# A Study of Insurance Coverage and Diabetes Outcomes in Two Care Models

by

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A THESIS

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**Abbreviations Used**

| | |
|---|---|
| AIC | Akaike Information Criterion |
| BMI | Body Mass Index |
| CDC | Centers for Disease Control and Prevention |
| CIM | Chronic Illness Management model of care |
| GIM | General Internal Medicine model of care |
| HbA1c | Hemoglobin A1c (glycosylated hemoglobin) |
| IRB | Internal Review Board |
| LDL | Low Density Lipoprotein |
| MA | Medical Assistant |
| MRN | Medical Record Number |
| OHSU | Oregon Health and Sciences University |
| OR | Odds Ratio |
| PCP | Primary Care Provider |
| PDSA | Plan Do Study Act |
| ROC | Receiver Operating Characteristic |
| SD | Standard Deviation |
| VA | Veterans Affairs |

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**Abstract**

***Background:*** Diabetes is one of the most clinically burdensome and financially costly chronic diseases in the United States. To date, medical management of this condition has been largely unsuccessful; the majority of people with diabetes have poorly controlled disease, resulting in avoidable complications and cost. Additionally, individuals with public insurance may be disproportionately affected by the complications of diabetes compared to individuals with private insurance coverage. The chronic illness management (CIM) model of care has been shown to improve clinical outcomes for people with diabetes compared to a traditional general internal medicine (GIM) model of care. However, it is currently unknown if the CIM model provides equal benefit to publically and privately insured individuals.

***Objectives:*** This goal of this study was two-fold. First, the relationship between insurance status (public or private) and blood glucose (measured by HbA1c) was examined. Second, insurance status was studied to determine if individuals with one type of insurance derive greater benefit from the CIM model compared to the GIM model of care.

***Methods:*** This study utilized a database derived from clinical records of 662 patients with diabetes receiving care in a CIM specialty clinic or a GIM practice within an academic medical center between July 2005 and January 2008. A retrospective cohort design was used to examine the effects of insurance status and care model on HbA1c

outcomes over 335 days of follow-up, on average. Both logistic and linear regression analyses were conducted to examine the dependent variable as both a continuous and categorical outcome, adjusting for potential confounders. An interaction term was utilized in the model to determine if the care model influences the relationship between insurance type and HbA1c outcomes.

***Results:*** There were no independent or joint associations between median HbA1c during follow-up and insurance type or model of care. The odds of ever achieving glucose control during the follow up period was 62% less in privately insured individuals compared to publically insured individuals ($p < 0.001$), however this relationship was not modified by the model of care delivery (p for interaction=0.229).

***Conclusion:*** The publically insured group had better glucose control than the privately insured group. There was no difference in HbA1c outcomes between the two care models, and individuals with public and private insurance derived equal benefit from both care models.

## Introduction

### Background and Significance

Chronic disease is costly and causes significant morbidity and mortality in the United States each year. In 2004, the Centers for Disease Control and Prevention (CDC) reported that seven of the nine most common causes of death in the United States were attributable to chronic disease, such that chronic disease accounts for 66.7% of all deaths in the US. Seventy percent of the nation's health care budget is used for the treatment of chronic disease.[1]

Diabetes is one of the most common chronic diseases in the United States today and affects 23.6 million people, or 7.8% of the population, which is an increase of 13.5% from 2005. Approximately 1.6 million new cases of diabetes are diagnosed each year in the adult population.[2] According to 2007 Center for Disease Control estimates, nearly one quarter these people are undiagnosed. While diabetes affects a greater proportion of adults over 60 than individuals under 20 years of age, trends show an increase in childhood diabetes related to the epidemic of childhood obesity. Men are slightly more likely to be affected than women, and a greater proportion of African Americans are affected compared to Caucasians. Diabetes is also one of the most devastating of the chronic diseases in terms of the cost of usual treatment, complications, and lost productivity. Diabetes is the seventh most common cause of death in the US and is likely to be an underreported cause of death. Additionally, each year 12,000-24,000 people become blind because of diabetes, 43,000 begin treatment for kidney failure, and 82,000 undergo diabetes-related lower extremity amputations.[1,3]

As a result of the multitude of complications and lost productivity, the direct and indirect costs of diabetes totaled $169 billion in 2007; this is equal to one out of every ten health care dollars spent in the United States. Average medical expenditures for individuals with diabetes are 2.3 times higher than expected expenses in the absence of diabetes.[1,3] While the upfront costs of diabetes management may result in initially high expenditures, investing in preventive care and disease management and education may result in decreased overall costs by decreasing complications.

Fortunately, many of the complications of diabetes are preventable. Hemoglobin A1c (HbA1c) is a standard test used to measure blood sugar control in individuals with diabetes and represents the percent of hemoglobin molecules that are glycosylated (bound to glucose). It is directly related to blood sugar concentration over a three month period of time, with a HbA1c of 7 corresponding to an average blood sugar of approximately 170. For this reason, HbA1c is a better measurement of long-term glucose control than blood glucose measurements which represent glucose levels at a single point in time. Therefore, HbA1c measurements are recommended at diagnosis and at three month intervals thereafter in uncontrolled diabetics to monitor disease burden. The American Diabetes Association recommends that providers strive to achieve a HbA1c less than 7% for the purpose of blood sugar control and avoidance of diabetes-related complications. A HbA1c less than 7% is attainable through proper management and directly translates to improved outcomes.[4] There is also a direct correlation between glycemic control and cost of medical care, which suggests that controlling HbA1c will not only reduce complications but will also reduce costs.[5]

However, the current model for diabetes care is largely inadequate and most people with diabetes are not receiving necessary care or achieving a HbA1c less than 7%.[6] Additionally, the quality of diabetes care varies by insurance status, with uninsured individuals less likely to receive recommended HbA1c tests compared to individuals with private health insurance.[7] There may also be differences in the self-care and medical care received based on insurance type (public or private), and this may translate into differences in outcomes by insurance type. A study examining publically insured individuals with or without private insurance shows that a greater proportion of individuals covered by private health insurance take two or more insulin injections per day, self-monitor their blood glucose, have had an eye examination within the past year, have their cholesterol checked or are treated for their hypertension or dyslipidemia.[8] Access to care refers to an individual's ability to receive medical care and is affected by the general availability of providers in a community as well as the provider's willingness and ability to accept a patient. Access to care may be more difficult for individuals with public insurance because of socioeconomic factors and lower levels of reimbursement from publically insured patients which may affect providers' ability to adequately care for these populations. Studies show that patients with Medicaid insurance tend to have less access to preventive services and worse outcomes in the treatment of several different disease states than those with private insurance.[9,10,11,12,13] However, few studies have examined these relationships in diabetic patients. While one study in patients with diabetes shows no difference in the care provided to individuals with public versus private insurance, this study examines only self-management and preventive care process

measures, not outcome measures.[14] More research is needed to determine if diabetes outcomes differ by a patient's insurance status.

Poor adherence to current standards of care by providers can in part be attributed to lack of support from the society and the health care system in the management of diabetic patients and this may be contributing to poor diabetes outcomes. Providers state that time required for diabetes care is not supported by clinic administrators and reimbursement is not sufficient to provide comprehensive care.[15] Increased support in managing the treatment and complications of diabetes using a nurse case manager to help improve glycemic control results in better outcomes.[16] Additionally, incorporating a model of continual improvement of clinic practices and diabetes outcomes improves glycemic control.[17] General disease management which provides a more thorough, comprehensive care plan is also effective for management of glycemic control, screening for diabetic retinopathy, foot lesions, peripheral neuropathy and proteinuria, and on the monitoring of lipid concentrations.[18]

The Chronic Illness Management (CIM) model adhered to in this study relied on a team approach to provide patient-centered care focused on practicing evidence-based medicine and a continual improvement model which utilizes a plan-do-study-act approach.[19] In this model, all members of the team (including physicians, nurses, medical assistants, social workers and pharmacists) were encouraged to identify problems, examine outcomes and develop a strategy to address deficiencies in the clinical care model. Specifically, six elements were incorporated into the care model to maximize success: community resources and policies, health care organization, self-management support, delivery system design, decision support, and clinical information

systems.[20] In contrast to the CIM clinic, the general internal medicine (GIM) clinic provided traditional, physician-supervised care to patients with diabetes, without any of the additional features of the CIM model. Preliminary studies from this group have shown some improved outcomes from patients in the CIM model compared to a regular care model; however not all results reach statistical significance. Under the CIM model, a higher percentage of patients are able to obtain a HbA1c less than 7% (OR 1.3, 95% CI 0.8-2.3) and a blood pressure less than 130/80 (OR 2.8, 95% CI 2.1-4.5).[21]

For these reasons, the CIM model may be more effective compared to the GIM model in treating publically insured patients, and the CIM model has the potential to reduce the differences in diabetes clinical outcomes that may exist between individuals of different insurance types. Therefore, this study evaluated the effectiveness of the CIM approach to improve diabetes clinical outcomes in patients with public versus private insurance using data available from an academic general internal medicine practice and a CIM clinic. The results of this research may help to target different models of care to populations that derive maximum benefit from their use. Additionally, showing that such programs can significantly benefit publically insured individuals would support more widespread use of such models in the public health care system.

**Specific Aims**

This study examined the relationship between diabetes clinical outcomes in publically and privately insured individuals within two models of diabetes care.

The two specific aims of this study were:

1. Examine the association of insurance status to glucose control.

Hypothesis 1: Public insurance throughout the study period will be associated with poor diabetes control, as defined by a greater likelihood of individuals with private insurance having achieved HbA1c less than 7% compared to those with public insurance. Additionally, individuals with public insurance will have a larger median HbA1c throughout the study period than those with private insurance.

2. Determine if the model of care delivery (GIM care vs. CIM care) influences the relationship between insurance status and glucose control using a retrospective cohort study design.

Hypothesis 2: In providing opportunities for publically insured individuals to overcome barriers to care, the chronic illness management model (compared to GIM care) will provide greater improvements in clinical outcomes in publically insured patients compared to privately insured individuals.

## Methods

### Study Design

A retrospective cohort design was used to examine the relationship between the exposures, insurance status and care model, and the outcome, HbA1c. Due to the unique

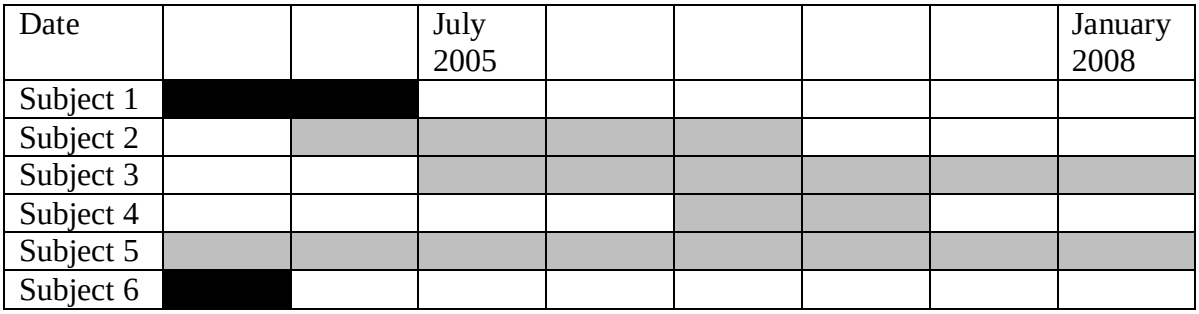
nature of care delivery under the CIM model, randomization and blinding was not possible in this study. The dataset used in this study included diabetic patients attending the GIM or CIM clinic at Oregon Health and Sciences University (OHSU) from July 2005 through January 2008. GIM subjects were patients who were newly-diagnosed diabetics or previously-diagnosed diabetics who were new patients to OHSU, identified by ICD-9 code 250.xx. CIM patients were diabetics who were referred from outside sources or from the GIM clinic specifically for diabetes management. Providers in the GIM clinic were informed of the CIM clinic as a referral practice for the larger GIM practice. Participants in the intervention arm of the study were therefore referred to the CIM clinic from their primary care provider (PCP) because the PCP believed that they would benefit from better chronic disease management, or they were invited to join the CIM practice by one of the CIM team members following approval from their PCP. Patients were often referred because of difficulty achieving glucose control; therefore the study was not randomized and a smaller percentage of patients in the CIM arm were expected to have been controlled compared to the GIM arm.

Enrollment dates for the population varied and may have occurred prior to July 2005. Each enrolled patient had a unique baseline period, start date and study period because of the rolling nature of enrollment in a clinic practice. For CIM patients, the enrollment date was designated as the first visit to the CIM clinic. CIM patients were likely to have been diagnosed as a diabetic at a visit prior to their first CIM clinic visit, therefore their first CIM clinic visit was likely not their first visit for diabetes care. To account for this, for GIM patients, the study enrollment date was designated as their second visit to the GIM clinic. The data collection method prevented inclusion of

subjects who were enrolled in either the CIM or GIM clinic prior to July 2005 and discontinued care prior to July 2005 (see Figure 1). For both CIM and GIM patients, the baseline HbA1c was designated as the most recent HbA1c obtained in the year prior to enrollment, or if this was not available, the earliest HbA1c obtained in the month following enrollment.

Approval for this investigation was obtained from the Oregon Health and Sciences University Internal Review Board (IRB).

Figure 1: Representation of subjects included in study dataset. Each row represents the time period that the subject was enrolled in the CIM or GIM clinic. Gray rows represent individuals included in this study dataset. Black rows represent subjects not included in the study dataset.




**Clinic Visits**

For CIM patients, the baseline visit consisted of measurement of diabetes-specific lab values, including HbA1c, blood pressure, weight, BMI, LDL, and microalbumin. A foot exam was performed and patients were questioned and counseled on tobacco use and self management goals (such as exercise and weight loss). Patients were also scheduled for an eye care appointment (if not obtained within the last year), and provided with

vaccinations if they were not up to date. Patients were encouraged to attend diabetes educational classes provided by the clinic.

Initial and follow-up visits in the GIM group were conducted and scheduled at the discretion of the primary care provider. Follow-up visits in the CIM group were scheduled as part of a team effort between physicians, nurses and social workers. Adherence to nationally accepted clinical guidelines (Table 1) was emphasized in the CIM group when deciding when to schedule appointments and conduct tests.

Table 1: Guidelines emphasized in the CIM model of care

| **Measure** | **Outcome** | **Process** |
|---|---|---|
| Blood pressure | <130/80 | Measured at each visit |
| HbA1c | <7% | Measured at least every 6 months |
| LDL | <100 | Measured at least yearly |
| Eye exam | | Yearly |
| Microalbuminuria | | Yearly |
| Monofilament exam | | Yearly |
| Brief foot exam | | Every visit |
| Tobacco counseling | | Every visit if applicable |
| Influenza vaccine | | Yearly |
| Pneumococcal | | Per CDC guidelines |
| Self management goals | | Discussed at each visit |

Each member of the care team was trained in specific tasks and was responsible for completing these tasks during the patient visit, as outlined below:

- Medical assistants (MAs) were responsible for monofilament exams (a standardized test of peripheral nervous system function), foot inspections, and measurements of height, weight, and blood pressure. They identified patient concerns for the visit and printed a summary of capillary blood glucose readings for the rest of the team.

- The nurse was responsible for diabetes education, follow-up, and care coordination, however the plan for education and follow-up was determined by the entire team during care conferences which occurred at the beginning and end of each clinic day.
- The social worker was responsible for assessing social and financial barriers to care and arranging assistance in these areas as needed and as directed by the team's care management plan.
- The pharmacist provided consultation regarding medication management for individual patients and also provided the team with up to date information on new pharmaceuticals related to diabetes care.
- Physicians and residents were responsible for assessing the patient's understanding of disease and treatment, reviewing diabetes symptoms, completing the physical exam, tailoring treatment to findings and making recommendation for the prevention of complications. Self-management goals were discussed and patients were referred to specialists and education classes as needed.

Several quality control mechanisms were in place to insure that providers adhered to the CIM model. Members of the care team were given responsibility for following-up on different improvement initiatives (known as PDSAs which stands for "Plan Do Study Act," the steps in improvement process). The electronic worksheets which gathered data on specific components of the CIM model were assessed for completeness by a physician at the end of each visit. Residents received a training session at the beginning of their

rotation by one of the physician CIM team members to ensure a standard protocol was followed during the CIM rotation. MAs received training in the areas of care for which they were responsible, including monofilament foot exams. Physicians in the CIM model attended meetings throughout the course of this study with other hospitals that were implementing the CIM model to share ideas and troubleshoot problems arising in the implementation of this model. Periodic reports of the percent of patients achieving HbA1c less than 7% were generated to follow the outcome in the CIM clinic. Additionally, adherence to diabetes-specific guidelines was measured in an attempt to generate ideas for PDSAs.

In the GIM group, there was no intentional utilization of the components of the CIM model. Practically, this meant that visits were patient-initiated and care and follow-up were primarily physician-directed, without coordination from a care team. There were no formal mechanisms in place to ensure appropriate follow-up or adherence to evidence-based guidelines. A team-approach was not emphasized and there was no structured study, evaluation or correction of ineffective procedures and outcomes. Regardless, the same follow-up data collected in the GIM group were collected in the CIM group, and the GIM group implemented use of the patient data worksheets that were originally developed in the CIM clinic.

**Dataset**

Data were collected from the GIM and CIM clinics and entered into an electronic registry for diabetes patients by clinic staff. Lab data from the OHSU lab were automatically populated into this registry for all patients in the registry. This combined

dataset was utilized for this study. To insure quality control of the data entered into this study, medical assistants initially populated the registry at each clinic visit and entries were confirmed by medical providers. The registry was created primarily for patient management and tracking of population outcomes, therefore patients who died or who no longer attended the clinic were dropped from the database and lost to follow-up. The registry of patients was monitored for accuracy, and patients were removed if they were not enrolled in the practice, if they did not meet criteria for the diagnosis of diabetes, or if they received their care exclusively from physicians at a different facility.

## Subject Selection

The full dataset consisted of 1,328 patients. Patients were ***included*** in the study sample for this analysis if they had:

- At least two HbA1cs drawn (at baseline and one follow-up) at least 3 months apart
- A least two clinic visits

Patients were ***excluded*** if any of the following variables were missing:

- Age
- Sex
- Race
- Insurance type (public or private)
- Enrollment visit date

## Study Variables

### *Exposure variables*

The predictor variable used for specific aim #1 was insurance status. At each visit, the patient's insurer for that visit was documented in the diabetes registry. An

insurance biller/coder was then consulted for classification of the insurance into the following categories: Medicaid, Medicare, Medicare Advantage, Private, VA, self-pay, dual eligible and other (including worker's comp, mental health, motor vehicle insurance). Medicare, Medicaid, Medicare Advantage and dual eligibles were considered public insurance plans. Individuals with VA or other insurance plans not classified above were not included in the analysis. Patients were grouped into two categories, publically insured and privately insured, based on the insurance type held for the majority of study visits during the enrollment period. In a secondary sensitivity analysis, Medicare Advantage, a plan which is paid for using public funds but primarily administered by private insurers, was classified as private insurance in an attempt to identify any changes in outcomes with changes in the classification of insurance. Using this methodology, insurance status did not account for any care that may have been received prior to study enrollment.

The predictor variable for specific aim #2 was type of care model, which was determined at entrance to the study.

***Outcome variables***

In both groups, HbA1c was automatically populated into the registry at each lab draw, which occurred in the OHSU lab. The goal timeline for measuring HbA1c in the CIM clinic was every 6 months for all patients, and every 3 months for poorly controlled diabetics. In the GIM group, timing for HbA1c measurements was assessed at the physician's discretion.

A flaw in the dataset occurred which resulted in several HbA1c lab values being entered under multiple dates (within several days of each other). Therefore, for any duplicate HbA1cs drawn within five days of each other, the second value was dropped from the dataset. This may have caused some true values to have been dropped, but this was deemed acceptable in the face of the alternative option of keeping duplicate values which could potentially skew the calculation of the outcome variable.

For the purposes of this study, two outcome measures for HbA1c were defined for each specific aim. The first variable was a dichotomous variable to designate if the individual ever achieved HbA1c control. An individual was considered to have achieved control if they ever obtained a HbA1c less than 7% throughout the course of the study period. This cutoff was chosen based on American Diabetes Association recommendations for glucose control in diabetics. The second variable used as a measure of an individual's HbA1c level throughout the follow-up period was median HbA1c. Other research performed on the correlation between HbA1c values and diabetes outcomes relies on average HbA1c values as a predictor for diabetes complications.[22] However, in such studies, HbA1c values are measured at regular intervals throughout the study period and therefore are likely to represent average HbA1c values over a period of time. In this study, median HbA1c values were used as an outcome variable because HbA1c values were not measured at regular intervals throughout the study period, therefore mean HbA1c values were less likely to adequately represent average HbA1c values over time, especially if outliers were present.

Diabetics were identified based on ICD-9 codes, therefore several individuals were included in the dataset who may not have been considered diabetics based on their

HbA1c values. There was one individual in the dataset who never had a HbA1c greater than 5, and there were an additional 14 individuals who never had a HbA1c greater than 6.

***Covariates***

Several variables were tested in the model as potential confounders: age, gender, race, baseline HbA1c, number of visits to clinic during the study period, number of HbA1c tests throughout the study, length of study period and a comorbidity index. The age data were calculated from the birth date data. Birth date data were cleaned by resolving discrepant birth dates using the hospital's electronic medical record system. For three patients that could not be resolved using this system, the discrepant birth dates were less than a year apart and the older birth date was retained in the dataset. Therefore, because the age variable was calculated from birth date data, these individuals may have been slightly older in this study than their true age. The age variable was created by subtracting the birth date from the date of study enrollment. Three HbA1c values were also erroneous and therefore not included in the final analysis. One enrollment date visit was listed as "2207", this was changed to 2007.

There were several categories for race in the original data collection tool. For the purposes of this study, these categories were condensed into a dichotomous Caucasian and non-Caucasian variable because the number of individuals in each of the non-Caucasian groups was small (78% of the population was Caucasian; Asian, African American and Hispanic populations were the primary constituents of the "other" group). The length of the study period varied for each individual and was also included as a

covariate because of presumed increased likelihood of obtaining a HbA1c less than 7 or achieving a lower median HbA1c for individuals enrolled in the study for a long period of time. There were two variables used to represent an individual's baseline HbA1c. A dichotomous co-variable was used to designate if the individual's baseline HbA1c was less than 7%. For the model using median HbA1c as an outcome measure, the numerical HbA1c value during the baseline period was used to represent that individual's baseline HbA1c.

The Deyo comorbidity index was created for each patient and was calculated based on a model which weights and sums co-existing diseases based on ICD-9 billing codes at baseline.[23] A variable was created to represent the number of days each individual was enrolled in the study. For patients who had left the study, this variable was created by subtracting the enrollment visit date from the last visit date. For individuals still in the study, this variable was created by subtracting the enrollment visit date from January 30, 2008, which was the last date of data collection.

## Statistical Analysis

### *Data Management*

For each month of the study, data were drawn from the registry on each patient and saved in a Microsoft Access® database. These data included all data points for a currently enrolled patient up to that point in time. The data were pulled from the registry in three different files: insurance, demographics and lab data. To create a complete dataset of all patient data for all 31 months of the study period, these monthly files were appended and duplicate data points dropped, creating a large file containing

demographics, insurance and lab data separately for the entire study period. These files were then merged by patient medical record number (MRN) to create a complete dataset of all patient information for the study period. Medical record numbers were dropped to de-identify the data prior to analysis.

### *Descriptive Analysis*

Descriptive analysis was performed on the full sample, the study population, and the excluded population. Among the eligible population, descriptive statistics were calculated for the two insurance groups and the two care models. Differences between the groups were tested using two-sided t-tests and chi-squared testing.

Additionally, prior to adjusting for potential confounders, the data were examined for trends. The percent of individuals achieving a HbA1c less than 7% was plotted at baseline and follow-up for all combinations of the study groups (CIM public, CIM private, GIM public, GIM private). The averages of all median HbA1cs in each of the four groups were also plotted at baseline and follow-up. Finally, the difference between the median HbA1c during the follow-up period and at baseline was calculated for each individual patient and plotted on a box plot for each of the four groups. The mean differences for each of the four groups were tested for differences from each other and from 0.

### *Regression Analyses*

*Hypothesis 1*: Public insurance throughout the study period is associated with poor diabetes control, as defined by a greater likelihood of achieving a HbA1c less than

7% for individuals with private insurance compared to those with public insurance. Additionally, individuals with public insurance will have a greater median HbA1c throughout the study period than those with private insurance.

A univariate linear regression analysis was conducted between median HbA1c and each of the following independent variables: gender, race, comorbidity index, number of HbA1c tests throughout the study period, number of study visits, insurance type, age, length of study period, and baseline HbA1c. The number of study visits and the number of HbA1c tests throughout the study period were not included in the final model because they were considered a component of the care model that contributed to the success of the model, therefore correcting for these variables may have resulted in over-adjustment and some of the ability of the care model to explain differences in HbA1c outcomes may have been lost.

A separate regression analysis was conducted for the dichotomous outcome variable designating whether or not the individual ever achieved control of their blood sugars. For this analysis, the following variables were analyzed using a univariate logistic regression design: gender, race, comorbidity index, number of HbA1c tests throughout the study, number of study visits, insurance type held for the majority of the study, age, length of study period, and baseline HbA1c (these are the same variables as for the linear regression analysis). The number of study visits and the number of HbA1c tests throughout the study period were not included in the final model for the reasons discussed previously.

For both the linear and logistic model, those variables that achieved a p-value of less than 0.25 in the univariate analysis were included in the multivariate analysis.

Variables were removed one at a time from the multivariate regression analysis if they did not achieve a significance less than 0.05, starting with the most non-significant variables first. For the final model, Akaike Information Criterions (AICs) were assessed for various classifications of the continuous variable of age (as a continuous variable as well as several different age classifications), and the model with the lowest AIC was chosen for the final model because lower AICs are indicative of a better model fit. Outliers were examined in decreasing order and removed if they changed coefficients by more than 10%. This method was continued until the removal of additional outliers did not change the coefficients by more than 10%.

*Hypothesis 2*: In providing opportunities for publically insured individuals to overcome barriers to care, the chronic illness management model (compared to GIM care) provides greater improvements in clinical outcomes in publically insured patients compared to privately insured individuals.

The variable designating GIM or CIM enrollment was added to both models created in hypothesis 1. An interaction term between insurance type and care model was created to determine if the relationship between insurance type and diabetes clinical outcomes varies by care model. For the final logit model, the assumption of linearity was checked for all continuous variables using a lowess curve. Goodness of fit was assessed using the Hosmer-Lemeshow method. ROC was calculated to assess model discernability. The final models were visually examined for outliers using a graph of the change in Pearson's versus predicted probability, with the size of each point proportional to the size of Cook's distance. Outliers were examined as described above and removed if they changed coefficients by more than 10%.

In addition to the preliminary analyses discussed above, a sensitivity analysis was conducted using the same methodology but a new definition of the insurance variable. Under this new definition, Medicare Advantage plans were classified as private insurance. Medicare Advantage plans are paid for by the government, but administered by private insurers and therefore generally have lower copays and extra benefits, but require the insured individuals to see providers within the plan.[24] This sensitivity analysis helped to determine if the results were affected by the classification system used to determine insurance status.

Data were abstracted from the diabetes registry and uploaded into Access software. Access files were then uploaded into STATA 10.0[25] and merged using this software. All tests and regression analyses were conducted using STATA.

## Results

### Descriptive Analysis

#### *Socio-demographics of Study population*

Of the 1,328 patients in the diabetes registry, the final study sample included 662 patients (666 excluded) after removing those individuals not meeting the inclusion and exclusion criteria and removing one individual who had an age value of 5.8 which was deemed erroneous given that the population was drawn from an adult internal medicine practice. An additional individual could not be included in the analysis because of an equal amount of time spent under public and private insurance, therefore the preliminary regression analyses were performed on 661 subjects. The primary reasons for exclusion from the study were fewer than two HbA1cs or fewer than two study visits.

For the sensitivity analysis, the number of subjects was 623 because an additional 43 individuals were dropped from the dataset because of an equal number of visits under public and private insurance occurred when the change in variable definition was made. Informed consent was not required given that data were de-identified and obtained retrospectively from medical records. This study did not utilize any public forms of recruitment.

***Excluded vs. Included***

No data were available on the number of type I vs. type II diabetics, however study clinicians estimated that less than 1% of the population were type I. A description of baseline characteristics of the included study population versus the excluded population is shown in Table 2. The study population had significantly more males and non-Caucasians. The study population was also significantly older than the excluded population. There was no significant difference in the baseline HbA1c between the included and excluded populations. The number of study visits and number of HbA1c labs drawn was smaller in the excluded population because these variables were used as criteria for study exclusion. The length of study enrollment was likely shorter in the excluded population because to be included individuals needed to have at least two HbA1cs drawn and at least two study visits. The number of times an individual went in and out of glucose control was less in the excluded population and can also be explained by the exclusion criteria that were used for this study. Finally, the study population had a higher comorbidity score (more comorbidities) compared to the excluded population.

Table 2: Baseline Characteristics of the Study Population, Comparing Included vs. Excluded

| | | **Total Population** | | **Excluded** | | **Included** | | **p*** |
|---|---|---|---|---|---|---|---|---|
| **N** | | 1328 | | 666 | | 662 | | |
| | | **n** | **%** | **n** | **%** | **n** | **%** | |
| **GENDER** | missing | 35 | 3% | 35 | 5% | 0 | 0% | <.001 |
| | Female | 720 | 54% | 357 | 54% | 363 | 55% | |
| | Male | 573 | 43% | 274 | 41% | 299 | 45% | |
| | | | | | | | | |
| **RACE** | missing | 35 | 3% | 35 | 5% | 0 | 1% | <.001 |
| | Caucasian | 1041 | 78% | 527 | 79% | 514 | 78% | |
| | Other | 230 | 17% | 86 | 13% | 144 | 22% | |
| | Unknown | 22 | 2% | 18 | 3% | 4 | 1% | |
| | | | | | | | | |
| **AGE** | missing | 330 | 25% | 330 | 50% | 0 | 0% | <.001 |
| | Obs | 998 | 75% | 336 | 50% | 662 | 100% | |
| | Min | 5.8 | | 5.8 | | 24.18 | | |
| | Max | 96.7 | | 88.7 | | 96.7 | | |
| | Mean (SD) | 58.4 | (13.6) | 56.2 | (14.2) | 59.50 | (13.2) | |
| | | | | | | | | |
| **BASELINE HBA1C** | missing | 527 | 40% | 527 | 79% | 0 | 0% | 0.478 |
| | Obs | 801 | 60% | 139 | 21% | 662 | 100% | |
| | Min | 4.7 | | 4.9 | | 4.7 | | |
| | Max | 16.8 | | 16.8 | | 16.2 | | |
| | Mean (SD) | 7.5 | (1.9) | 7.56 | (2.2) | 7.44 | (1.8) | |
| | | | | | | | | |
| **HBA1C CONTROL AT BASELINE** | missing | 527 | 40% | 527 | 79% | 0 | 0% | 0.210 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | Out of control | 396 | 30% | 62 | 9% | 334 | 50% | |
| | In control | 405 | 30% | 77 | 12% | 328 | 50% | |
| | | | | | | | | |
| **NUMBER OF HBA1C TESTS** | missing | 0 | 0% | 0 | 0% | 0 | 0% | <.001 |
| | Obs | 1328 | 100% | 666 | 100% | 662 | 100% | |
| | Min | 0 | | 0 | | 2 | | |
| | Max | 26 | | 12 | | 26 | | |
| | Mean (SD) | 4.3 | (5.5) | 0.3 | (0.8) | 8.3 | (5.2) | |
| | | | | | | | | |
| **LENGTH OF STUDY PERIOD** | missing | 335 | 25% | 335 | 50% | 0 | 0% | <.001 |
| | Obs | 993 | 75% | 331 | 50% | 662 | 100% | |
| | Min | 3 | | 3 | | 59 | | |
| | Max | 1956 | | 1953 | | 1956 | | |
| | Mean (SD) | 1028.0 | (589.5) | 869.5 | (675.5) | 1107.2 | (524.3) | |
| | | | | | | | | |
| **NUMBER OF STUDY VISITS** | missing | 335 | 25% | 335 | 50% | 0 | 0% | <.001 |
| | Obs | 993 | 75% | 331 | 50% | 662 | 100% | |
| | Min | 1 | | 1 | | 1 | | |
| | Max | 143 | | 143 | | 124 | | |
| | Mean (SD) | 17.1 | (17.7) | 11.7 | (15.9) | 19.9 | (18.0) | |
| | | | | | | | | |
| **COMORBIDITY INDEX** | missing | 0 | 0% | 0 | 0% | 0 | 0% | <.001 |
| | Obs | 1328 | 100% | 666 | 100% | 662 | 100% | |
| | Min | 1 | | 1 | | 1 | | |
| | Max | 14 | | 10 | | 14 | | |
| | Mean (SD) | 2.6 | (2.2) | 1.6 | (1.4) | 3.4 | (2.5) | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |
| **NUMBER OF TIMES HBA1C FLUCTUATES IN AND OUT OF CONTROL** | missing | 0 | 0% | 0 | 0% | 0 | 0% | <.001 |
| | Obs | 1328 | 100% | 666 | 100% | 662 | 100% | |
| | Min | 0 | | 0 | | 0 | | |
| | Max | 10 | | 2 | | 10 | | |
| | Mean (SD) | 0.9 | (1.7) | 0.02 | (0.2) | 1.7 | (2.1) | |

*T-test was used to test for differences between means, chi-squared test was used to test for differences between proportions.

***Study Groups***

There were over one hundred individuals in each of the four arms of the study. A greater proportion of publically insured patients were enrolled in the CIM model compared to the GIM model. This remained true when the insurance variable was reclassified (Table 3).

Table 3: Number of Subjects by Model of Care and Insurance Status

| | **CIM** | **GIM** |
|---|---|---|
| **Public Insurance** | 263 (40%) | 193 (29%) |
| **Private Insurance** | 104 (16%) | 101 (15%) |
| | | |
| **Public Insurance (reclassified*)** | 209 (34%) | 152 (24%) |
| **Private Insurance (reclassified*)** | 139 (22%) | 123 (20%) |

*Reclassified refers to the reclassification of Medicare Advantage from public to private insurance which was done for the sensitivity analysis

The publically insured group had significantly more males than females, was older, and had lower baseline HbA1c values compared to the privately insured group (Table 4). Publically insured individuals had significantly more study visits, HbA1c blood draws and were enrolled for a longer study period compared to privately insured individuals. Publically insured individuals had more comorbidities and had more episodes of switching from out of glucose control to in control, or vice versa. There were no significant differences in the race distribution between the two groups.

The intervention group (CIM) had a similar sex, race and age distribution as the non-intervention (GIM) group (Table 2). The number of study visits in the CIM group was significantly higher than the GIM group, which is consistent with the CIM model's focus on high rates of follow-up. Regardless, the GIM group had significantly more

HbA1c tests during the study period, possibly resulting from the longer study enrollment times in the GIM group compared to the CIM group. The CIM group had a significantly higher baseline HbA1c which was expected given that difficult to control individuals were often referred to the CIM clinic. There was no difference in the average number of times an individual patient went in and out of glucose control between the CIM and GIM groups.

Table 4: Characteristics of Study Populations by Public vs. Private Insurance and CIM Care Model vs. GIM Care Model

| | | PUBLIC INSURANCE | % | PRIVATE INSURANCE | % | p* | CIM | % | GIM | % | p* |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **N** | | 456 | | 205 | | | 367 | | 295 | | |
| | | | | | | | | | | | |
| **SEX** | missing | 0 | | | | 0.016 | 0 | | 0 | | 0.223 |
| | Female | 264 | 58% | 98 | 48% | | 209 | 57% | 154 | 52% | |
| | Male | 192 | 42% | 107 | 52% | | 158 | 43% | 141 | 48% | |
| | | | | | | | | | | | |
| **RACE** | missing | 0 | | | | 0.137 | 0 | | 0 | | 0.177 |
| | Caucasian | 348 | 76% | 165 | 80% | | 278 | 76% | 236 | 80% | |
| | Other | 107 | 23% | 37 | 18% | | 87 | 24% | 57 | 19% | |
| | Unknown | 1 | <1% | 3 | 1% | | 2 | 1% | 2 | 1% | |
| | | | | | | | | | | | |
| **AGE** | missing | 0 | | 0 | | <.001 | 0 | | 0 | | 0.103 |
| | Obs | 456 | | 205 | | | 367 | | 295 | | |
| | Min | 24.18 | | 24.57 | | | 26.13 | | 24.18 | | |
| | Max | 96.7 | | 89.56 | | | 87.33 | | 96.7 | | |
| | Mean (SD) | 63.07 | (12.7) | 51.58 | (10.7) | | 58.75 | (12.6) | 60.43 | (13.8) | |
| | | | | | | | | | | | |
| **BASELINE HBA1C** | missing | 0 | | 0 | | 0.003 | 0 | | 0 | | 0.002 |
| | Obs | 456 | | 205 | | | 367 | | 295 | | |
| | Min | 4.7 | | 5.3 | | | 5.1 | | 4.7 | | |
| | Max | 15.7 | | 16.2 | | | 15.7 | | 16.2 | | |
| | Mean (SD) | 7.3 | (1.6) | 7.74 | (2.08) | | 7.63 | (1.9) | 7.19 | (1.6) | |
| | | | | | | | | | | | |
| **HBA1C CONTROL AT** | missing | 0 | | 0 | | 0.1423 | 0 | | 0 | | 0.031 |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **BASELINE** | | | | | | | | | | | |
| | Out of control | 221 | 48% | 112 | 55% | | 199 | 54% | 135 | 46% | |
| | In control | 235 | 52% | 93 | 45% | | 168 | 46% | 160 | 54% | |
| | | | | | | | | | | | |
| **NUMBER OF HBA1Cs DRAWN** | missing | 0 | | 0 | | <.001 | 0 | | 0 | | 0.003 |
| | Obs | 456 | | 205 | | | 367 | | 295 | | |
| | Min | 2 | | 2 | | | 2 | | 2 | | |
| | Max | 26 | | 26 | | | 23 | | 26 | | |
| | Mean (SD) | 8.99 | (5.2) | 6.79 | (5.02) | | 7.75 | (4.9) | 8.99 | (5.5) | |
| | | | | | | | | | | | |
| **LENGTH OF STUDY PERIOD** | missing | 0 | | 0 | | <.001 | 0 | | 0 | | <.001 |
| | Obs | 456 | | 205 | | | 367 | | 295 | | |
| | Min | 59 | | 87 | | | 59 | | 125 | | |
| | Max | 1956 | | 1935 | | | 1668 | | 1956 | | |
| | Mean (SD) | 1166.51 | (508.8) | 978.639 | (535.3) | | 975.7 | (436.1) | 1270.8 | (577.0) | |
| | | | | | | | | | | | |
| **NUMBER OF STUDY VISITS** | missing | 0 | | 0 | | <.001 | 0 | | 0 | | 0.017 |
| | Obs | 456 | | 205 | | | 367 | | 295 | | |
| | Min | 1 | | 1 | | | 1 | | 1 | | |
| | Max | 124 | | 77 | | | 110 | | 124 | | |
| | Mean (SD) | 22.82 | (19.2) | 13.11 | (12.72) | | 21.29 | (18.3) | 17.49 | (17.5) | |
| | | | | | | | | | | | |
| **COMORBIDITY INDEX**** | missing | 0 | | 0 | | <.001 | 0 | | 0 | | <.001 |
| | Obs | 456 | | 205 | | | 367 | | 295 | | |
| | Min | 1 | | 1 | | | 1 | | 1 | | |
| | Max | 14 | | 13 | | | 14 | | 13 | | |

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Mean (SD) | 3.82 | (2.6) | 2.4 | (2.0) | | 3.66 | (2.6) | 3.01 | (2.2) | |
| | | | | | | | | | | | |
| **NUMBER OF TIMES HBA1C FLUCTUATES IN AND OUT OF CONTROL** | missing | 0 | | 0 | | <.001 | 0 | | 0 | | 0.208 |
| | Obs | 456 | | 205 | | | 367 | | 295 | | |
| | Min | 0 | | 0 | | | 0 | | 0 | | |
| | Max | 10 | | 10 | | | 8 | | 10 | | |
| | Mean (SD) | 1.88 | (2.1) | 1.18 | (1.9) | | 1.57 | (1.9) | 1.77 | (2.3) | |

*T-test was used to test for differences between means, chi-squared test was used to test for differences between proportions.

**Calculated based on the Deyo comorbidity index, see reference 26

***Unadjusted Assessment of Study Results***

Prior to conducting the regression analysis, the raw data were graphed to examine un-adjusted relationships between model of care delivery, insurance status and HbA1c (measured as both median HbA1c and percent of individuals achieving a HbA1c less than 7%) at the population level. These graphs are shown in Figures 2 and 3. While all groups showed improvements in median HbA1cs and in the percent of individuals achieving a HbA1c less than 7%, the CIM public group showed greater improvement in the percent of individuals ever achieving a HbA1c less than 7% when compared to the other study groups. The public and private groups appeared to derive equal benefit from the CIM model of care when median HbA1c was the outcome measure.

Figure 2: Proportion of Individuals Achieving a HbA1c less than 7 at Baseline and During the Follow-up Period by Model of Care and Insurance Status

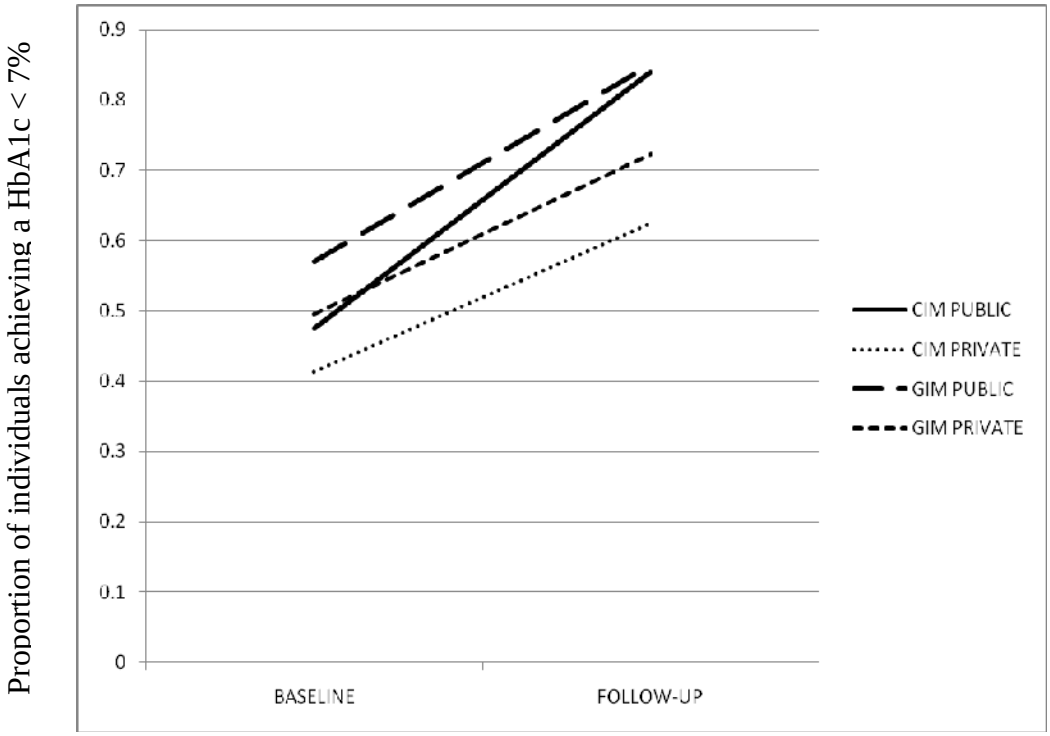
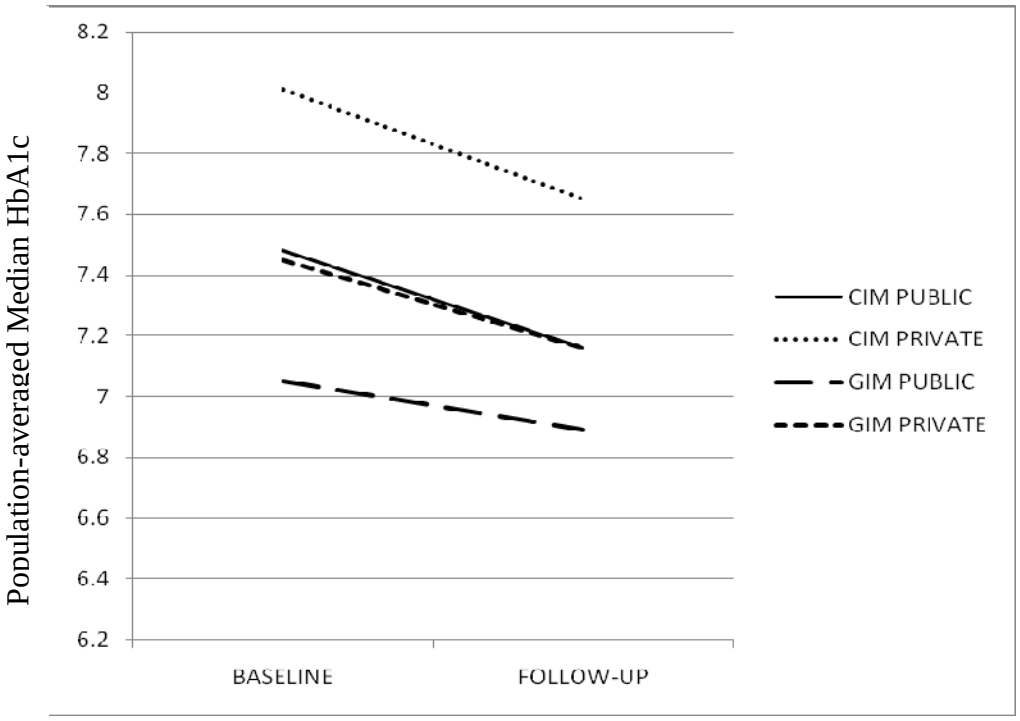
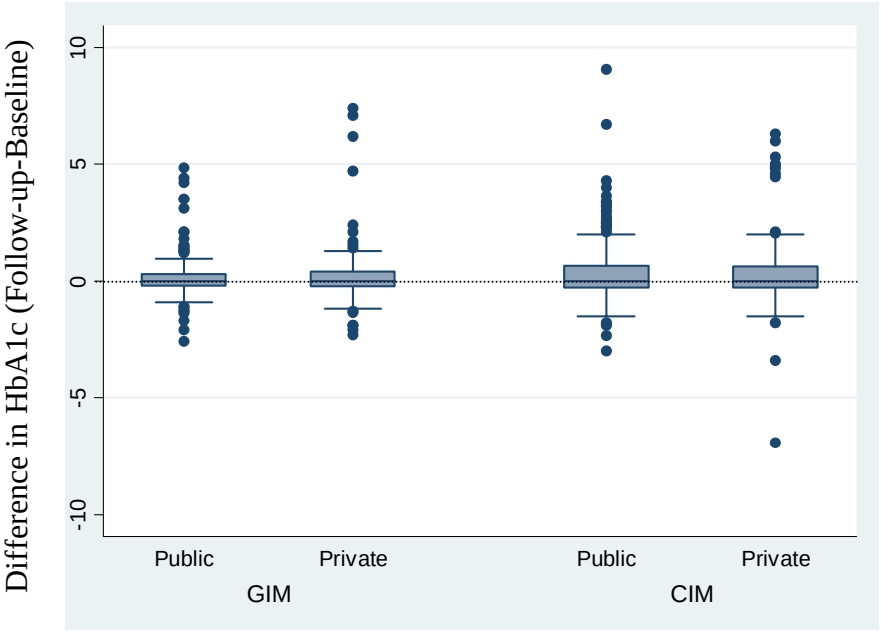


Figure 3: Population-Averaged Median HbA1c at Baseline and HbA1c at Follow-up by Model of Care and Insurance Status




Additionally, the change in HbA1c from baseline to follow-up was determined for each individual and plotted by model of care and study group as box and whisker plots (Figure 4).

Figure 4: Difference between Baseline and Follow-up HbA1c by Model of Care and Insurance Status




Prior to adjusting for covariates, an analysis was performed to determine if the there was a significant difference between the average individual change in HbA1c for each of the four study groups. All groups showed improvement from baseline (as indicated by a positive difference between follow-up and baseline values), and most differences were significant (Table 5). Regardless, in an unadjusted analysis, no significant difference was seen between the four study groups (F stat = 0.77, p= 0.512).

Table 5: Effect of Model of Care and Insurance Status on Change in HbA1c from Baseline to Follow-up*

| Study Group | Coef. | 95% Conf. Interval | |
|---|---|---|---|
| | | | |
| **CIM Public Insurance** | 0.317 | 0.160 | 0.475 |
| **CIM Private Insurance** | 0.367 | 0.117 | 0.618 |
| **GIM Public Insurance** | 0.161 | -0.023 | 0.345 |
| **GIM Private Insurance** | 0.290 | 0.036 | 0.544 |

* This model was constructed using four indicator variables fit without intercept

## Regression Models

### *Specific Aim 1*

*Linear Regression Model*

In the univariate linear regression (using median HbA1c as the outcome variable), the following variables were significant at the 0.25 level: race, comorbidity, insurance type, age, length of study period, and baseline HbA1c (Table 6). In the multivariate analysis, all variables remained significant except for race and insurance types. Race was dropped from the preliminary main effects model, but insurance type was retained because it was the variable of interest. When age was entered as a continuous variable the AIC was lower than when age was entered as a categorical variable, therefore it was retained as a continuous variable. The final multivariate model is shown in Table 7.

Table 6: Expected Increase in Median HbA1cs Associated with Predictor Variables, Unadjusted for Confounding

| Variable | Coefficient | 95% Confidence Interval | | p* |
|---|---|---|---|---|
| **NON-CAUCASIAN** | 0.235 | -0.004 | 0.475 | 0.054 |
| **COMORBIDITY** | 0.034 | -0.006 | 0.074 | 0.092 |
| **PRIVATE INSURANCE** | 0.363 | 0.151 | 0.575 | 0.001 |
| **AGE** | -0.022 | -0.029 | -0.014 | <0.001 |
| **LENGTH OF STUDY PERIOD** | 0.000 | -0.000 | -0.000 | 0.014 |
| **BASELINE HBA1C** | 0.497 | 0.456 | 0.5379 | <0.001 |

*P-value for the regression parameter

Table 7: Expected Increase in Median HbA1cs Associated with Predictor Variables, with Non-Significant Variables Removed and with Adjustment for Confounding*

| Variable | Coefficient | 95% Confidence Interval | |
|---|---|---|---|
| **COMORBIDITY INDEX** | 0.048 | 0.018 | 0.079 |
| **PRIVATE INSURANCE** | 0.114 | -0.059 | 0.287 |
| **AGE** | -0.009 | -0.015 | -0.004 |
| **BASELINE HBA1C** | 0.481 | 0.440 | 0.522 |

Among participants with private insurance, median HbA1c was 0.114 units higher during the follow-up period compared to patients with public insurance, however this difference was not significant (p=0.197, 95% CI –0.059 to 0.287).

*Logistic Regression Model*

To determine if insurance status was associated with an individual's ability to achieve a HbA1c less than 7%, a logistic regression analysis was conducted. In the univariate logistic regression, all variables were significant at the 0.25 level except for race (Table 8). When entered into a multivariate logistic regression, all variables remained significant except for comorbidity. The categorical age variable provided a

better fit (based AIC values) than the continuous age variable, therefore the final model contained a categorical age variable. The final multivariate model is shown in Table 9.

Table 8: Expected Odds of Achieving a HbA1c less than 7% Associated with Predictor Variables, Unadjusted for Confounding

| Variable | OR | log likelihood | P* |
|---|---|---|---|
| **FEMALE GENDER** | 0.790 | -338.139 | 0.2224 |
| **NON-CAUCASIAN** | 0.899 | -336.505 | 0.6412 |
| **COMORBIDITY INDEX** | 1.103 | -336.073 | 0.0177 |
| **PRIVATE INSURANCE** | 0.380 | -326.749 | <.001 |
| **AGE** | Wald test for categorical | | <.001 |
| **LENGTH OF STUDY PERIOD** | 1.001 | -321.082 | <.001 |
| **HBA1C IN CONTROL AT BASELINE** | 15.952 | -272.817 | <.001 |

*P-value for the regression parameter

Table 9: Expected Odds of Achieving a HbA1c less than 7% Associated with Predictor Variables, with Non-Significant Variables Removed and with Adjustment for Confounding

| Variable | OR | 95% Confidence Interval | |
|---|---|---|---|
| **FEMALE GENDER** | 0.603 | 0.380 | 0.958 |
| **PRIVATE INSURANCE** | 0.383 | 0.238 | 0.616 |
| **30≤ AGE <35*** | 0.117 | 0.016 | 0.852** |
| **35≤ AGE <40*** | 0.174 | 0.029 | 1.037** |
| **40≤ AGE <45*** | 0.120 | 0.023 | 0.629** |
| **AGE>45*** | 0.467 | 0.106 | 2.058** |
| **LENGTH OF STUDY PERIOD** | 1.001 | 1.001 | 1.002 |
| **HBA1C IN CONTROL AT BASELINE** | 19.937 | 10.207 | 38.942 |

*Compared to age <30
**Wald statistic for age<0.001

The odds of ever achieving glucose control during the study period (HbA1c less than 7%) was 62% less in private compared to publically insured individuals (OR 0.383, p value of <0.001, 95% CI 0.238 to 0.616).

***Specific Aim 2***

*Linear Regression Model*

To test this hypothesis, a variable designating the type of clinic in which the patient was enrolled was added to the models created to test the first hypothesis. A term representing the interaction between insurance type and type of clinic was also added to the model to test for homogeneity of treatment effects across clinic-type subgroups. This analysis was performed for both the linear (Table 10) and logistic (Table 11) regression models.

Table 10: Expected Increase in Median HbA1cs Associated with Insurance and Care Model, Adjusted

| Variable | Coefficient | 95% Confidence Interval | |
|---|---|---|---|
| **COMORBIDITY INDEX** | 0.047 | 0.017 | 0.078 |
| **PRIVATE INSURANCE** | 0.028 | -0.212 | 0.268 |
| **AGE** | -0.009 | -0.015 | -0.003 |
| **BASELINE HBA1C** | 0.478 | 0.437 | 0.520 |
| **CIM MODEL** | 0.013 | -0.164 | 0.191 |
| | | | |
| **INTERACTION** | 0.173 | -0.138 | 0.484 |

In this model, neither the insurance variable nor the model of care variable were significant. The interaction term in this model was also not significant, with a p value of 0.275, suggesting that the relationship between insurance type and HbA1c outcomes did not differ by model of care.

*Logistic Regression Model*

Table 11: Expected Odds of Achieving a HbA1c less than 7% Associated with Insurance and Care Model, Adjusted

| Variable | OR | 95% Confidence Interval | |
|---|---|---|---|
| **FEMALE GENDER** | 0.594 | 0.373 | 0.944 |
| **PRIVATE INSURANCE** | 0.401 | 0.248 | 0.646 |
| **30≤ AGE <35*** | 0.117 | 0.016 | 0.854** |
| **35≤ AGE <40*** | 0.184 | 0.031 | 1.088** |
| **40≤ AGE <45*** | 0.114 | 0.022 | 0.597** |
| **AGE >45*** | 0.467 | 0.107 | 2.047** |
| **LENGTH OF STUDY PERIOD** | 1.001 | 1.001 | 1.002 |
| **HBA1C IN CONTROL AT BASELINE** | 21.251 | 10.757 | 41.983 |
| **CIM MODEL** | 1.514 | 0.932 | 2.458 |
| | | | |
| **INTERACTION** | 0.565 | 0.223 | 1.434 |

*Compared to age <30
**Wald stat for age 0.001

In this model, the insurance variable continued to be significant, suggesting that the odds of achieving glucose control with private insurance was 60% less than with public insurance. The odds of achieving glycemic control was 1.514 times greater in the CIM model compared to the GIM model, but this did not reach statistical significance (p=0.094, CI 0.932, 2.458). The interaction term was also not statistically significant in this model, with a p value of 0.229, further supporting the previous result showing that the relationship between insurance type and HbA1c outcomes does not differ by care model.

### *Sensitivity Analysis with Reclassification of Insurance Variable*

The methodology described above was repeated using the new definition of the insurance variable where Medicare Advantage insurance was classified as a type of private insurance to reflect privately administered care despite public funding. The following linear regression (Table 12) and logistic regression (Table 13) models resulted from this analysis.

Table 12: Expected Increase in Median HbA1cs Associated with Insurance and Care Model, Adjusted, with Medicare Advantage Classified as Private Insurance

| Variable | Coefficient | 95% Confidence Interval | |
|---|---|---|---|
| **COMORBIDITY INDEX** | 0.047 | 0.017 | 0.076 |
| **PRIVATE INSURANCE** | 0.106 | -0.047 | 0.259 |
| **AGE** | -0.009 | -0.014 | -0.003 |
| **BASELINE HBA1C** | 0.487 | 0.446 | 0.529 |
| **CIM MODEL** | 0.044 | -0.103 | 0.191 |
| | | | |
| **INTERACTION** | 0.199 | -0.092 | 0.491 |

Using the new definition of public and private insurance, neither insurance nor care model was significant however the direction of the association was in the same direction as in the previous model where Medicare advantage was classified as public insurance. The interaction term remained non-significant at 0.180.

Table 13: Expected Odds of Achieving a HbA1cless than 7% Associated with Insurance and Care Model, Adjusted, with Medicare Advantage Classified as Private

| Variable | OR | 95% Confidence Interval | |
|---|---|---|---|
| **PRIVATE INSURANCE** | 0.539 | 0.335 | 0.867 |
| **30≤ AGE <35*** | 0.097 | 0.012 | 0.768** |
| **35≤ AGE <40*** | 0.263 | 0.044 | 1.557** |
| **40≤ AGE <45*** | 0.110 | 0.021 | 0.587** |
| **AGE >45*** | 0.570 | 0.130 | 2.506** |
| **LENGTH OF STUDY PERIOD** | 1.001 | 1.001 | 1.002 |
| **HBA1C IN CONTROL AT BASELINE** | 22.623 | 11.072 | 46.225 |
| **FEMALE GENDER** | 0.624 | 0.387 | 1.006 |
| **CIM MODEL** | 1.745 | 1.064 | 2.861 |
| | | | |
| **INTERACTION** | 0.453 | 0.177 | 1.158 |

*Compared to age <30
**Wald stat for age 0.001

Using the revised definition of private insurance, the odds of achieving glucose control was 46% less for privately insured individuals compared to publically insured individuals (OR=0.539, p=0.011). Additionally, the odds of achieving glucose control in the CIM model was 1.75 times the odds of achieving control in the GIM model (95% CI 1.064 to 2.861, p=0.027). The interaction term remained non-significant at 0.098.

### *Model Diagnostics*

Model diagnostics were conducted on the four final models: logistic and linear regression models for each of two categorizations of insurance type (with Medicare Advantage classified as public and private), prior to adding the interaction term (because the interaction term was not found to be significant). These results are presented in Appendix 1. While there was some deviance from normality, normality was not improved by log transforming the outcome variables in the linear regression models.

Analysis of outliers resulted in the removal of one datapoint in one linear model, and no datapoints in the other linear model model. No datapoints were removed in the logistic models based on the analysis of outliers. In the logistic models, Hosmer-Lemeshow testing showed poor goodness of fit as evidenced by significant p-values for this test, however the ROC curve showed good discernability for both models.

## Discussion

Insurance status did affect an individual's ability to achieve a HbA1c less than 7%, with publically insured individuals more likely to achieve a HbA1c less than 7% compared to privately insured individuals (OR=0.383, $p < 0.001$) during an average 3 year follow-up period. However, insurance status did not influence median HbA1c (B-coefficient=0.114, p=0.197) during this same period. Therefore, while individuals with public insurance may have been more likely to reach an acceptable level of HbA1c, this did not equate with improved overall glucose control compared to privately insured individuals. While there are examples in the literature of publically insured individuals achieving worse outcomes than privately insured individuals,[9-13] this study showed that outcomes for publically insured individuals are equal to, if not better than, outcomes achieved by privately insured populations.

While it was unclear why these results differed from the published literature, the difference may be explained by the nature of the study population that presents to an academic teaching hospital. For example, private insurance is often more portable than public insurance, therefore privately insured individuals may be more likely to seek treatment from a teaching hospital compared to publically insured individuals when they

have a difficult to manage disease. This would have resulted in worse HbA1c outcomes in privately insured individuals compared to publically insured individuals, as was observed in this study. Additionally, OHSU physicians were blinded to the insurance status of their patients, and therefore may have been less likely to alter treatment strategies based on insurance status than would physicians who are aware of the type of insurance held by their patients. Finally, the publically insured population in this analysis may have had better access to care than previously studied populations. In order to have been included in this study, patients must have been able to schedule an appointment and arrive at the clinic for at least two visits, suggesting at least a minimal ability to access care. In other studies showing significant differences in outcomes between publically insured and privately insured individuals, data is obtained from a general population sample or from a sample of patients presenting for acute care.[8,9] Therefore, these populations may have worse outcomes because of their inability to access care, whereas the population studied in this analysis already had some access to care and was therefore less likely to have experienced poor outcomes than the general publically insured population.

The raw data showed an increase in the percent of individuals achieving a HbA1c less than 7% for the CIM public group compared to all other groups, although all groups showed some improvement. When this relationship was further examined using a multivariate logistic regression model controlling for confounders, the interaction term between insurance type and care model was not significant (OR=0.565, p=0.229), suggesting that patients received equal benefit from the CIM model regardless of insurance status. This suggests that the CIM model had the potential to improve care

equally for publically and privately insured individuals. Although the observed improvement was not significant in this model, this interaction should be evaluated in future research in a larger population with a longer follow-up time. Additionally, a greater percent of OHSU patients achieved a HbA1c less than 7% compared to diabetes patients nationally (37% of diabetes patients nationally achieve HbA1c values less than 7% compared to 81% among the population in the current study of OHSU patients).[26] Therefore, a ceiling affect may have been present and differences in improvement may have been difficult to observe in the OHSU population.

The raw data also showed that, when examined at the population level, all groups experienced nearly equal improvement in median HbA1c values. When the average change in HbA1c was compared between the four study groups, no significant difference was detected. This was confirmed by the linear regression analysis after adjusting for potential confounding variables which produced a non-significant interaction term (B-coefficient=0.173, p=0.275). This suggests that there was no difference in median HbA1c between the different insurance types or models of care. Furthermore, the relationship between insurance type and HbA1c outcomes was not modified by care model. Therefore, this analysis also suggests that the CIM model can be applied with equal efficacy across different insurance types.

A sensitivity analysis was performed with Medicare Advantage plans re-classified as private insurance in an effort to determine if the classification of insurance type affects study outcomes. Because Medicare Advantage plans are administered by private insurers, access to care and care management may more closely resemble that of private plans even though the care is publically funded. With median HbA1c as the outcome

measure, little change was seen in the magnitude or direction of the coefficients and p values of the insurance, care model and interaction terms. However, in the logistic regression model, insurance status continued to be a significant predictor of HbA1c control, and care model emerged as a significant predictor of HbA1c control (p=0.027). The interaction term did not reach significance. Furthermore, when the reclassification occurred, the odds ratio associated with insurance type approached the null, suggesting that the effect size was smaller in the sensitivity analysis. Therefore, reclassifying this variable may have introduced some misclassification error which decreased the explanatory power of the variable. Because socioeconomic status was not controlled for in this study, the explanatory power may have decreased in part because the correlation between socioeconomic status and insurance type was decreased when the insurance variable was reclassified.

In summary, this study provids moderate support for improved HbA1c outcomes in publically insured patients compared to privately insured patients. Care model did not modify the association between insurance status and glucose control. This suggests that it is not necessary to tailor care models to populations based on insurance type and this model can be applied to both insurance populations with equal efficacy in an academic medical center.

## Limitations

There are several limitations inherent to this study design. First, the study was powered to detect a 10% difference between insurance types in the percent of individuals achieving a HbA1c less than 7%. The study population may not have been large enough

to detect a significant difference by care model. The appearance of a difference by care model in the raw data despite the non-significant interaction in multivariable analysis may have been indicative of inadequate power.

Data were not available to adjust for socioeconomic variables such as income and education, which were likely to be closely correlated with insurance status and outcomes. While adjustment for these variables may have accounted for some of the variation in the model, they are may also have led to over-adjustment in the model that would have decreased the ability of the model to detect a relationship between insurance and HbA1c outcomes. Regardless, socioeconomic characteristics were potential confounders in this study.

One disadvantage of this study was that it was not a randomized, double-blind trial. It was impossible to blind the trial because providers needed to be trained in the CIM model of care and the delivery of care was significantly different under this model. Future trials would certainly benefit from randomization and randomized studies have been conducted in other populations and have shown a benefit with the CIM model.[27] The current study was not randomized which explains the higher baseline HbA1c values in the CIM group and may also have resulted in immeasurable differences that ultimately may have influenced results of the study. In future studies, a propensity score covariate could be added to adjust for these potential differences. Regardless, the methods of referral that led to higher HbA1c values in the CIM group were likely to represent real-world referral patterns, therefore making the results generalizable to current clinical practice.

Studies suggest that lower levels of glycemia at the time of initial therapy are associated with lower HbA1c over time and a decrease in long term complications, therefore these differences present at baseline may have affected the results of the study.[28] This was controlled for by including baseline HbA1c values as a covariate. Additionally, diabetics with long-standing disease are often more difficult to control than individuals with newly diagnosed disease. Information about the duration of disease in the study population was not available, and these individuals may have been differentially distributed in our study population with more difficult to control individuals in the CIM group. This may have accounted for the lack of benefit observed in the final linear regression model.

The trial had the benefit of being conducted in an academic center, however the disadvantage of this design was that medical residents were constantly rotating through both the CIM and the GIM practice, meaning that a given resident may have practiced first in the CIM clinic, then utilized some of the techniques learned in the CIM clinic when they rotated through the GIM practice at a later date. Additionally, one of the GIM providers was trained in the CIM methodology. This would bias results toward the null, and may have contributed to the non-significant results observed in this study.

Another limitation of this study was that insurance status was measured as the type of insurance held by the study participant for the majority of the study period. Therefore, some individuals designated as holding private insurance may have held public insurance for some of the study period, which may dilute the results. However, this bias was likely to be non-differentially distributed, therefore the reported effects are likely conservative.

The HbA1cs drawn during this study were not drawn at regular intervals. Therefore, median HbA1c values were used to approximate the median value over the follow-up period. For example, an individual who had three HbA1c values drawn during the study period (say 5, 7 and 9) was considered to have a median HbA1c value of 7 even if they had a HbA1c of 5 for 1 month, 7 for one month and 9 for 2 years. Given the nature of the data collection process, it was not possible to account for these variations, however they were expected to be non-differentially distributed in the data.

The results obtained in the logistic regression analysis should also be interpreted cautiously because HbA1c control was defined as having ever reached a HbA1c less than 7% during the study period. This may be a poor reflection of HbA1c control because an individual who achieved a HbA1c less than 7% at any point during the study, regardless of other HbA1c values, was considered to have met this goal. This potential limitation was highlighted in descriptive analysis which showed that individuals fluctuated in and out of glucose control (or vice versa) an average 1.66 times, ranging from 0-10 times. Therefore, an individual may have been out of glucose control for the majority of the study period, achieved one value less than 7%, and was still considered to have achieved the goal endpoint. For this reason, median HbA1c values were also evaluated as an outcome.

The data collection process was also imperfect in that the methods used for data collection were not able to capture all individuals enrolled in the GIM or CIM clinic (see Figure 1). Unfortunately, no information was available on these individuals, therefore it was impossible to determine how exclusion of this group ultimately affected the study results.

The diagnostics performed on the models showed deviance from the assumption of normality in the linear models and lack of fit in the logistic models. However, the linear models could not be improved by log transformation of the outcome variables, suggesting that this was an underlying problem with the distribution of the data, rather than poor modeling. Despite poor fit based on Hosmer-Lemeshow testing, the ROC curves suggested that the model has good discernability.

## Future Research

Future studies may benefit from randomization, increased length of study period, regular measurement of HbA1c values and an increased sample size, thereby increasing the power to detect a difference in the influence of insurance status on glucose control by care model. Other aspects of insurance status, such as continuity of insurance coverage and lack of insurance may also affect HbA1c status and were not specifically examined in this study and may add strength to future studies in this area. Additionally, a study conducted in a population with broader demographics is likely to be more generalizable to the United States population.

## Conclusion

Contrary to the existing literature, this study provided evidence to suggest that public insurance was associated with at least equal, if not better, HbA1c outcomes than private insurance in one academic medical center. Overall, this study did not support previous research showing that the CIM model of care results in improved HbA1c control compared to the GIM model, however one of the four final models did show an

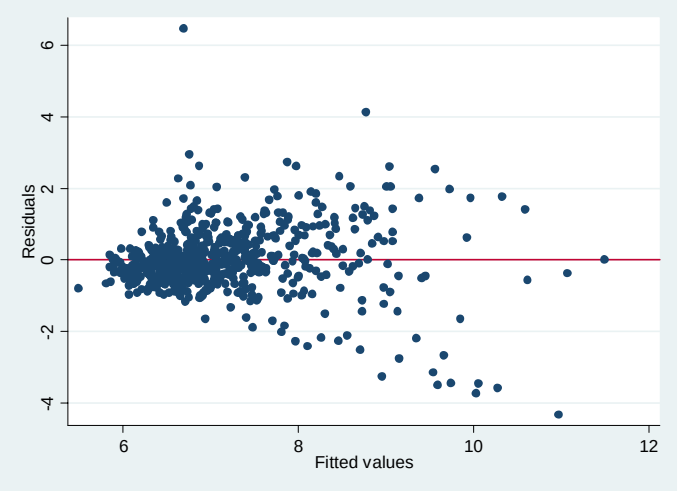
improvement in outcomes with the CIM model. Finally, this study showed that the relationship between insurance status and diabetes outcomes was not influenced by model of care delivery; therefore this model has the potential to provide equal benefit to both publically and privately insured populations.

## Appendix

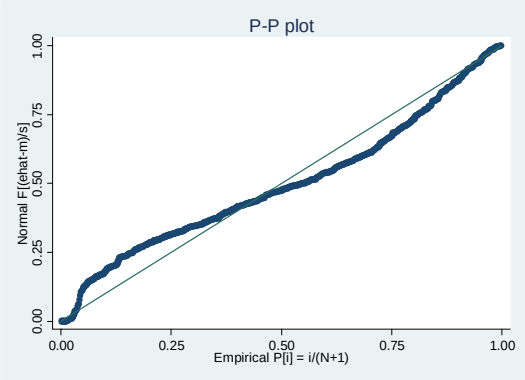
### Model Diagnostics

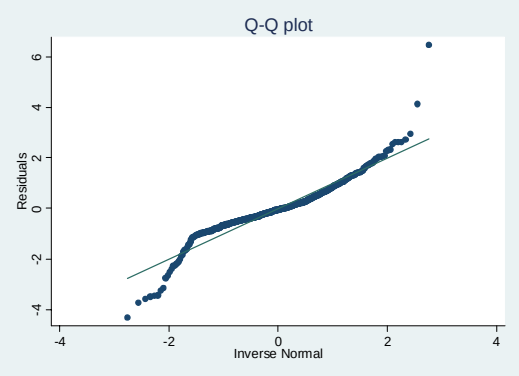
*Diagnostics for linear regression where Medicare Advantage was classified as public:*

The fanning shape of the fitted values versus residuals curve below suggested non-constant variance. This was not improved by log transformation of the outcome variable, therefore the original model was not altered.

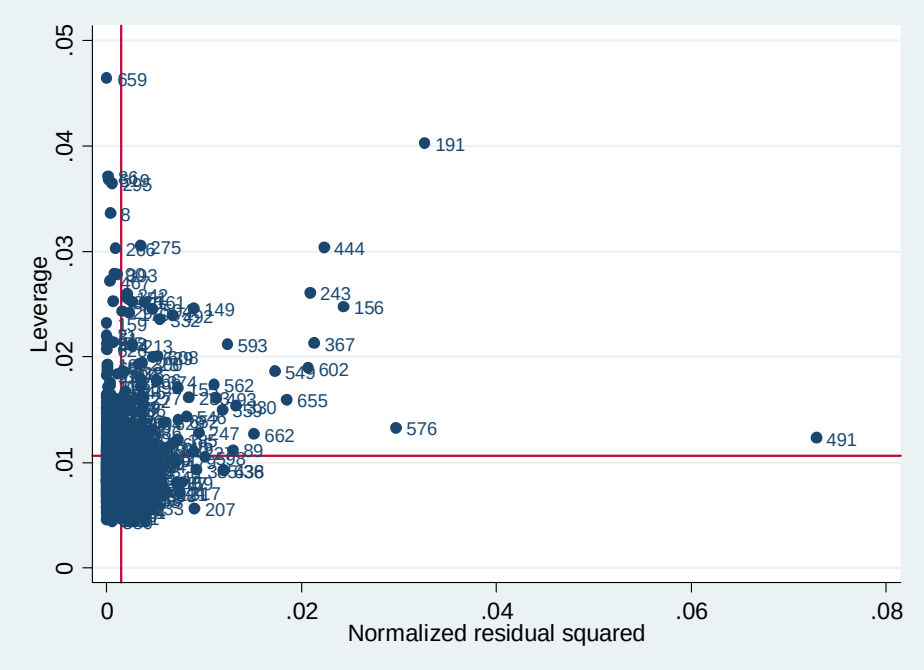



Deviance from linearity in the p-p and q-q plots (following page) suggested departures from normality in the distribution. This was not improved by log transformation of the outcome variable, therefore the original model was not altered.



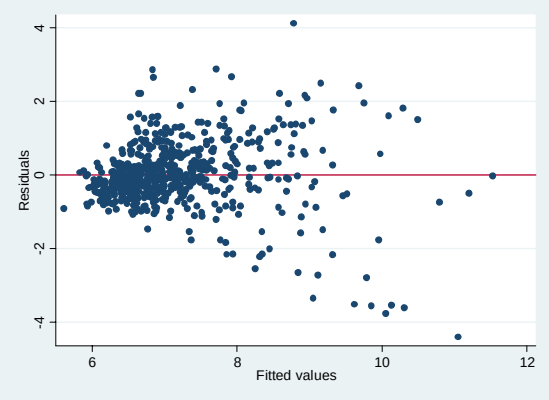




The leverage vs. residuals squared plot showed several potential outliers (below). Outlying observations were dropped one at a time until coefficents did not change by more than 10%. This resulted in the removal of one datapoint (491).

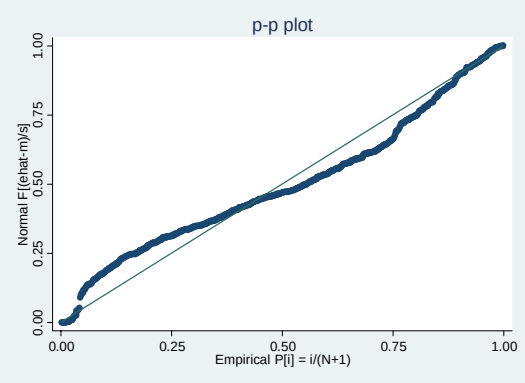


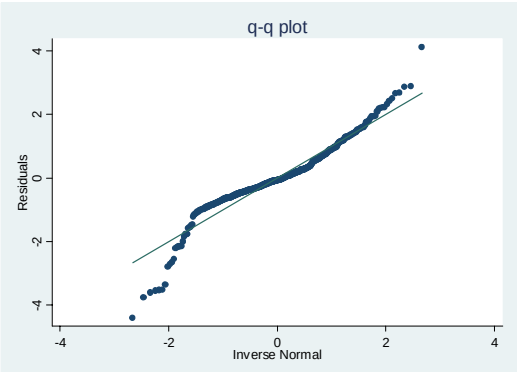
*Diagnostics for linear regression where Medicare Advantage was classified as private:*

Fanning was present in the plot of residuals vs. fitted values (below), suggesting non-constant variance, however log transformation of the outcome did not improve the model.

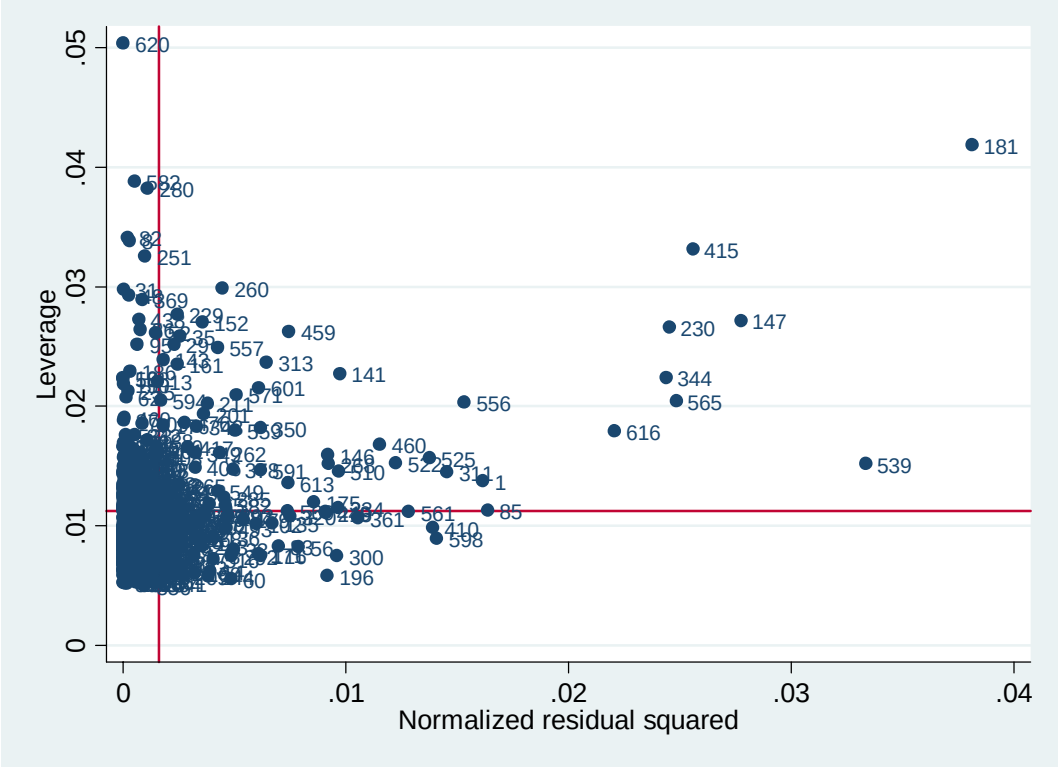



Deviance from linearity in the p-p and q-q plots suggested departures from normality in the distribution (below). This was not improved by log transforming the outcome.



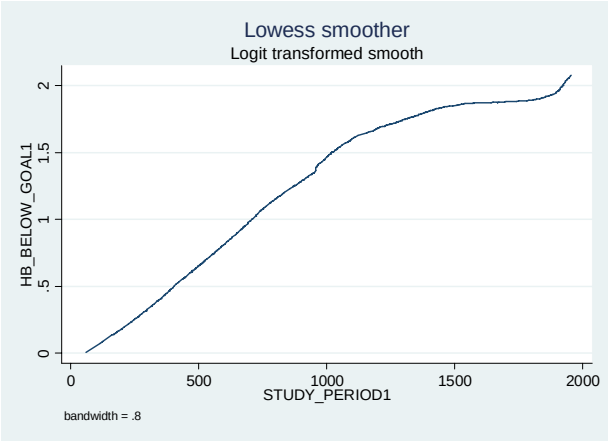



The leverage vs. residuals squared plot showed several potential outliers (below). Removal of the outliers one at a time did not change the coefficients by more than 10%, therefore they were not removed from the model.

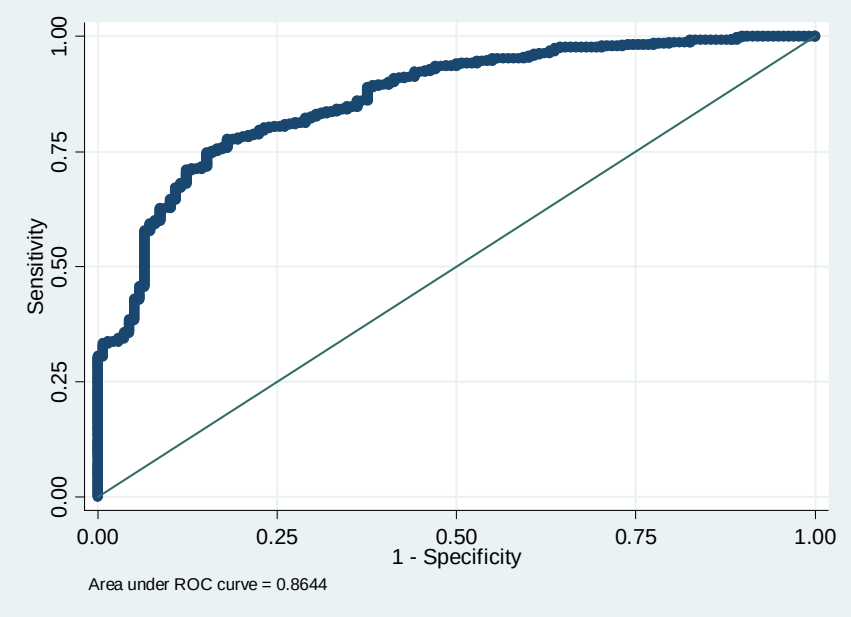



*Diagnostics for logistic regression where Medicare Advantage was classified as public*

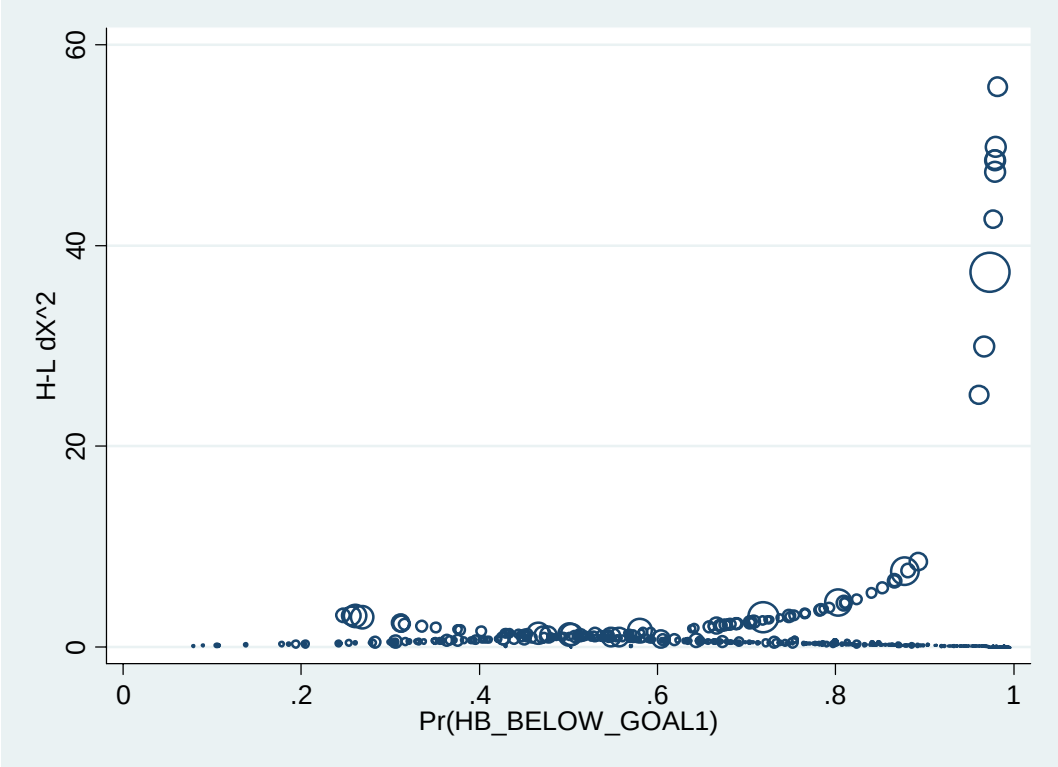
The only continuous variable in this model was the study period variable. This variable was assessed for the assumption of linearity using a lowess curve (following page). The relationship was generally linear, therefore no transformations were made.




The model fit was assessed using the Hosmer-Lemeshow method. The chi-squared value was 24.83 which corresponds to a p value of 0.0017 (this compares to a chi-squared value of 12.49 and 0.1307 with old age cats), therefore the null hypothesis was rejected, which did not support a good model fit. The ROC curve below did support good fit and discernability, with an area under the curve of 0.8644.



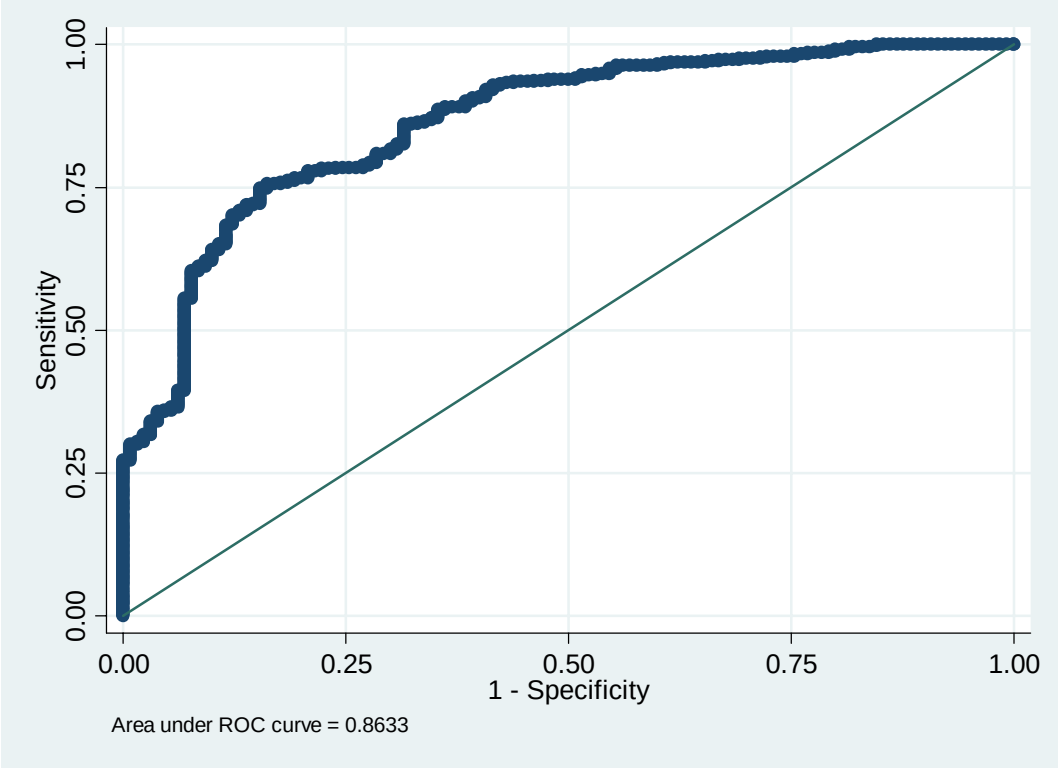
A plot of Pearson's chi-squared vs. predicted probability, with the size of each point proportional to the size of Cook's distance, was used to identify potential outliers (below). Removal of the top outlier did not change the values of the coefficients more than 10%, therefore no points were removed for the final model.



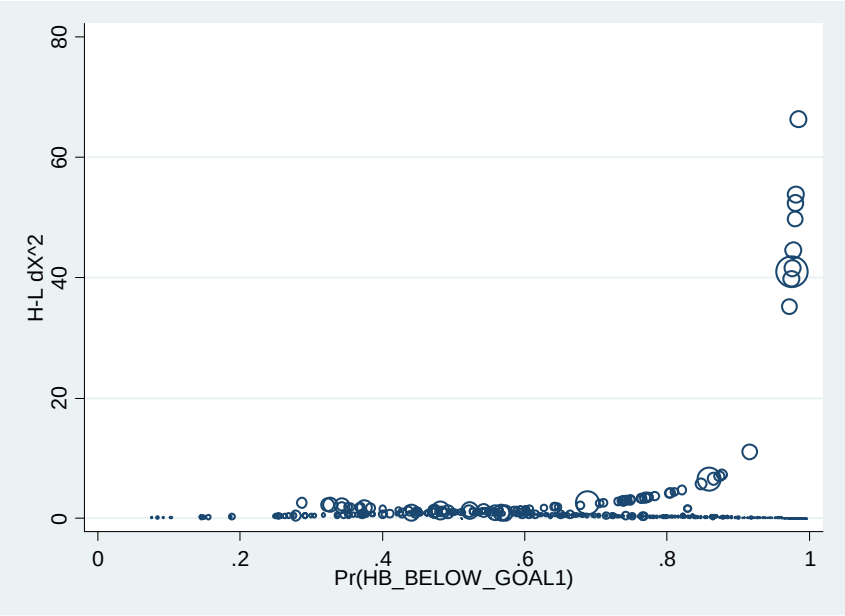

*Diagnostics for logistic regression where Medicare Advantage was classified as private*

Again, the study period variable was the only continuous variable included in the model. A lowess plot (following page) showed a generally linear relationship, therefore no transformation was necessary.


The Hosmer-Lemeshow test gives a chi-squared value of 41.39 which corresponded to a p value of <0.001, therefore the null hypothesis was rejected, which did not support a good model fit. The ROC curve, with an area under the curve of 0.8633, supported good discernability (below).



A plot of Pearson's chi-squared vs. predicted probability, with the size of each point proportional to the size of Cook's distance, was used to identify potential outliers (below). Removal of the outlier in this case did not change the beta coefficients more than 10%, therefore the outlier was retained in the analysis.



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