in the process of identifying patients with Type 2 diabetes and was used to adjust models of the effect of health insurance plan type for prior health care resource utilization.

To adjust for the possibility that oral medication regimens for glycemic control could be changed or intensified in the remaining 18 months of the study period, the actual count of all non-index medications prescribed for treatment of Type 2 diabetes was determined after the index MPR was computed [27]. This variable was constructed as a simple count of the number of new drugs added to or switched from the index regimen. Non-index medication counts were aggregated into values of 0 (no new medications for diabetes added), 1 (one medication added), or ≥ 2 (two or more medications added). The counts were used in the main statistical models of the effect of insurance plan type as a continuous variable.

The presence of comorbidities reflects the concurrent manifestation of two or more diseases that are etiologically independent and not causally linked to the index disease of interest [28]. It is important to note that complications, e.g., presence of ketoacidosis in patients with diabetes, are not considered co-morbidities. The presence of increasing numbers of co-morbidities with various levels of severity can be viewed as a partial measure of the underlying health status of individuals in a population [29, 30]. Unlike randomized clinical trials it is not possible to control for differences in patient baseline characteristics by randomization. The goal of adjusting statistical analyses for the presence of baseline co-morbidities in health services research is to minimize the risk of confounding and to be able to interpret inferences with greater reliability and accuracy [29]. Although review of the recent literature suggests that the Charlson Co-morbidity Index [31], as adapted by Deyo [32] has been the most frequently used measure of co-

morbidity in studies of patients with diabetes [18, 33-35]; the D'Hoore modification was used in the present study based on its simplicity [36-39]. This co-morbidity score is based on only the first three digits of the ICD-9 codes in the claims dataset. Therefore the D'Hoore modification captures all patients with diabetes but cannot distinguish between complicated versus uncomplicated diabetes. In the present study it was not essential to make this distinction, and the D'Hoore modification has similar characteristics compared to other adaptations of the Charlson score [39]. Likewise, the literature does not recommend use of a particular measure of co-morbidity when administrative claims data are used even though many studies have been conducted in patients with diabetes. Because the Charlson co-morbidity index includes diabetes which has a weight of 2 in this scoring system, all patients in the final analytic file were assigned a default co-morbidity weight of at least 2 [40]. Higher scores are correlated with increased risk of 1-year mortality. The co-morbidity score was a continuous variable computed for study year 2000. Co-morbidity burden was considered a need based factor in the Behavioral Model of access to health care.

Diabetic patients diagnosed with mental health conditions, especially depression, have been shown to receive more healthcare services on a cumulative basis than diabetics without mental disorders but are less likely to receive complete diabetes-specific care [41]. The proportion of patients with poorer glycemic control increases with the presence of concurrent mental health conditions [42]. Likewise, patients with mental health conditions may be less able to adhere to diabetes self-management behaviors, such as, diet, medication compliance and keeping out-patient office visit appointments. [34]. Although a significant proportion of patients, i.e., >2% with mental health conditions is not anticipated to be found in the population represented in the MarketScan database, a categorical indicator variable was constructed for the analyses to adjust

for whether a patient with Type 2 diabetes was also diagnosed with a mental health condition [41-43]. For this study, patients will be considered to have a mental health condition, if any of the following ICD-9-CM codes are present in any of the diagnosis fields (dx1 – dx15) in the MarketScan dataset [44]:

Anxiety disorder: 293.84, 293.89, 300.00-300.09, 300.2-300.30, 300.90, 308.30, 309.81

Substance abuse disorder: 291-292.90, 303-305

Although it was not possible to determine the exact insulin regimen that diabetics used during the study period, a categorical variable was constructed to adjust the models for insulin use, or not. This variable was used to control for disease progression and regimen complexity [16].

As in study year 2001 for the processes of care dependent variables described above, use of ACE inhibitors and statins in study year 2000 also represented the standard of care of patients with Type 2 diabetes [45]. To adjust the logistic regression models for treatment of dyslipidemia and hypertension in 2000, categorical variables were constructed to reflect whether patients were receiving prescriptions for statins and ACE inhibitors as specified in the 2000 treatment practice guidelines [46]. Prescriptions for statins and ACE inhibitors were identified in pharmacy records contained in the MarketScan dataset using the National Drug Codes (NDC numbers) for these medications that were commercially available in the study period. MPR values were not computed for these therapies.

Propensity Score Analysis to Control for Selection Bias

A propensity score analysis was conducted for Model 2 to control for potential selection bias. In the propensity score analysis, a separate unique logistic regression model was developed based on published data from the TRIAD study [47]. Propensity scores were derived from a logistic

regression model of the odds of choosing between health care plan types based on how restrictive plans are with respect to seeking care from out-of-net-work providers. The four plan type categories, capitated, POS, PPO and FFS were recoded into two groups – plans with more emphasis on preventive services and more restrictive access to out-of-network providers (HMO and capitated POS plans) and plans with less emphasis on preventive services and less restrictive access to out-of-network providers – (traditional FFS plans, PPO plans and non-capitated POS plans). The propensity scores were patient level probabilities that an individual selected a particular insurance plan type given their health status at the time. The variables derived from the TRIAD study for inclusion in the propensity score model were: age, comorbidity score, insulin use, ACE inhibitor use and regimen complexity. These variables represent factors that could influence selection of a particular health insurance plan type and confound the analyses. For the propensity score analysis, non-index medication count was used as a categorical variable where 0 indicated no additional medications for glycemic control were added to a regimen, and 1 indicated that one or more new classes of drugs were added to a regimen.

The predicted probabilities from the regression model (i.e., the propensity scores) were then used to stratify the dataset into quintiles. Quintile 1 represents individuals with the lowest propensity (probability) of being enrolled in plan types with more emphasis on preventive services and more restrictive access to out-of-network providers (i.e., less likely to be in a capitated plan type). Quintile 5 represents individuals with the highest propensity (probability) of being enrolled in plan types with more emphasis on preventive services and more restrictive access to out-of-network providers (i.e., more likely to be in a capitated plan type). The effect of health insurance plan type on the dependent variable was compared between the overall dataset and within each quintile of the dataset adjusted for individual propensity scores. The distribution of propensity

scores within each quintile was anticipated to substantially overlap within the recoded groups ranging from lowest to highest levels of restrictiveness to access health care from out-of-network providers.

Model Specification for Cross-Sectional Analysis

Multiple logistic regression models were specified to estimate the odds of MPR exceeding 0.8 for oral antihyperglycemic therapy in the study period by insurance plan type. Two models were specified:

Model 1 – Odds that MPR is ≥ 0.8; adjusted for plan type

Model 2 – Odds that MPR is ≥ 0.8; adjusted for plan type and the covariates

All of the logistic regression models were analyzed using SPSS version 17.0. The variables were constructed using SAS version 9.1. The capitated plan type was referent in all regression analyses of the effect of health insurance plan type.

RESULTS

The characteristics of the study cohort are contained in Table 1. The average age of cohort was 52.9 years and was 53.4% male. The frequency of inpatient stays and ER visits was 7.5% and 0.04%, respectively. The frequency of treatment for mental health conditions was 1.6%. The proportion of individuals using insulin was 29.3%. The frequencies of statin and ACE inhibitor use were 26.4% and 28.6%, respectively. The proportion of individuals enrolled in capitated, FFS, PPO and POS plan type was 27.4%, 23.5%, 30.6% and 18.5%, respectively). Approximately 6.2% of patients with Type 2 diabetes (n = 3174) switched plan types study period. The co-morbidity score was 2.13 (SD 0.57). Non-index medication count, used to adjust for the existence of more complicated treatment regimens, ranged from 0 to 5 in the dataset. Count frequencies of 2 or more were aggregated into values of 0 (62.5%), 1 (30.5%) and ≥ 2 (7.0%). Only 7.0% of the study cohort was taking two or more non-index oral medications for Type 2 diabetes. MPR was expressed in several ways. First, the mean MPR overall, a continuous variable, was 82.4% (SD = 0.21), which indicated that on average medication possession in the study cohort was "good" [14, 19]. The proportion of patients with MPR $\geq$ 80% was 67.0%. In the propensity score analysis, non-index medication count was dichotomized into two categories where values of 0 and 1 referred to no additional medications added (0) and one or more new medications added (1) as an estimate of regimen complexity. In the study cohort, 62.6% had no new medications added and 37.4% of the cohort had 1 or more new medications added to their regimen for Type 2 diabetes. The variable for the propensity score was computed as the predicted probability of whether an individual was enrolled in more restrictive plans (i.e., capitated plans) or less restrictive plans (i.e., FFS plans). On average, the propensity score was

0.459. In other words, the likelihood that an individual was enrolled in a more restrictive plan type was approximately a 45.9%. The propensity score ranged from 0.313 to 0.978.

Table 1: Characteristics of the study cohort

Variable	Frequency
Age in years, mean (SD)	**52.9** (9.2)
Sex (% male)	**53.4%**
In-Patient Stay (% with ≥ 1 overnight stays)	**7.5%** (4686/62243)
ER Visit (% with ≥ 1 ER visits)	**0.04%** (27/61257)
Mental Health Condition (%)	**1.6%** (994/62243)
Insulin Use (%)	**29.3%** (18209/62243)
Statin Use (%)	**26.4%** (16407/62243)
ACE Inhibitor Use (%)	**28.6%** (17822/62243)
Insurance Plan Type Category	
Capitated (referent)	**27.4%** (17032/62212)
POS	**18.5%** (11496/62212)
PPO	**30.6%** (19063/62212)
FFS	**23.5%** (14621/62212)
Switched Plans (%)	**6.2%** (3174/51446)
Co-morbidity Score, mean (SD)	**2.13** (0 57)
Medication Possession (% "Good")	
Overall Mean MPR (SD)	**0.824** (0 205)
MPR ≥ 50%	**90.8%** (38752/42689)
MPR ≥ 70%	**77.7%** (33172/42689)
Index MPR ≥ 80%	**67.0%** (28587/42689)
MPR ≥ 90%	**50.4%** (21501/42689)
MPR ≥ 100%	**19.0%** (8107/42689)
Non-Index Medication Count (%)	
0	**62.5%** (26883/42966)
1	**30.5%** (13088/42966)
≥ 2	**7.0%** (2995/42966)
Regimen Complexity[1]	
No new oral medications added	**62.6%** (26883/42966)
≥ 1 new medications added	**37.4%** (16083/42966)
Propensity Score (Range)	**0.459** (0 313-0 978)
(n = 42966)	
Quintile 1 (n)	9068
Quintile 2 (n)	8414
Quintile 3 (n)	8518
Quintile 4 (n)	8558
Quintile 5 (n)	8408

[1] Regimen complexity was defined as whether subjects in the cohort had at least 1 new oral medication added to their non-index medication regimen

Effect of Health Insurance Plan Type on Odds of MPR ≥ 80

Logistic regression analysis (Model 1) for MPR ≥ 80% by health insurance plan type, unadjusted for the covariates indicates that there were significant differences in MPR by insurance plan type (Table 2). Before adjusting for the covariates, patients enrolled in either FFS (OR = 0.77, p < 0.001), PPO (OR = 0.88, p < 0.011) or POS (OR = 0.77, p < 0.001) plan types were all significantly less likely to have MPR ≥ 80% compared to patients enrolled in capitated plan types.

Table 2: MPR 80%, Model 1: Logistic regression analysis of MPR in the study period (unadjusted for the covariates)

			95% C.I. for OR[1]	
Plan Type	**p-value**	**OR**	**Lower**	**Lower**
FFS	<0.001	0.77	0.73	0.82
PPO	<0.001	0.88	0.84	0.93
POS	<0.001	0.77	0.73	0.82
Capitated (referent)	--	--	--	--

[1]OR = Odds Ratio

After adjusting for the covariates (Model 2, Table 3), the significant differences in MPR by insurance plan type remained. Patients enrolled in either FFS (OR = 0.75, p < 0.001), PPO (OR = 0.81, p < 0.011) or POS (OR = 0.81, p < 0.001) plan types were all significantly less likely to have MPR ≥ 80% compared to patients enrolled in capitated plan types. Among the covariates, the likelihood of having MPR ≥ 80% increased among those who switched insurance plans in the study period (OR = 1.57, < 0.001). These individuals were approximately 60% more likely to have MPR ≥ 80%. Likewise, increasing age (OR = 1.04, p <0.001), male sex (OR = 1.25, p <0.001), and prior in-patient stay (OR = 1.21, p <0.001) were each associated with having MPR ≥ 80%. The likelihood of having MPR ≥ 80% was significantly lower in patients who had

increasing non-index medication count and who were prescribed statins (OR = 0.78, $p < 0.001$) or ACE inhibitors (OR = 0.94, $p = 0.012$). The presence of a mental health disorder, insulin use and comorbidity score were not significant in this analysis.

Table 3: MPR 80%, Model 2: Logistic regression analysis of MPR by insurance plan type (adjusted for the covariates)

			95% C.I. for OR[1]	
Variable	**p-value**	**OR**	**Lower**	**Upper**
FFS	<0.001	0.75	0.71	0.80
PPO	<0.001	0.81	0.76	0.86
POS	<0.001	0.81	0.76	0.87
Capitated (referent)	--	--	--	--
Switched Plans	<0.001	1.57	1.43	1.71
Age	<0.001	1.04	1.04	1.05
Sex	<0.001	1.25	1.20	1.31
Prior Inpatient Stay	<0.001	1.21	1.09	1.34
Mental Health Condition	ns	1.11	0.92	1.33
Insulin Use	ns	1.04	0.98	1.11
Comorbidity Score	ns	1.00	0.75	1.05
Non-Index Medication Count	0.015	0.96	0.93	0.99
Statin Use	<0.001	0.78	0.75	0.82
ACE Inhibitor Use	0.012	0.94	0.90	0.99

[1] OR = Odds Ratio

Propensity Score Analysis

Table 4 contains a summary by quintile for MPR ≥ 80% in the propensity score analysis for this dependent variable. The decreased odds of individuals in FFS, PPO and POS plan types having MPR ≥ 80% remained across the quintiles. Interestingly, the FFS plan type was not significantly different than the capitated plan type in quintile 5, where the odds of individuals enrolling in a FFS plan was lowest. Similarly, the POS plan type was not significantly different than the

capitated plan type in quintiles 1 and 2, where the odds of individuals enrolling in a FFS plan was highest. Among the covariates in the propensity score, individuals who switched plans in the study period were consistently more likely to have MPR $\geq$ 80% across the quintiles. As in the logistic regression model adjusted for the covariates (Table 18), increasing age and sex were associated with increased odds of having MPR $\geq$ 80%. Prior inpatient stay was only significant in quintile 5 and was consistent with the result in the overall cohort (Table 19). In the overall dataset, ACE inhibitor use was associated with decreased odds of having MPR $\geq$ 80%; however, in the propensity score analysis, there were no differences between FFS or capitated plans across the quintiles. Conversely, the association between the odds of having MPR $\geq$ 80% and statin use was significantly lower in FFS plan types across the quintiles.

Table 4: Propensity Score analysis for medication possession ratio (MPR) greater than of equal to 80%; values are odds ratios (p-values)

Variable	Overall Dataset	Quintile 1	Quintile 2	Quintile 3	Quintile 4	Quintile 5
FFS	0.75 (<0.001)	0.63 (<0.001)	0.65 (<0.001)	0.78 (<0.001)	0.82 (0.005)	0.91 (ns)
PPO	0.81 (<0.001)	0.76 (<0.001)	0.82 (0.003)	0.86 (0.022)	0.72 (<0.001)	0.86 (0.025)
POS	0.81 (<0.001)	0.84 (ns)	0.86 (ns)	0.77 (0.001)	0.76 (<0.001)	0.86 (0.019)
Capitated (referent)	--	--	--	--	--	--
Switched Plans	1.57 (<0.001)	1.30 (0.023)	1.57 (<0.001)	1.60 (<0.001)	1.57 (<0.001)	1.84 (<0.001)
Age	1.04 (<0.001)	1.06 (<0.001)	1.05 (0.047)	1.06 (0.002)	1.06 (<0.001)	1.04 (<0.001)
Sex	1.25 (<0.001)	1.20 (0.001)	1.29 (<0.001)	1.26 (<0.001)	1.26 (<0.001)	1.25 (<0.001)
Prior Inpatient Stay	1.21 (<0.001)	0.95 (ns)	1.14 (ns)	1.23 (ns)	1.17 (ns)	1.40 (<0.001)
Mental Health Condition	1.11 (ns)	0.68 (ns)	1.07 (ns)	1.06 (ns)	1.03 (ns)	1.42 (0.025)
Insulin Use	1.04 (ns)	1.03 (ns)	0.95 (ns)	0.99 (ns)	0.88 (ns)	1.00 (ns)
Comorbidity Score	1.00 (ns)	--[1]	0.76 (ns)	0.69 (ns)	0.81 (ns)	1.05 (ns)
Non-Index Medication Count	0.96 (0.015)	0.98 (ns)	0.98 (ns)	1.02 (ns)	0.93 (ns)	0.94 (ns)
Statin Use	0.78 (<0.001)	0.73 (<0.001)	0.86 (0.008)	0.76 (<0.001)	0.78 (<0.001)	0.79 (<0.001)
ACE Inhibitor Use	0.94 (0.012)	0.95 (ns)	0.92 (ns)	0.96 (ns)	1.00 (ns)	0.92 (ns)

[1] Comorbidity scores in quintile 1 were constant; all values equal 2

Sensitivity Analysis

In the sensitivity analysis of the effect of varying the cut-off values for the definition of "good" and "poor" MPR, the cut-off values of ≥ 50%, ≥ 70%, ≥ 90% and 100% were used. The generally accepted minimal value that is associated with adverse clinical outcomes is MPR < 80% [16]. The 100% cut-off value was chosen because a significant proportion of individuals represented in the dataset had an MPR of 100%. As shown in Table 5, the proportion of individuals with "poor" MPR increases as the cut-off value increases. "Poor" medication possession ratios were lowest at the MPR 50% cut-off value with approximately 6% to 13% of patients in the "poor" category, whereas the greatest proportion of individuals in the "poor" category was at the 100% cut-off value. As indicated by the p-values, there was a significant difference between insurance plan type and the MPR cut-off value used to define "good" and "poor" MPR. Capitated insurance plans consistently had the lowest rate of "poor" MPR compared to the other plan types.

Table 5: Frequencies of MPR values meeting the definition of "poor" by health insurance plan type and cut-off value

MPR Cut-Off	Health Insurance Plan Type				X^2	p-value
	Capitated	FFS	PPO	POS		
50	**6.6%**	13.1%	8.8%	9.2%	271.2	< 0.001
70	**19.3%**	25.5%	21.7%	24.0%	136.8	< 0.001
80	**29.9%**	35.5%	32.5%	35.6%	105.9	< 0.001
90	**46.8%**	51.3%	49.4%	52.3%	71.8	< 0.001
100	**79.2%**	81.8%	81.5%	82.1%	39.2	< 0.001

The logistic regression models used for the 80% cut-off for defining "good" MPR were repeated at each of the additional cut-off values used for the sensitivity analysis. Models were used to compare the effect of insurance plan type on MPR before and after adjustment for the covariates.

The results of the analyses are contained in Table 6 and Table 7. For all values of the cut-off used patients enrolled in capitated plan types were consistently more likely to have MPR $\geq$ 80% compared to FFS, PPO and POS plan types. This relationship was observed with and without adjustment for the covariates. Among the covariates used to adjust the models the subset of individuals who switched plans were associated with increased odds of having MPR $\geq$ 80% regardless of the cut-off value. The same relationship was seen for increasing age, male sex and prior in-patient stay. This finding is consistent with the propensity score analysis described above. Statin use and non-index medication count were associated with a significantly decreased likelihood of having a "good" MPR. Neither the presence of an existing mental health nor increasing co-morbidity score were significant predictors of having a "good" MPR at any cut-oof value. Non-index medication count was associated with significantly decreased likelihood of having a "good" MPR only when the cut-off values were at 90% and 100% (Table 23). Statin use was associated with decreased odds of having MPR $\geq$ 80% at all values of the cut-off, whereas, ACE inhibitor use was associated with decreased odds of having MPR $\geq$ 80% when the cut-off was set at either 90% or 100%.

Table 6: MPR Sensitivity Analysis: Logistic regression analysis of MPR in the study period when the cut-off value for defining "poor" MPR was set at 50% and 70%

	Medication Possession Ratios							
	MPR 50%				MPR 70%			
Variable	OR[1]	p-value	OR	p-value	OR	p-value	OR	p-value
FFS	0.47	<0.001	0.49	<0.001	0.70	<0.001	0.70	<0.001
PPO	0.74	<0.001	0.68	<0.001	0.86	<0.001	0.78	<0.001
POS	0.70	<0.001	0.76	<0.001	0.75	<0.001	0.80	<0.001
Capitated (referent)	--	--	--	--	--	--	--	--
Switched Plans	--	--	2.46	<0.001	--	--	1.83	<0.001
Age	--	--	1.05	<0.001	--	--	1.05	<0.001
Sex	--	--	1.33	<0.001	--	--	1.26	<0.001
Prior Inpatient Stay	--	--	1.36	<0.001	--	--	1.23	<0.001
Mental Health Condition	--	--	1.25	ns	--	--	1.26	0.021
Insulin Use	--	--	1.10	0.048	--	--	1.08	0.035
Comorbidity Score	--	--	1.04	ns	--	--	0.97	ns
Non-Index Medication Count	--	--	1.00	ns	--	--	0.97	ns
Statin Use	--	--	0.74	<0.001	--	--	0.75	<0.001
ACE Inhibitor Use	--	--	0.91	0.020	--	--	0.92	0.002

[1] OR = Odds Ratio

Table 7: MPR Sensitivity Analysis: Logistic regression analysis of MPR in the study period when the cut-off values for defining "poor" was set at 90% and 100%

	Medication Possession Ratios							
	MPR 90%				MPR 100%			
Variable	OR[1]	p-value	OR	p-value	OR	p-value	OR	p-value
FFS	0.84	<0.001	0.81	<0.001	0.84	<0.001	0.76	<0.001
PPO	0.90	<0.001	0.82	<0.001	0.86	<0.001	0.78	<0.001
POS	0.80	<0.001	0.84	<0.001	0.83	<0.001	0.81	<0.001
Capitated (referent)	--	--	--	--	--	--	--	--
Switched Plans	--	--	1.43	<0.001	--	--	1.15	<0.001
Age	--	--	1.04	<0.001	--	--	1.04	<0.001
Sex	--	--	1.21	<0.001	--	--	1.18	<0.001
Prior Inpatient Stay	--	--	1.26	<0.001	--	--	1.34	<0.001
Mental Health Condition	--	--	1.14	ns	--	--	1.23	ns
Insulin Use	--	--	1.04	ns	--	--	0.96	ns
Comorbidity Score	--	--	0.99	ns	--	--	1.04	ns
Non-Index Medication Count	--	--	0.96	0.027	--	--	1.08	0.001
Statin Use	--	--	0.79	<0.001	--	--	0.86	<0.001
ACE Inhibitor Use	--	--	0.97	ns	--	--	0.99	ns

[1] OR = Odds ratio

DISCUSSION

Overall, the study cohort had good medication possession behavior at the standard cut-off of MPR $\geq$ 80% (Table 1). The proportion of the cohort with MPR $\geq$ 80% was 67.0%.

Whether or not the relationship between MPR and health insurance plan type was adjusted for the covariates, members of capitated plans were significantly more likely to have MPR > 80%. Members if FFS, PPO or POS plan types were found to be approximately 25% to 30% less likely to have MPR $\geq$ 80%. In patients with Type 2 diabetes, MPR can be considered as a surrogate measure of the level of glycemic control [16]. The MPR can also be considered as a measure of patient access to and acquisition of prescription drugs [17]. It might be expected that with FFS plans physicians would provide services of high volume and low cost to increase income, while under capitated plans they would focus on prevention and disease management to minimize future costs [48]. In this study there were clear and significant differences between health insurance plan types and the proportion of patients with MPR $\geq$ 80% with capitated plans consistently indicating better medication possession behavior. This finding is consistent with a retrospective study of the impact of managed care on chronic medication usage, where members of managed care plans were more likely to persist in their use of medications [49]. This finding also leads to the conclusion that the hypothesis tested, that compared to less restrictive plan types, members of capitated plans would have increased odds of having good medication possession behavior compared to FFS, PPO and POS plan types, appears to be supported by these data.

The propensity score analysis was based on the predicted probability that patients enrolled in capitated plans. Quintile 1 represented the portion of the cohort with the lowest probability of

enrollment in a capitated plan and quintile 5 represented the highest probability of enrollment in a capitated plan. The observation that POS plans were not significantly different than capitated plans in quintiles 1 and 2 could be the result of random chance since the PPO plan types remained significantly different than capitated plans. Alternatively, the POS plans in the MarketScan dataset, which are intermediate in terms of restrictiveness, may have been similar to capitated plans regarding coverage for and access to prescription drugs. In quintile 5, the FFS plan type was not significantly different that the capitated plans (Table 4) for having MPR > 80%. The odds ratio was directionally the same as in quintiles 1 – 4 (OR = 0.01) but did not reach statistical significance. Further analysis of the data in quintile 5 indicated that approximately 45% of patients in FFS plans had poor MPR compared to 40% in for those in capitated plans. It is possible that in this case, statistical power to detect a difference between plan types was lost; however, the FFS plan type in quintile 5 did follow the trend for poorer MPR.

Among the covariates use to adjust the models of MPR, non-index medication count, statin use and ACE inhibitor use were all associated with decreased odds of having MPR > 80%. Although blood pressure maintenance and control of dyslipidemia are important aspects of the standard of care, it is possible that these variables reflect the impact of more complex regimens on patient medication possession behavior beyond the oral treatment regimen for Type 2 diabetes. Patients who switched health insurance plans in the study period consistently had increased odds of having MPR > 80%. Although reasons for switching plans were not available, it is possible that this subset of the cohort was motivated to change plans to improve access to care. Analysis of the data for those who switched plans reveals that most of the switches occurring in 2000-2001 could attributed to the rapid growth of the PPO market in this timeframe with patients leaving

traditional FFS plans and enrolling in emerging discounted FFS arrangements, such as PPO and non-capitated POS plans.

In the sensitivity analysis, capitated plans consistently had lower rates of poor MPR. This trend persisted regardless of the cut-off value for the boundary between "good" and "poor" MPR (Table 6 and Table 7). Varying the MPR cut-off value above and below 80% revealed that those who switched plans also consistently had better odds of having good medication possession behavior. Also, at the lower cut-off values (50% and 70%) ACE inhibitor use was associated with decreased odds of having MPR > 80%.

Plans with capitation arrangements were significantly more likely to have MPR values ≥ 80% [14] compared to PPO plans which is consistent with the suggestion that capitated plans are associated with more preventive measures. Improved medication compliance is clearly warranted and has been the subject of research projects for some time [50]. Also, because MPR can vary when the number of prescribed medications is high or when mental illness is present or when prescribed medications have troublesome side effects or when treatment regimens are complex regimen simplification and behavioral interventions may offer improvements in medication adherence.

This study had limitations. The MarketScan dataset may not be generalizable to all parts of the United States because the employers contributing to claims data are predominantly located in the southern states and less concentrated in western states. The MarketScan dataset also has a greater proportion of females compared to the general population. Healthcare plans in other parts of the United States, particularly the western states may operate differently. Likewise, data from public forms of health insurance, Medicare and Medicaid, were not included in the MarketScan dataset, therefore the results reported here may not be applicable to these segments

of the health care system. The study period was years 2000-2001. The results obtained from this time period may not be applicable today. Given the rapidity and extent of the evolution of the health care system in the US, these data may not reflect the current state of health insurance in the United States, and especially so if the United States adopts public insurance legislation that competes with or eliminates the private health insurance sector.[51, 52].

The ICD-9-CM code algorithm used to identify patients with Type 2 diabetes may have captured some Type 1 diabetics depending on the accuracy of the billing process. This is not expected to be a significant source of error given the high specificity and sensitivity of the method used [20]. The MarketScan dataset includes 7 insurance plan types that were consolidated into 4 categories. It is not clear to what extent the consolidation affected the results; however, the patterns of utilization documented in the literature were supported by this work.

The MarketScan dataset includes provisions to capture data on 7 insurance plan types. Of these, two plan types in the study period had frequencies of zero. The remaining 5 plan types were consolidated into 4 categories ranging from most (capitated) to least (traditional FFS) restrictive in terms of accessing out-of-network providers. It is not clear to what extent the consolidation affected the results; however, this pattern of consolidation has been documented previously in the literature [21]. Within each of the 4 categories, multiple plans of a given type were assumed to have similar affects on the dependent variables. This could influence the results based on the fact that the characteristics of physician practices are variable. Variability could arise from the number of physicians in the practice, most practices are not exclusively tied to FFS or capitation arrangements but generally have mixed forms of payment and differing incentives may be used within a practice based on productivity, quality of care or patient satisfaction measures. It is not clear to what extent the consolidation affected the results; however, the pattern of consolidation

was documented in the literature and the only consolidation done was to group together the capitated plans since there were no occurrences of either Basic/Major Medical or EPO plans.

In the analysis of medication possession, there was no evaluation of costs. Health insurance is not free. There are provisions for premiums, copayments, deductibles and coinsurance in all policies and some of these variables may be accessed in the MarketScan dataset. Additional research is needed to link the findings in the present study to out-of-pocket costs to patients.

The literature describes three methods in which selection bias may be minimized in observational studies [53, 54] using propensity scores. These methods are: stratification, matching, and covariate adjustment. There is no preferred method [55]; however, stratification was used in the present study. The results of this study may have been different had an alternative method been used. The theoretical framework used to derive the variables in the propensity score analysis was based on the TRIAD study [56]. TRIAD was a multicenter prospective cohort study in diverse population of patients with diabetes who were over 18 years of age. TRIAD compared managed care structure to processes of care among 6 study sites and 10 insurance plans, including: staff, network and IPA HMO models, POS plans and PPO plans. Numerous studies have been published based on TRIAD. The literature based on the TRIAD study was reviewed with respect to published studies that included variables for resource utilization, medication adherence and receipt of appropriate processes of care to develop a set of predictor variables to include in the propensity score model. The following variables were selected for inclusion in the propensity score model because the data suggested there could some influence on health care plan type selection or that potential confounding may exist among the variables: ACE inhibitor and insulin use [57]; insulin use; age and comorbidity burden [58]; and treatment intensification to maintain glycemic control [27]. Because propensity score analyses

are dependent on the variables used to compute the scores, it is critical to base the process on a rationale theoretical framework. The TRIAD study was focused on manage care and utilization of health care resources were considered; however, the selection of the set of variables could have varied from the five variables used in this study. It is reasonable to expect that the combination of age, comorbidity score, insulin use, ACE inhibitor use and regimen complexity represent potentially confounding variables that should be accounted for in the analyses.

CONCLUSIONS

There were clear and significant differences between health insurance plan types and the proportion of patients with MPR $\geq$ 80% with capitated plans consistently indicating better medication possession behavior.

The propensity score analysis confirmed that member of both FFS and PPO plan types had decreased odds of having an MPR $\geq$ 80% compared to capitated plans. MPR for members of POS plan types were not significantly different than capitated in quintiles 1 and 2, where the odds of enrollment in capitated plans were lowest.

In the sensitivity analysis, there was a consistent trend within all four plan types for the proportion of patients to increase as the cut-off ranged from 50% to 100%.

Patients who switched plans during the study period were associated with increased odds of having an MPR $\geq$ 80%. This finding was observed in all quintiles of the propensity score analysis.

The presence of a mental health condition, insulin use and comorbidity score were not predictors of the odds of having an MPR $\geq$ 80% in any of the analyses.

Statin use was associated with decreased odds of having an MPR $\geq$ 80% in all analyses, whereas, ACE use was not a predictor of the odds of having an MPR $\geq$ 80% in the propensity score analysis but was significant in the overall dataset. Patients in capitated plans appeared to use statins more often compared to the other plan types. After adjustment for propensity scores, there were no differences in ACE inhibitor use among any of the plan types.

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APPENDIX 3: PAPER #3

ASSOCIATION BETWEEN HEALTH INSURANCE PLAN TYPE AND PROCESSES OF CARE IN ADULT WORKING AGE PATIENTS WITH TYPE 2 DIABETES MELLITUS: ACE INHIBITOR AND STATIN USE

ASSOCIATION BETWEEN HEALTH INSURANCE PLAN TYPE AND PROCESSES OF CARE IN ADULT WORKING AGE PATIENTS WITH TYPE 2 DIABETES MELLITUS: ACE INHIBITOR AND STATIN USE

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ABSTRACT

The objective of this study was to evaluate the main effect of health insurance benefit plan type on the odds of filling prescriptions for ACE inhibitors and statins, first line therapies for the treatment of hypertension and dyslipidemia in privately insured patients with Type 2 diabetes between the ages of 18 to 64 years were. The data source was the 2000-2001 MarketScan data base, which is comprised of administrative claims data for over 2.5 million privately insured individuals in the United States. The odds of patients receiving prescriptions for ACE inhibitors and statins were evaluated using multiple logistic regression models specified to control for demographic and clinical characteristics of the target patient population. A propensity score analysis using the stratification approach was also done to further control for selection bias. Patients enrolled in capitated plans were significantly more likely to use statins compared to patients in FFS, PPS and POS plans (odds ratios: 0.85, $p \leq 0.001$; 0.81, $p \leq 0.001$; 0.66, $p \leq 0.001$, respectively). This relationship remained robust after adjusting for selection bias using propensity score analysis. Compared with capitated plans, patients in FFS plans were more likely to receive prescriptions for ACE inhibitors (odds ratio: 1.16 $p<0.05$). No differences were found between other plans and capitated plans. Patients in FFS plans were more likely to be using ACE inhibitors.

INTRODUCTION

Prevention of the expensive, episodic short-term and chronic long-term complications associated with Type 2 diabetes has been the basis for clinical practice recommendations published by the American Diabetes Association (ADA) for years [1-6]. Maintaining good glycemic control to minimize the occurrence of microvascular complications in patients with Type 2 diabetes involves appropriate processes of care that include routine HbA1c monitoring, retinal eye examinations, control of hypertension and correction of dyslipidemia [7]. Hypertension is known to contribute to the development and progression of chronic complications of diabetes. Control of hypertension has been demonstrated conclusively to reduce the rate of progression of diabetic nephropathy and to reduce the associated complications of hypertensive nephropathy, cerebrovascular disease, and cardiovascular disease. The presence of diabetes increases the risk for atherosclerotic vascular disease. Patients with Type 2 diabetes also have increased risk for obesity and lipid abnormalities independent of the level of glycemic control. Therefore, guidelines for diabetes management treatment of dyslipidemia to reduce the risk of cardiovascular events associated in patients with and without documented coronary heart disease. Good processes of care of patients with diabetes includes regular physical activity [8], and a meal plan to lower glucose levels and to normalize lipid patterns. If diet and exercise are not sufficient, lipid-lowering treatment is indicated. HMG-Co-A reductase inhibitors (statins) are most frequently used in patients with diabetes. The primary goal of therapy for adult patients with diabetes is to lower LDL-cholesterol to $\leq$ 100 mg/dL.

Control of hypertension in patients with Type 2 diabetes can be accomplished with different drug classes including ACE inhibitors, angiotensin II receptor antagonists (ARBs), diuretics and β-blockers. Data from clinical trials has provided strong evidence that these therapies provide patients with significant reductions in cardiovascular and microvascular events and nephropathy [7, 9]. Although drugs in both ACE inhibitor and ARB drug classes are currently recommended as first line therapy for control of hypertension in patients with Type 2 diabetes, the ACE inhibitor class was the first drug category to be recognized as first line treatment [5]. The initial treatment goal in diabetics is to control hypertension below 130mmHg/80mmHg. It is not uncommon for some patients to be treated with multiple drugs to achieve and maintain a normotensive state. In patients with Type 2 diabetes it is not uncommon for hypertension to be present as part of a cluster of co-morbidities known as the metabolic syndrome which includes obesity and dyslipidemia. Obesity was not addressed in this study, however, correction of dyslipidemia is an important component of the management of Type 2 diabetes.

In patients with diabetes, the most common pattern of dyslipidemia includes elevated triglycerides and decreased HDL-cholesterol. Systemic LDL-cholesterol has been shown to consist of small dense particles that may confer risk of atherosclerosis. Clinical trials have demonstrated significant decreases in the risk of coronary heart disease result from treatment with classes of drugs including HMG Co-A reductase inhibitors (statins), fibric acid derivatives and niacin. Prior to pharmacologic intervention, diet and exercise interventions should be used when appropriate. Clinical practice guidelines indicate that treatment of dyslipidemia in patients with Type 2 diabetes should be designed to provide a lipid profile of LDL-cholesterol < 100 mg/dL, HDL > 45 mg/dL in males (>55 mg/dL in females) and triglycerides < 150 mg/dL.

Reduction of elevated LDL-cholesterol is generally the first priority, which is achieved with statins as the first drug class of choice.

Limited data are available in the literature describing the association between health insurance plan type and the use of ACE inhibitors and statins. This study examined whether there were associations between health insurance plan types, and the odds of ACE inhibitor and statin use to control blood pressure and correct dyslipidemia in working age individuals with Type 2 diabetes enrolled in private health insurance plans. The hypothesis tested was that both capitated and FFS plans would tend to increase the odds of adhering to the standard processes of care as determined by ACE inhibitor and statin use. Capitated plans were expected to be consistent with current clinical practice guidelines which indicate control of hypertension and dyslipidemia, whereas FFS plans were expected to be associated with increased prescription drug use, including prescription of ACE inhibitors and statins to patients with Type 2 diabetes. Thus it was hypothesized that no differences would be observed among the plan types for ACE inhibitor and statin use.

METHODS

Data Source

The 2000-2001 MarketScan Commercial Claims and Encounters administrative claims database (available from MedStat; Ann Arbor, MI) was used in this retrospective study of adult patients with Type 2 diabetes. This 2-year database contains inpatient, outpatient and pharmacy insurance claims information on approximately 2.5 million covered lives in the United States. Patients of working age between 18 and 64 years were included in the study cohort. The individual patient was the unit of analysis. To be eligible for inclusion in the analytic file, patients must have been continuously enrolled in their health insurance plan throughout the study period.

Population

A patient's index date is the first date in the claims data at which the inclusion criteria were met for a diagnosis of Type 2 diabetes. The Index Date must have occurred in the first half of the year 2000. Patients were excluded if they had an inpatient admission prior to the index date of the study or were pregnant or admitted for child birth. Patients with Type 2 diabetes were identified in the dataset according to both outpatient and inpatient claims for reimbursement using the methodology reported by O'Connor [10]. A patient was considered to be diagnosed with Type 2 diabetes if the claims record included at least one of the three following criteria: at least one inpatient hospitalization with a diagnosis of diabetes; two outpatient encounters with a primary ICD-9-CM diagnosis code specific for diabetes; or a prescription for an anti-hyperglycemic medication in 2000 – 2001. A primary diagnosis of diabetes was defined as the ICD-9-CM code 250.x. Microvascular complications of diabetes included ICD-9-CM codes

250.5 (renal), 362.0x (ophthalmic), 366.41 (ophthalmic), 250.6 (neurological) and 357.2 (neurological). This method has demonstrated a sensitivity of 0.91 and a specificity of 0.99 for the identification of patients with Type 2 diabetes in an HMO claims database [10].

Main Effects

In the analyses presented below, health insurance plan type was the main effect of interest. Possession of health insurance coverage is an enabling factor according to the Behavioral Model of access to health care. The MarketScan dataset includes provisions to collect variables for seven (7) different health insurance plan types: Traditional FFS plans Basic/Major Medical and Comprehensive policies, and Managed Care plans: EPOs, HMOs, POS (with either capitation or FFS physician payment arrangements) and PPOs. With the potential availability of 7 different plan types, it was necessary to consider appropriate ways to consolidate the plan types into fewer categories, as has been done in other studies using the MarketScan dataset [11]. Categories were created to reflect decreasing levels of restrictiveness on seeking care from specialists or other out-of network providers, where capitated plans would be expected to be most restrictive and traditional FFS plans would be least restrictive. PPO and non-capitated POS plans would be intermediate with respect to restrictiveness. The four consolidated insurance plan type categories were:

1 - HMO plans (capitated) and POS plans (capitated/partially capitated) and;

2 - Non-capitated POS plans (POS);

3 - Preferred Provider Organizations (PPO) plans;

4 - Traditional FFS arrangements: Basic/Major Medical and Comprehensive plans (FFS)

In the analyses below, the plan types were referred to as "capitated", "POS", "PPO" and "FFS" to reflect decreasing level of restrictiveness for accessing out-of-plan health care service use.

Dependent Variables

Use of ACE inhibitors and statins in study year 2001, represented the standard of care of patients with Type 2 diabetes [7]. Receipt of the standard of care is an enabling factor according to the Behavioral Model of access to health care. Two dependent categorical variables were constructed to reflect whether patients were receiving treatment for hypertension and dyslipidemia as specified in the 2000 treatment practice guidelines as a function of health insurance plan type [9]. ACE inhibitor and statin use in 2001 were evaluated by health insurance plan type. Prescriptions for ACE inhibitors and statins were identified using the National Drug Codes (NDC numbers) contained in the MarketScan dataset for these medications that were commercially available in the study period. MPR values were not computed for these therapies.

Covariates

A series of covariates was used to adjust for potential biases and confounders in the analyses. This set of variables was referred to as "the covariates" in the analyses presented below.

Models were adjusted for demographic variables, age and sex. Age was used as a continuous variable.

The MarketScan dataset covers years 2000-2001. To account for the possibility that individuals who were eligible for entry into the analytic file in year 2000 and may remain in the dataset but switched to another plan type during the study period, a categorical variable was created to indicate whether individuals remained in their existing plan or switched to another plan type.

A categorical variable was created to indicate prior resource utilization according to whether patients experienced either an ER visit or inpatient stay, or not [12] in study year 2000. This variable was created in the process of identifying patients with Type 2 diabetes and was used to adjust models of the effect of health insurance plan type for prior health care resource utilization.

Oral anti-diabetic medications were identified in the MarketScan dataset using product NDC numbers for products that were commercially available in the first six months of the study period [13]. Index-MPR values were determined for each individual in the cohort in the first 6 months of study year 2000 by first computing a continuous variable based on oral anti-diabetic medications included in the first 6 months of the study period, where the MPR is the sum of days of supply of a particular oral anti-diabetic medication divided by the number of days between the first and last prescription fill dates plus the number of days for the last refill:

MPR = Σ(days supply)/#days between 1st & last refill + days supply for last refill

This continuous variable was then dichotomized according to the definition of "good" medication possession, i.e., whether the MPR was greater than or equal (good) to 0.8, or not (poor). If more than one medication was found for a single patient, separate MPR values were computed for each active ingredient, then averaged for those patients on multiple medications. MPR values were computed only for oral anti-diabetic medications, not for ACE inhibitors, statins or insulin. Computing accurate MPR values for insulin use was not possible using administrative data because the variability in daily insulin regimens was not captured in the administrative dataset [14-16].

To adjust for the possibility that oral medication regimens for glycemic control could be changed or intensified in the remaining 18 months of the study period, the actual count of all non-index medications prescribed for treatment of Type 2 diabetes was determined after the index MPR

was computed [17]. This variable was constructed as a simple count of the number of new drugs added to or switched from the index regimen. Non-index medication counts were aggregated into values of 0 (no new medications for diabetes added), 1 (one medication added), or ≥ 2 (two or more medications added). The counts were used in the main statistical models of the effect of insurance plan type as a continuous variable.

The presence of comorbidities reflects the concurrent manifestation of two or more diseases that are etiologically independent and not causally linked to the index disease of interest [18]. It is important to note that complications, e.g., presence of ketoacidosis in patients with diabetes, are not considered co-morbidities. The presence of increasing numbers of co-morbidities with various levels of severity can be viewed as a partial measure of the underlying health status of individuals in a population [19, 20]. Unlike randomized clinical trials it is not possible to control for differences in patient baseline characteristics by randomization. The goal of adjusting statistical analyses for the presence of baseline co-morbidities in health services research is to minimize the risk of confounding and to be able to interpret inferences with greater reliability and accuracy [19]. Although review of the recent literature suggests that the Charlson Comorbidity Index [21], as adapted by Deyo [22] has been the most frequently used measure of comorbidity in studies of patients with diabetes [23-26]; the D'Hoore modification was used in the present study based on its simplicity [27-30]. This comorbidity score is based on only the first three digits of the ICD-9 codes in the claims dataset. Therefore the D'Hoore modification captures all patients with diabetes but cannot distinguish between complicated versus uncomplicated diabetes. In the present study it was not essential to make this distinction, and the D'Hoore modification has similar characteristics compared to other adaptations of the Charlson score [30]. Likewise, the literature does not recommend use of a particular measure of

comorbidity when administrative claims data are used even though many studies have been conducted in patients with diabetes. Because the Charlson comorbidity index includes diabetes which has a weight of 2 in this scoring system, all patients in the final analytic file were assigned a default comorbidity weight of at least 2 [31]. Higher scores are correlated with increased risk of 1-year mortality. The comorbidity score was a continuous variable computed for study year 2000. Comorbidity burden was considered a need based factor in the Behavioral Model of access to health care.

Diabetic patients diagnosed with mental health conditions, especially depression, have been shown to receive more healthcare services on a cumulative basis than diabetics without mental disorders but are less likely to receive complete diabetes-specific care [32]. The proportion of patients with poorer glycemic control increases with the presence of concurrent mental health conditions [33]. Likewise, patients with mental health conditions may be less able to adhere to diabetes self-management behaviors, such as, diet, medication compliance and keeping out-patient office visit appointments. [25]. Although a significant proportion of patients, i.e., >2% with mental health conditions is not anticipated to be found in the population represented in the MarketScan database, a categorical indicator variable was constructed for the analyses to adjust for whether a patient with Type 2 diabetes was also diagnosed with a mental health condition [32-34]. For this study, patients will be considered to have a mental health condition, if any of the following ICD-9-CM codes are present in any of the diagnosis fields (dx1 – dx15) in the MarketScan dataset [35]:

Anxiety disorder: 293.84, 293.89, 300.00-300.09, 300.2-300.30, 300.90, 308.30, 309.81

Substance abuse disorder: 291-292.90, 303-305

Although it was not possible to determine the exact insulin regimen that diabetics used during the study period, a categorical variable was constructed to adjust the models for insulin use, or not. This variable was used to control for disease progression and regimen complexity [16].

As in study year 2001 for the processes of care dependent variables described above, use of ACE inhibitors and statins in study year 2000 also represented the standard of care of patients with Type 2 diabetes [7]. To adjust the logistic regression models for treatment of dyslipidemia and hypertension in 2000, categorical variables were constructed to reflect whether patients were previously receiving prescriptions for statins and ACE inhibitors as specified in the 2000 treatment practice guidelines [9]. Prescriptions for statins and ACE inhibitors were identified in pharmacy records contained in the MarketScan dataset using the National Drug Codes (NDC numbers) for these medications that were commercially available in the study period. MPR values were not computed for these therapies.

Propensity Score Analysis to Control for Selection Bias

Each of the models specified below for health care resource utilization were also evaluated using a propensity score analysis. In the propensity score analysis, a separate unique logistic regression model was developed based on published data from the TRIAD study [36]. Propensity scores were derived from a logistic regression model of the odds of choosing between health care plan types based on how restrictive plans are with respect to seeking care from out-of-net-work providers. The four plan type categories, capitated, POS, PPO and FFS were recoded into two groups – the most restrictive plan types (HMO and capitated POS plans) and the least restrictive plan types – (traditional FFS plans, PPO and non-capitated POS plans). The propensity scores were patient level probabilities that an individual selected a particular insurance plan type given their health status at the time. The variables derived from the TRIAD

study for inclusion in the propensity score model were: age, comorbidity score, insulin use, ACE inhibitor use and regimen complexity. These variables represent factors that could influence selection of a particular health insurance plan type and confound the analyses. For the propensity score analysis, non-index medication count was used as a categorical variable where 0 indicated no additional medications for glycemic control were added to a regimen, and 1 indicated that one or more new classes of drugs were added to a regimen.

The predicted probabilities from the regression model (i.e., the propensity scores) were then used to stratify the dataset into quintiles. Quintile 1 represents individuals with the lowest propensity (probability) of being enrolled in more restrictive plan types (i.e., more likely to be in a FFS plan type). Quintile 5 represents individuals with the highest propensity (probability) of being enrolled in more restrictive plan types (i.e., more likely to be in a capitated plan type). The effect of health insurance plan type on each of the dependent variables was compared between the overall dataset and within each quintile of the dataset adjusted for individual propensity scores. The distribution of propensity scores within each quintile are anticipated to substantially overlap within the re-coded groups ranging from lowest to highest levels of restrictiveness to access health care form out-of-network providers.

Multiple logistic regression models were specified to estimate the odds of ACE inhibitor and statin use in study year 2001 by plan type, as follows:

Model 1 – Odds of ACE inhibitor use in year 2001; adjusted for plan type only

Model 2 – Odds of ACE inhibitor use in year 2001; adjusted for plan type and the covariates

Model 3 – Odds of Statin use in year 2001; adjusted for plan type only

Model 4 – Odds of Statin use in year 2001; adjusted for plan type and the covariates

All of the logistic regression models were analyzed using SPSS version 17.0. The variables were constructed using SAS version 9.1. The capitated plan type was referent in all regression analyses of the effect of health insurance plan type.

RESULTS

The characteristics of the study cohort are contained in Table 1. The average age of cohort was 52.9 years and was 53.4% male. The frequency of inpatient stays and ER visits was 7.5% and 0.04%, respectively in study year 2000. The frequency of treatment for mental health conditions was 1.6%. The proportion of individuals using insulin was 29.3%. The frequency of both statin and ACE inhibitor use was 26.4% and 28.6%, respectively. The proportion of individuals enrolled in capitated, FFS, PPO and POS plan type was 27.4%, 23.5%, 30.6% and 18.5%, respectively). Approximately 6% of patients with Type 2 diabetes (n = 3174) switched plan types between 2000 and 2001. The average comorbidity score was 2.13 (SD 0.57). Non-index medication count, used to adjust for the existence of more complicated treatment regimens, ranged from 0 to 5 in the dataset. Count frequencies of 2 or more were aggregated into values of 0 (62.5%), 1 (30.5%) and ≥ 2 (7.0%). Only 7.0% of the study cohort was taking two or more non-index oral medications for Type 2 diabetes. Mean MPR overall was 82.4% (SD = 0.21). The proportion of patients with MPR $\geq$ 80% was 67.0%. In the propensity score analysis, non-index medication count was dichotomized into two categories where values of 0 and 1 referred to no additional medications added (0) and one or more new medications added (1) as an estimate of regimen complexity. In the study cohort, 62.6% had no new medications added and 37 4% of the cohort had 1 or more new medications added to their regimen for Type 2 diabetes. The variable for the propensity score was computed as the predicted probability of whether an individual was enrolled in more restrictive plans (i.e., capitated plans) or less restrictive plans (i.e., FFS plans). On average, the propensity score was 0.459. In other words, the likelihood that an individual was enrolled in a more restrictive plan type was approximately a 45.9%. The propensity score ranged from 0.313 to 0.978.

Table 1: **Characteristics of the study cohort**

Variable	Frequency	
Age in years, mean (SD)	**52.9** (9 2)	
Sex (% male)	**53.4%**	
In-Patient Stay (% with ≥ 1 overnight stays)	**7.5%** (4686/62243)	
ER Visit (% with ≥ 1 ER visits)	**0.04%** (27/61257)	
Mental Health Condition (%)	**1.6%** (994/62243)	
Insulin Use (%)	**29.3%** (18209/62243)	
Statin Use (%)	**26.4%**[1] (16407/62243)	**35.0%**[2] (18048/51501)
ACE Inhibitor Use (%)	**28.6%**[1] (17822/62243)	**33.6%**[2] (17297/51501)
Insurance Plan Type Category		
Capitated (referent)	**27.4%** (17032/62212)	
POS	**18.5%** (11496/62212)	
PPO	**30.6%** (19063/62212)	
FFS	**23.5%** (14621/62212)	
Switched Plans (%)	**6.2%** (3174/51446)	
Comorbidity Score, mean (SD)	**2.13** (0 57)	
Medication Possession (% "Good")		
Overall Mean MPR (SD)	**0.824** (0 21)	
MPR ≥ 80%	**67.0%** (28587/42689)	
Non-Index Medication Count (%)		
0	**62.5%** (26883/42966)	
1	**30.5%** (13088/42966)	
≥ 2	**7.0%** (2995/42966)	
Regimen Complexity[3]		
No new oral medications added	**62.6%** (26883/42966)	
≥ 1 new medications added	**37.4%** (16083/42966)	
Propensity Score (Range)	**0.459** (0 313-0 978)	
(n = 42966)		
Quintile 1 (n)	9068	
Quintile 2 (n)	8414	
Quintile 3 (n)	8518	
Quintile 4 (n)	8558	
Quintile 5 (n)	8408	

[1] Study year 2001

[2] Study year 2000

[3] Regimen complexity was defined as whether subjects in the cohort had at least 1 new oral medication added to their non-index medication regimen

The frequencies of the dependent variables by plan type are presented in Table 2 below.

Table 2: Dependent variable frequencies by health insurance plan type

Variable[1]	FFS	Capitated	POS	PPO	N	p-value[2]
ACE Inhibitor Use	4149 (34.7%)	4653 (32.6%)	3019 (32.6%)	5464 (34.2%)	17285	<0.001
Statin Use	4318 (36.1%)	5380 (37.7%)	2633 (28.4%)	5708 (35.7%)	18039	<0.001

[1] Outcomes are for year 2001
[2] Chi-Square statistics

These data indicate that there were significant differences between health insurance plan type and the primary outcomes of this study, and confirms that the frequency of emergency room visits in the study period was low.

Results of logistic regression Model 1 for ACE inhibitor use are contained in Table 3. These data indicate that individuals in capitated were significantly less likely to fill prescriptions for ACE inhibitors compared to those in FFS and PPO plan types (OR = 1.10, p = < 0.001 and OR = 1.07, p = 0.004, respectively). There was no difference between POS and capitated plans.

Table 3: Model 1: Logistic regression analysis of ACE inhibitor use in study year 2001 (unadjusted for the covariates);

			95% C.I. for OR[1]	
Variable	**p-value**	**OR**	**Lower**	**Upper**
FFS	< 0.001	1.10	1.04	1.16
PPO	0.004	1.07	1.02	1.13
POS	ns	1.00	0.95	1.06
Capitated (referent)	--	--	--	--

[1] OR = Odds Ratio

After adjusting Model 1 using the covariates, the significant difference observed between capitated plans and PPO was lost (see Model 2,

Table 4). As in the Model 1, the FFS plan type was associated with increased odds of ACE inhibitor use (OR = 1.16, p = 0.001). Among the covariates, increasing age (OR = 1.01, p = 0.003), male sex (OR = 1.17, p < 0.001) and increasing non-index medication count (OR = 1.22, p < 0.001) were each associated with significantly increased odds of filling prescriptions for ACE inhibitors in study year 2001. Increasing comorbidity score (OR = 0.90, p = 0.004), having an MPR $\geq$ 80% (OR = 0.91, p = 0.005), insulin use (OR = 0.86, p < 0.001) and prior use of ACE inhibitors (OR = 0.03, p < 0.001) were each associated with significantly decreased odds of filling prescriptions for ACE inhibitors in study year 2001. Switching plan types, prior inpatient stay, presence of a mental health condition and prior statin use were not significant predictors of ACE inhibitor use in year 2001.

Table 4: Model 2: Logistic regression analysis of ACE inhibitor use in study year 2001 (adjusted for the covariates)

			95% C.I. for OR[1]	
Variable	**p-value**	**OR**	**Lower**	**Upper**
FFS	0.001	1.16	1.07	1.27
PPO	ns	1.07	0.99	1.16
POS	ns	0.99	0.90	1.08
Capitated (referent)	--	--	--	--
Switched Plans	ns	1.13	0.99	1.29
Age	0.003	1.01	1.00	1.01
Sex	< 0.001	1.17	1.10	1.24
Prior Inpatient Stay	ns	1.11	0.96	1.27
Mental Health Condition	ns	1.23	0.94	1.61
Insulin Use	< 0.001	0.86	0.79	0.94
Comorbidity Score	0.004	0.90	0.84	0.97
Non-Index Medication Count	< 0.001	1.22	1.17	1.28
MPR ≥ 80%	0.005	0.91	0.86	0.97
Statin Use, 2000	ns	0.94	0.88	1.01
ACE Inhibitor Use, 2000	< 0.001	0.03	0.03	0.03

[1] OR = Odds Ratio

Results of logistic regression Model 1 for statin use in 2001 are contained in Table 5. FFS (OR = 0.93, p = 0.008), PPO (OR = 0.92, p < 0.001) and POS (0.66, p < 0.001) plan type were each significantly associated with decreased odds of filling prescriptions for statins compared to capitated plans.

Table 5: Model 3: Logistic regression analysis of statin use in study year 2001 (unadjusted for the covariates)

			95% C.I. for OR[1]	
Variable	**p-value**	**OR**	**Lower**	**Upper**
FFS	0.008	0.93	0.89	0.98
PPO	< 0.001	0.92	0.88	0.96
POS	< 0.001	0.66	0.62	0.70
Capitated (referent)	--	--	--	--

[1] OR = Odds Ratio

After adjusting Model 3 using the covariates, individuals in capitated plan types were significantly more likely to fill prescriptions for statins compared to those in the other three plans types (see Model 4, Table 6). Among the covariates, increasing age (OR = 1.02, $p < 0.001$), male sex (OR = 1.19, $p < 0.001$) and increasing non-index medication count (OR = 1.27, $p < 0.001$) were each associated with increased odds of filling prescriptions for statins. Individuals who switched plan types during the study period, (OR = 0.84, $p = 0.007$), used insulin (OR = 0.86, $p < 0.001$), had an MPR $\geq$ 80% (OR = 0.72, < 0.001) or had previously used either statins (OR = 0.03, $p < 0.001$) or ACE inhibitors (OR = 0.88, $p < 0.001$) were each significantly less likely to fill prescriptions for statins in year 2001. Prior inpatient stay, presence of a mental health condition and comorbidity score were not significant predictors of statin use in 2001.

Table 6: Model 4: Logistic regression analysis of statin use in study year 2001 (adjusted for the covariates)

			95% C.I. for OR[1]	
Variable	**p-value**	**OR**	**Lower**	**Upper**
FFS	< 0.001	0.85	0.78	0.92
PPO	< 0.001	0.81	0.75	0.87
POS	< 0.001	0.66	0.60	0.72
Capitated (referent)	--	--	--	--
Switched Plans	0.007	0.84	0.75	0.96
Age	< 0.001	1.02	1.02	1.03
Sex	< 0.001	1.19	1.23	1.26
Prior Inpatient Stay	ns	0.98	0.86	1.12
Mental Health Condition	ns	1.24	0.96	1.56
Insulin Use	< 0.001	0.86	0.80	0.94
Comorbidity Score	ns	1.00	0.93	1.07
Non-Index Medication Count	< 0.001	1.27	1.21	1.33
MPR ≥ 80%	< 0.001	0.72	0.68	0.77
Statin Use, 2000	< 0.001	0.03	0.026	0.03
ACE Inhibitor Use, 2000	< 0.001	0.88	0.83	0.94

[1] OR = Odds Ratio

In the propensity score analysis of ACE inhibitor use in 2001, the significant effect of the FFS plan type observed in the overall dataset was also observed in quintiles 4 and 5 where the odds of enrollment in capitated plan types was highest (Table 7). There were no differences in ACE inhibitor use between the PPO and POS plan types compared to capitated plans. Among the covariates used to adjust the models, switching health care plans had no effect on ACE inhibitor use in either the overall dataset or in any of the quintiles. Although age was associated with significantly increased odds of ACE in the overall dataset, the effect was lost in quintiles 2 though 5 but was present in quintile 1. Male sex remained significantly associated with

increased odds of ACE inhibitor use in quintiles 3 through 5 but was lost in quintiles 1 and 2. Prior inpatient stay, insulin use and statin use were not associated with ACE inhibitor use in the overall dataset as well as none of the quintiles. Conversely, increasing non-index medication count was significantly associated with ACE inhibitor use in the overall dataset as well as all of the quintiles. Interestingly, prior ACE inhibitor use in 2000 was strongly associated with decreased odds of subsequent ACE inhibitor use in 2001.

In the propensity score analysis for statin use in 2001, the significant effects of FFS and PPO plan types in the overall dataset were also observed quintiles 1 through 3 but not in quintiles 4 and 5 (Table 8). The POS plan type remained associated with significantly decreased odds of statin use across all five quintiles. Although plan switchers were associated with decreased odds of statin use in the overall dataset, this effect was not observed in any of the quintiles. Male sex, increasing non-index medication count and having MPR $\geq$ 80% were significantly associated with statin use in 2001 in the overall dataset and across all of the quintiles. As seen with ACE inhibitor use above, prior statin use was strongly associated with decreased odds of subsequent statin use in 2001.

Table 7: Propensity score analysis of ACE inhibitor use by health insurance plan type; all values are Odds Ratios (p-value)

Variable	Overall Dataset	Quintile 1	Quintile 2	Quintile 3	Quintile 4	Quintile 5
FFS	1.16 (0.001)	1.12 (ns)	1.18 (ns)	1.13 (ns)	1.22 (0.043)	1.14 (ns)
PPO	1.07 (ns)	0.98 (ns)	1.11 (ns)	1.02 (ns)	1.16 (ns)	1.17 (ns)
POS	0.99 (ns)	0.94 (ns)	0.91 (ns)	0.90 (ns)	1.01 (ns)	1.16 (ns)
Capitated (ref)	--	--	--	--	--	--
Switched Plans	1.13 (ns)	1.33 (ns)	1.28 (ns)	0.97 (ns)	1.15 (ns)	1.01 (ns)
Age	1.01 (0.003)	0.95 (0.012)	1.00 (ns)	0.99 (ns)	0.99 (ns)	1.01 (ns)
Sex	1.17 (< 0.001)	1.10 (ns)	1.09 (ns)	1.17 (0.022)	1.34 (< 0.001)	1.17 (0.026)
Prior Inpatient Stay	1.11 (ns)	1.09 (ns)	1.11 (ns)	1.24 (ns)	1.05 (ns)	1.14 (ns)
Mental Health Condition	1.23 (ns)	0.81 (ns)	1.16 (ns)	1.87 (ns)	2.36 (0.020)	0.93 (ns)
Insulin Use	0.86 (< 0.001)	0.84 (ns)	0.88 (ns)	1.06 (ns)	1.14 (ns)	0.91(ns)
Comorbidity Score	0.90 (0.004)	--[1]	0.52 (ns)	1.75 (ns)	1.51 (ns)	0.88 (0.019)
Non-Index Medication Count	1.22 (< 0.001)	1.16 (0.007)	1.15 (0.017)	1.23 (< 0.001)	1.22 (0.001)	1.30 (< 0.001)
MPR ≥ 80%	0.91 (0.005)	1.02 (ns)	0.89 (ns)	0.91 (ns)	0.81 (0.003)	0.96 (ns)
Statin Use	0.94 (ns)	0.90 (ns)	0.90 (ns)	1.05 (ns)	0.99 (ns)	0.88 (ns)
ACE Inhibitor Use	0.03 (< 0.001)	0.029 (< 0.001)	0.03 (< 0.001)	0.02 (< 0.001)	0.03 (< 0.001)	0.03 (< 0.001)

[1]Comorbidity score was constant in Quintile 1; all values equal 2

Table 8: Propensity score analysis for statin use by health insurance plan type; all values are Odds Ratios (p-value)

Variable	Overall Dataset	Quintile 1	Quintile 2	Quintile 3	Quintile 4	Quintile 5
FFS	0.85 (< 0.001)	0.78 (0.010)	0.80 (0.014)	0.80 (0.007)	0.91 (ns)	1.01 (ns)
PPO	0.81 (< 0.001)	0.76 (0.001)	0.75 (< 0.001)	0.81 (0.008)	0.93 (ns)	0.90 (ns)
POS	0.66 (< 0.001)	0.54 (< 0.001)	0.81 (0.033)	0.56 (< 0.001)	0.64 (< 0.001)	0.79 (0.014)
Capitated (referent)	--	--	--	--	--	--
Switched Plans	0.84 (0.007)	0.91 (ns)	0.85 (ns)	0.80 (ns)	0.86 (ns)	0.84 (ns)
Age	1.02 (< 0.001)	0.92 (< 0.001)	0.98 (ns)	1.04 (ns)	1.04 (0.039)	1.03 (< 0.001)
Sex	1.19 (< 0.001)	1.19 (0.011)	1.16 (0.022)	1.14 (0.041)	1.15 (0.037)	1.41 (< 0.001)
Prior Inpatient	0.98 (ns)	0.77 (ns)	1.13 (ns)	1.04 (ns)	1.10 (ns)	0.97 (ns)
Mental Health	1.24 (ns)	1.17 (ns)	1.37 (ns)	1.21 (< 0.001)	1.60 (ns)	1.04 (ns)
Insulin Use	0.86 (< 0.001)	0.92 (ns)	1.06 (ns)	0.79 (ns)	0.80 (ns)	1.03 (ns)
Comorbidity Score	1.00 (ns)	--[1]	0.73 (ns)	0.97 (ns)	0.83 (ns)	1.00 (ns)
Non-Index	1.27 (< 0.001)	1.29 (< 0.001)	1.16 (0.007)	1.30 (< 0.001)	1.30 (< 0.001)	1.31 (< 0.001)
MPR 80%	0.72 (< 0.001)	0.78 (0.001)	0.68 (< 0.001)	0.74 (< 0.001)	0.67 (< 0.001)	0.75 (< 0.001)
Statin Use	0.023 (< 0.001)	0.03 (< 0.001)	0.03 (< 0.001)	0.03 (< 0.001)	0.02 (< 0.001)	0.03 (< 0.001)
ACE Inhibitor Use	0.88 (< 0.001)	1.08 (ns)	0.83 (0.026)	0.87 (ns)	0.95 (ns)	0.78 (0.001)

[1]Comorbidity score was constant in quintile 1: all values equal 2

DISCUSSION

The guidelines for control of hypertension in patients with Type 2 diabetes have been defined in the literature for some time. Although different classes of antihypertensive drugs have been evaluated in clinical trials, the ACE inhibitors were identified as first line therapy in the study period [7, 9, 37, 38]. The goal of treatment was and continues to be blood pressure of 130/80 or less [1]. The data for the likelihood of ACE inhibitor use in year 2001 suggested that after adjustment for the covariates, FFS plans were associated with increased odds of ACE inhibitor use; however, after applying propensity scores to the dataset to further control for selection bias, this observation was no longer seen. Assuming the validity of the propensity score model that was used in the analysis, the hypothesis that there were no differences in ACE inhibitor use between capitated and FFS plans should be accepted. This suggests that in the study period the clinical benefits of ACE inhibitors were widely accepted by health care providers, whether the motivation stemmed from adherence to clinical practice guidelines in place at the time or from the increased resource utilization that was associated with FFS arrangements [39, 40]. In either case, this study suggests that ACE inhibitor use was relatively uniform among the different health insurance plan types. This conclusion is supported by the observation that patients who switched plan types in the study period were as likely to use ACE inhibitors as those who did not switch plans. Similar studies comparing health insurance plan types are limited. In a study of patients with Type 2 diabetes over the age of 18 years enrolled in a capitated HMO in the mid-western United States, adherence to ACE inhibitor therapy was good (92.7%) with no significant association with systolic blood pressure [41]. In another study that analyzed diabetes preventive assessments covered under 20 different health insurance plans (7 HMOs, 7 PPOs, 5 POS and 1 indemnity plan) from two Fortune 500 companies and the Federal Employees Health Benefits

Plan found that HMO and PPO plan types had a higher frequency of assessment coverage [42]. In the examination of the association between physician organizational model and diabetes processes of care, there were no significant differences between managed care models in terms of systolic blood pressure control [43].

The data for statin use suggest a different scenario for control of dyslipidemia. Like the ACE inhibitors, guidelines for the treatment of dyslipidemia in patients with Type 2 diabetes have been established for a long time [7, 44]. Treatment goals are based on the level of risk of coronary heart disease. In the study period treatment guidelines stated that diabetics were at high, borderline or low levels of risk when LDL-cholesterol levels were $\geq$ 130 mg/dL, 100-129 mg/dL or < 100 mg/dL [37]. However, unlike the ACE inhibitors, after adjusting for the covariates, patients in capitated plans were significantly more likely to fill prescriptions for statins than patients in either FFS, PPO or POS plan types. In the propensity score analysis for statin use, the greater likelihood of statin use by patients in capitated plans remained in all of the quintiles, except in quintiles 4 and 5 for FFS and PPO plans. In the latter case, the only difference between the plan types remained between POS and capitated plans. It is possible that capitated plans either had lower out-of-pocket costs for lipid management or this plan type exhibited earlier adoption of statin use in the years following the diffusion of the landmark clinical trials, WOSCOPS [45] and SSSS [46] into clinical practice guidelines [47]. POS plans have been characterized as having more choices in providers by allowing selection of providers outside of the network but at a higher cost to the patient [48], which might explain the trend toward low odds of statin use in this plan type. The FFS and PPO plans had somewhat higher odds ratios but were still significantly lower than for capitated plans. Interestingly, in the overall dataset switching insurance plan types was associated with significantly decreased odds of statin

use; however, this effect was lost after adjustment for selection bias in the propensity score analysis (Table 8).

Prior healthcare resource utilization, as represented by a prior in-patient stay in year 2000, was not a significant predictor in the adjusted model for ACE inhibitor use. Neither the presence of a mental health condition nor increasing non-index medication count was associated with ACE inhibitor and statin use in 2001. As expected in the working age population of patients with Type 2 diabetes who also have employer based private health insurance, comorbidity score was not a significant predictor of the odds of either ACE inhibitor or statin use in 2001. Mean MPR overall was 82.4% (SD = 0.21), which indicated that on average medication possession in the study cohort was "good" [49, 50].

This study had limitations. The MarketScan dataset may not be generalizable to all parts of the United States because the employers contributing to claims data are predominantly located in the southern states and less concentrated in western states. The MarketScan dataset also has a greater proportion of females compared to the general population. Healthcare plans in other parts of the United States, particularly the western states may operate differently. Likewise, data from public forms of health insurance, Medicare and Medicaid, were not included in the MarketScan dataset, therefore the results reported here may not be applicable to these segments of the health care system. The study period was years 2000-2001. The results obtained from this time period may not be applicable today. Given the rapidity and extent of the evolution of the health care system in the US, these data may not reflect the current state of health insurance in the United States, and especially so if the United States adopts public insurance legislation that competes with or eliminates the private health insurance sector.[51, 52].

The ICD-9-CM code algorithm used to identify patients with Type 2 diabetes may have captured some Type 1 diabetics depending on the accuracy of the billing process. This is not expected to be a significant source of error given the high specificity and sensitivity of the method used [10]. The MarketScan dataset includes 7 insurance plan types that were consolidated into 4 categories. It is not clear to what extent the consolidation affected the results; however, the pattern of consolidation has been documented in the literature [11].

The MarketScan dataset includes provisions to capture data on 7 insurance plan types. Of these, two plan types in the study period had frequencies of zero. The remaining 5 plan types were consolidated into 4 categories ranging from most (capitated) to least (traditional FFS) restrictive in terms of accessing out-of-network providers. It is not clear to what extent the consolidation affected the results; however, this pattern of consolidation has been documented previously in the literature [11]. Within each of the 4 categories, multiple plans of a given type were assumed to have similar affects on the dependent variables. This could influence the results based on the fact that the characteristics of physician practices are variable. Variability could arise from the number of physicians in the practice, most practices are not exclusively tied to FFS or capitation arrangements but generally have mixed forms of payment and differing incentives may be used within a practice based on productivity, quality of care or patient satisfaction measures. It is not clear to what extent the consolidation affected the results; however, the pattern of consolidation was documented in the literature and the only consolidation done was to group together the capitated plans since there were no occurrences of either Basic/Major Medical or EPO plans.

In the analysis of health care resource utilization, there was no evaluation of costs. Health insurance is not free. There are provisions for premiums, copayments, deductibles and coinsurance in the MarketScan dataset. Additional research is needed to link the findings in the

present study to out-of-pocket costs to patients. Further research should be done to determine the affect of direct out of pocket costs on ACE inhibitor and statin use in patients with Type 2 diabetes.

As indicated above, both ER visits and inpatient stays were identified in the dataset on an all-cause basis, not whether the utilization was due to complications of diabetes. The low frequency of ER visits, especially in study year 2000 prevented use of this predictor variable in some of the logistic regression analyses.

The analysis of ACE inhibitor and statin use did not distinguish between specific drugs within these therapeutic classes. In the study period, in addition to ACE inhibitors, angiotensin II receptor antagonists (ARBs) were also available as antihypertensive medications that were commonly used in patients with diabetes. Although in the study period ARBs were mentioned in the clinical practice guidelines, the ACE inhibitors were recognized as first line therapy [7, 9]. In the most recent clinical practice guidelines either class of antihypertensive could be used as first line therapy [44]. Further research could be done to examine the differences in drug use by class. Also, for both ACE inhibitors and statins, medication possession ratios (MPR) were not computed so it is only possible to know that prescriptions were filled at least once, not whether medication possession behavior was adequate. Further research may be warranted to examine the effects of different classes of drugs and drugs within classes for control of hypertension and dyslipidemia. Medication possession rates were not evaluated for any prescription drugs other than the oral antihyperglycemic products available in the study period [13].

In terms of additional processes of care, additional variables could have been included, such as evidence of HbA1c testing, urinalysis for the presence of proteinuria and whether patients

underwent ophthalmic examinations. Further research is needed to evaluate a more comprehensive range of processes of care for patients with Type 2 diabetes.

The literature describes three methods in which selection bias may be minimized in observational studies [53, 54] using propensity scores. These methods are: stratification, matching, and covariate adjustment. There is no preferred method [55]; however, stratification was used in the present study. The results of this study may have been different had an alternative method been used. The theoretical framework used to derive the variables in the propensity score analysis was based on the TRIAD study [56]. TRIAD was a multicenter prospective cohort study in diverse population of patients with diabetes who were over 18 years of age. TRIAD compared managed care structure to processes of care among 6 study sites and 10 insurance plans, including: staff, network and IPA HMO models, POS plans and PPO plans. Numerous studies have been published based on TRIAD. The literature based on the TRIAD study was reviewed with respect to published studies that included variables for resource utilization, medication adherence and receipt of appropriate processes of care to develop a set of predictor variables to include in the propensity score model. The following variables were selected for inclusion in the propensity score model because the data suggested there could some influence on health care plan type selection or that potential confounding may exist among the variables: ACE inhibitor and insulin use [57]; insulin use; age and comorbidity burden [58]; and treatment intensification to maintain glycemic control [17]. Because propensity score analyses are dependent on the variables used to compute the scores, it is critical to base the process on a rationale theoretical framework. The TRIAD study was focused on manage care and utilization of health care resources were considered; however, the selection of the set of variables could have varied from the five variables used in this study. It is reasonable to expect that the

combination of age, comorbidity score, insulin use, ACE inhibitor use and regimen complexity represent potentially confounding variables that should be accounted for in the analyses.

CONCLUSIONS

In the main analysis of the overall dataset, the hypothesis that no differences in ACE inhibitor use in year 2001 would be observed between FFS and capitated plans was not confirmed. Members in FFS plans were more likely to use ACE inhibitors than members in capitated plans; however, a statistically significant difference among the plan types was not observed in the propensity score analysis. The effect was lost after adjusting for selection bias. There was no difference between either PPO or POS plans compared to capitated plans in any of the analyses.

Switching health insurance plan types during the study period was not associated with ACE inhibitor use in year 2001.

In the main analysis of the overall dataset, the hypothesis that no differences in statin use in year 2001 would be observed between FFS and capitated plans was confirmed in the main analysis on the overall dataset as well as in the propensity score analysis. Patients enrolled in capitated plans were significantly more likely to use statins in year 2001 compared to either FFS, PPO or POS plan types in all analyses, except in quintiles 4 and 5 for the FFS and PPO plans.

In the main analysis on the overall dataset of statin use in year 2001, both switching health insurance plan types and insulin use were significant predictors of reduced statin use; however, this observation was lost in the propensity score analysis. After correction for selection bias, neither switching health insurance plan types nor insulin use were predictors of statin use.

Regimen complexity was associated with increased statin use in 2001 in all analyses. Similarly, having MPR $\geq$ 80 % was associated with decreased statin use in 2001 in all analyses.

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