Outcomes Assessment

Diabetes Mellitus Disease Management

Prepared for Kansas Medical Assistance Program in July, 2009

EXECUTIVE SUMMARY

Purpose of Intervention	To determine opportunities for improving the quality and safety of drug therapy for patients with diabetes mellitus following the 2007 clinical practice recommendations published by the American Diabetes Association.

Intervention	Intervention Type	Population-based mailing
	Intervention Mailing Date	June 2008
	Pre-intervention Period (Baseline)	December 2007 – June 2008
	Post-intervention Period (Post)	August 2008 – November 2008
	Number of Letters Mailed	598
	Number of Targeted Physicians	598
	Number of Targeted Patients	2,043
	Adjusted Targeted Patients	1,190

Changes in Clinical Indicators

Clinical Indicators	Baseline	Target Nov-08	% Change
Medication Non-Compliance	124	53	-57.3%
Increased Risk of ADE	818	615	-24.8%
Underutilization	183	102	-44.3%
Total	1,125	770	-31.6%

Savings Calculation

Intervention-Related Drug Therapy	
Target Group: Actual Average Paid Amount Per Patient Per Month (Baseline)	$176.10
Target Group: Actual Average Paid Amount Per Patient Per Month (Post)	$175.56
% Change in Target Group from Baseline to Post	-0.31%
Estimated Savings Per Patient Per Month	$0.55
Total Number of Target Patients	1,190
4-Month Total Savings	$2,607.34

Intervention-Related Medical Expenditures	
Target Group: Actual Average Paid Amount Per Patient Per Month (Baseline)	$272.19
Target Group: Actual Average Paid Amount Per Patient Per Month (Post)	$229.21
% Change in Target Group from Baseline to Post	-15.79%
Estimated Savings Per Patient Per Month	$42.98
Total Number of Target Patients	1,190
4-Month Total Savings	$204,582.59

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BACKGROUND

Diabetes mellitus is a heterogenous mix of chronic metabolic disorders characterized by hyperglycemia, which is due to defects in insulin secretion, insulin action, or both. The disorder can be classified as either type 1 (insulin deficiency), type 2 (insulin resistance), gestational diabetes (during pregnancy) or other specific types due to other causes (e.g., genetic defects, drug-induced). Before the development type 2 diabetes, there is almost always "pre-diabetes", characterized by blood glucose levels that are higher than normal but not yet high enough to be diagnosed as diabetes.[1,2] There are 41 million people in the United States, ages 40 to 74, who have pre-diabetes. Recent research has shown that some long-term damage to the body, especially the heart and circulatory system, may already be occurring during pre-diabetes.[3] An estimated 18.2 million people in the United States have diabetes (13 million with a diagnosis of diabetes; 5.2 million undiagnosed).[1,2]

In 2002, the total annual economic costs of diabetes approximated $132 billion. Just over $91.8 billion is attributed to direct medical and treatment costs and $39.8 billion attributed to indirect costs such as disability and mortality.[1,2] Serious long-term complications result from microvascular (small vessel) and macrovascular (large vessel) disease. These include, but are not limited to, heart disease, hypertension, stroke, blindness, end stage renal disease, lower extremity amputations, and dental disease.

There are a variety of drug classes used for the treatment of diabetes, particulary type 2. Oral medications used to treat type 2 dabetes include the first and second generation sulfonylureas, biguanides (metformin), alpha-glucosidase inhibitors (acarbose and miglitol), thiazolidinediones (TZDs; rosiglitazone and pioglitazone), meglitinides (repaglinide and nateglinide) and dipetidyl peptidase-4 (DPP-4) inhibitors (sitagliptin). Since the drug classes have different, yet complimentary, mechanisms of action, combination therapy often leads to improved glycemic control. Currently, four different class combinations are available: sulfonylurea/biguanide, TZD/biguanide, TZD/sulfonyurea, DDP-4 inhibitor/biguanide. Injectable medications for the treatment of diabetes include insulins, pramlintide (synthetic human amylin), and exenatide (an incretin mimetic). Insulin is also available in an orally inhaled formulation.

The target HbA1C level for a population of patients is less than 7% for adequate control of blood glucose; some individuals may benefit from an HbA1C level below 6%. In addition to managing hyperglycemia, it is critical to manage and treat associated disorders such as hypertension, obesity and dyslipidemia. The risk factors identified by the American Diabetes Association (ADA) for the development of diabetes (see table below are also risk factors for coronary heart disease. Because of the high mortality rate of diabetic patients after a first myocardial infarction, the ADA and the National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) have recommended that dyslipidemia be treated more aggressively in patients with diabetes [8,9] Additionally, low dose enteric-coated aspirin therapy (75-162 mg daily) is recommended as a strategy for both secondary prevention in adult diabetics with evidence of large vessel disease and as primary prevention for adult diabetics with cardiovascular risk factors. Candidates who may not be eligible for aspirin therapy include patients under the age of 21 years, those with an allergy to aspirin, those with a bleeding tendency or receiving anticoagulant therapy, and patients with active liver disease or who have had a recent gastrointestinal bleed.[1,2]

[1] American Diabetes Association. Standards of medical care in diabetes - 2007. Diabetes Care 2007;30 (Suppl 1):S4-S41.
[2] American Diabetes Association. Standards of medical care in diabetes - 2006. Diabetes Care 2006;29 (Suppl 1):S4-S42.
[3] American Diabetes Association. What is pre-diabetes? Available at: http://diabetes.org/pre-diabetes.jsp

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Diabetes Mellitus – Risk Factors	
• Primary relative (parent or sibling) with a history of **Diabetes Mellitus** • **Obesity** (more than 20% over ideal weight) BMI >27.3 kg/m^2 in women, >27.8 kg/m^2 in men • **Hypertension** (blood pressure ≥140/90 mmHg) • **Albuminuria** (micro or macro)	• Current **Cigarette Smoking** or **tobacco use** • **Dyslipidemia** HDL < 35 and/or triglycerides >150 mg/dl. • **Age** over 30 years

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METHODOLOGY

Changes in intervention-related pharmacy dollars paid, pharmacy dollars paid per patient per month (PPPM), and number of pharmacy claims were examined. This intervention identified providers whose patients were affected by medication non-compliance, increased risk of ADE, and underutilization. To assess the impact of the intervention, pharmacy drug claims were reviewed from August 2008 through November 2008.

Clinical Criteria: Criteria, rationale, and text message(s) to providers are listed below. All physicians with recipients "hitting" on criteria received letters.

- Medication Non-Compliance
  This indicator identifies patients taking maintenance diabetes, antihypertensive and antilipemic medications that may be non-compliant with therapy because they have received less than 66% of the cumulative amount prescribed.

  Rationale: Compliance with prescribed maintenance drug regimens is paramount to successful patient outcomes. More than $100 billion is spent yearly for problems related to noncompliance. Over half of written prescriptions are taken incorrectly.[4]

  Sample Provider Paragraph:

  > Your patient may be non-compliant with the identified chronic antilipemic therapy. From prescription data, it appears that your patient received <60 days of maintenance therapy in a 90 day period. Please review this information to determine the best course of action for your patient.

- Increased Risk of Adverse Drug Events
  The increased risk of adverse drug event indicator identifies patients receiving medications who are at risk of experiencing an adverse drug event due to predisposing medical conditions. Additionally, certain concomitant medication therapy may result in additive effects resulting in adverse events.

  Rationale: Medication related adverse events are common in primary care, and many are preventable or ameliorable. Improvements in monitoring for and responding to symptoms are especially important for the prevention of adverse drug events in outpatients.

  Sample Provider Paragraph:

  > Increased risk of adverse effect: Metformin-Containing Product(s) with hepatic impairment. According to pharmacy and medical claims data, it appears your patient has a diagnosis of hepatic impairment and received a metformin-containing product. Because hepatic impairment may significantly limit the ability to clear lactate, metformin-containing products should be avoided in patients with clinical or laboratory evidence of hepatic disease due to the increased risk of developing lactic acidosis. Please review the need for this medication, consider the use of appropriate alternatives, or regularly monitor for clinical signs and symptoms of lactic acidosis or worsening of existing hepatic impairment.

- Underutilization
  Because nephropathy may not routinely be submitted as a diagnosis, this measure identifies patients with a diagnosis of nephropathy, as well as patients without a diagnosis of nephropathy but who have hypertension and diabetes and are not taking an

[4] Berg JS, Dischler J, Wagner DJ, Raia JJ, Palmer-Shevlin N. Medication compliance: a healthcare problem. Annals of Pharmacotherapy. 1993;27(suppl 9):S1-S19

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angiotensin modulating agent as potential candidates for either ACE-inhibitor or AIIRA therapy.

Rationale: Clinical studies have shown that ACE-inhibitors and certain angiotensin II receptor antagoinists (AIIRA) agents (specifically, losartan and irbesartan) decrease or stabilize albuminuria in incipient nephropathy and slow the rate of progression of advanced nephropathy. They should be utilized in all patients with proteinuria, without a contraindication to receiving them, who are type 1 diabetics (normotensive or hypertensive), and hypertensive type 2 diabetic patients.[5,6,7,8,9]

Sample Provider Paragraph:

> Potential underutilization: Hypertension diagnosis & diabetes medication without an angiotensin-modulating agent. In the absence of contraindications, consider an angiotensin-modulating agent (ACE inhibitor or Angiotensin II Receptor Antagonist) if your patient has incipient or advanced diabetic nephropathy.

Definitions:

Adjusted Target Patients – All patients of physicians who were included in the intervention, who had pharmacy claims and were active plan members throughout the post-intervention time period. Additionally, when outcomes are performed, these patients' pre-intervention (baseline) hits are re-evaluated to make certain that the status of clinical indicators haven't changed for each patient due to late pharmacy and medical claims.

Intervention-Related Pharmacy – Antidiabetic agents, angiotensin modulating containing products, cardiac calcium channel blockers, central antiadrenergics, alpha-1 adrenergic blockers, peripheral antiadrenergics, ACE Inhibiotrs, beta blockers, antihypertensives, thiazides, indapamide, vasodilators, antiotensin II antagonists, amiloride products, spironolactone products, triamterene products, antilipemics, digestive enzymes, metoclopramide, oral cyclosporine, rifampin, azoles, chloramphenicol, MAOI antidepressants, salicylates, warfarin, macrolides, quinolones, penicillins, chephalosporins, tetracyclines, sulfonamides, clindamycin, co-trimoxazole, erythromycin/sulfisoxazole, nitrofurantoin, trimethoprim, oral metronidazole, telithromycin, becaplermin, cardiac glycosides, propafenone, pentoxifylline, cilostazol, clopidogrel, nitroglycerin.

[5] American Diabetes Association. http://diabetes.org. Diabetic nephropathy. Diabetes Care 2003;26(1):94-98.
[6] Remuzzi G, Schieppati A, Ruggenenti P. Nephropathy in patients with type 2 diabetes. N Engl J Med .2002; 346(15): 1145-1151.
[7] Lewis EK, Hunsicker LG, Clarke WR, et.al. Renprotective effect of the angiotensin receptor antagonist irbesartan in patients with nephropathy due to type 2 diabetes. N Engl J Med. 2001; 345(12): 851-860.
[8] Brenner BM, Cooper ME, De Zeeuw D, et.al. Effects of losartan on renal and cardiovascular outcomes in patients with type 2 diabetes and nephropathy. N Engl J Med. 2001; 345(12): 861-869.
[9] Parving HH, Lehnert J, Bröchner-Mortensen J, et.al. The effect of irbesartan on the development of diabetic nephropathy in patients with type 2 diabetes. . N Engl J Med. 2001; 345(12): 870-878.

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RESULTS

Characteristics

Table 1 describes the patient populations for the target group included in the population-based intervention based upon mean age, gender, number of providers, average number of prescriptions per patient per month, and total drug utilization. As can be seen from the table, the target group had a mean age of 45.6 years, was mostly female, saw 3.4 providers, and utilized 6.1 prescriptions per month in the baseline period.

Table 1: Patient Characteristics

	Target (N=1,190)
Mean Age	45.6
Percentage Male	32.4%
Percentage Female	67.6%
Number of Providers	3.4
Average Number of Prescriptions PPPM*	6.1
Intervention-Related Drug Utilization**	
Average Number of Drugs***	4.7
Average Number of Claims	14.7
Average Days Supply	394.3
Average Amount Paid	$881.45

* Number of prescriptions per patient per month (PPPM) is the average for the 6 month baseline period

** Based on 6 months of baseline claims data

*** A distinct drug is defined by using a coding system similar to the Hierarchical Ingredient Code List (HICL) in that distinct drugs are identified at the ingredient level.

Medication Non-Compliance

Table 2 displays the changes in target patients who were flagged for non-compliance. Overall, this indicator decreased by 57.3% in the target group.

Table 2: Changes in Non-Compliance

Medication Non-Compliance	Target		
	Baseline	Nov-08	% Change
Antidiabetics	29	15	-48.3%
Antilipemics	15	3	-80.0%
Cardiovascular med, no HTN dx	2	1	-50.0%
HTN med & dx = HTN	78	34	-56.4%
Total	124	53	-57.3%

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Increased Risk of ADE

The changes in the number of patients flagged for being at an increased risk of adverse drug events are displayed in Table 3. Overall, there was a 24.8% reduction in the number of target patients.

Table 3: Changes in Increased Risk of ADE

Increased Risk of ADE	Baseline	Target Nov-08	% Change
Diabetes Dx <2 Hemoglobin A1C labs in 550d	201	119	-40.8%
Diabetes Dx No Fasting Lipid Panel in 550d	56	35	-37.5%
Diabetes Dx No Microalbumin in 550d	159	132	-17.0%
Diabetes Dx No SrCr in 550d	60	36	-40.0%
Diabetes Dx: No eye exam within last 550d	25	18	-28.0%
Diabetes Dx: No foot exam within the last 550d	269	240	-10.8%
Metformin-Containing Product(s) with Heart Failure	9	8	-11.1%
Thiazolidinediones & HF DX	4	4	0.0%
Thiazolidinediones & Liver Disease	7	3	-57.1%
TZD and Risk of Macular Edema	28	20	-28.6%
Total	818	615	-24.8%

Underutilization

The changes in the number of patients flagged for underutilization of therapy are displayed in Table 4. Overall, there was a 44.3% reduction in the number of target patients.

Table 4: Changes in Underutilization

Underutiliztion	Baseline	Target Nov-08	% Change
Diabetes & HTN Diagnosis: no angiotensin-modulating agent	66	50	-24.2%
Diabetes Meds & HTN Dx: no angiotensin-modulating agent	1	1	0.0%
Discontinued Use: Antilipemic Therapy (diabetes mellitus)	47	2	-95.7%
Discontinued Use: Antilipemic w/Lipid Panel (Diabetes)	5	0	-100.0%
Underutilization of lipid lowering tx (diabetes mellitus)	1	1	0.0%
Underutilization of Metformin (DM type 2)	63	48	-23.8%
Total	183	102	-44.3%

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BUSINESS ANALYSIS

The overall savings for the intervention are calculated in Tables 5 and 6. Per patient per month (PPPM) drug amount paid for intervention-related drugs and intervention-related medical costs were separately calculated for the target group for the six-month baseline and four-month post-intervention periods. First, the PMPM savings was calculated by finding the difference between the baseline and post-period PPPM paid amount. Then, the PPPM savings was multiplied by the number of intervention months and number of targeted patients.

Table 5 shows the intervention-related drug amount paid for target patients decreased $0.55 PPPM in the post-intervention period. This yielded an overall estimated savings of $2,607 in intervention-related drug expenditures during the four-month post-intervention period.

Table 5: Intervention-Related Pharmacy Savings

Savings Calculation:	
Target Group: Actual Average Paid Amount Per Patient Per Month (Baseline)	$176.10
Target Group: Actual Average Paid Amount Per Patient Per Month (Post)	$175.56
% Change in Target Group from Baseline to Post	-0.31%
Estimated Savings Per Patient Per Month	$0.55
Total Number of Target Patients	1,190
4-Month Total Savings	$2,607.34

Table 6 shows the intervention-related medical amount paid for target patients decreased $42.98 PPPM in the post-intervention period. This yielded an overall estimated savings of $204,583 in intervention-related medical expenditures during the four-month post-intervention period.

Table 6: Intervention-Related Medical Savings

Savings Calculation:	
Target Group: Actual Average Paid Amount Per Patient Per Month (Baseline)	$272.19
Target Group: Actual Average Paid Amount Per Patient Per Month (Post)	$229.21
% Change in Target Group from Baseline to Post	-15.79%
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LIMITATIONS

A control group was not utilized for this intervention. This limited the comparisons that could be performed in the analysis. Therefore, instead of being able to compare an intervention group with a non-intervention group, the analysis is essentially limited to changes in the intervention group before and after intervention.

The time frame of 4 months may not capture the full extent of the impact of the intervention. Providers may be required some time before they can change their patient's drug regimens.

CONCLUSIONS

This intervention focused on improving prescribing practices and reducing the overall cost of care. Overall, the intervention was successful in reducing the total number of clinical indicators for target patients by 31.6%.

In terms of financial outcomes, the amount paid for intervention-related drugs decreased $0.55 PPPM in the post-intervention period. This yielded an overall estimated savings of $2,607 in intervention-related drug expenditures during the four-month post-intervention period. Additionally, the amount paid for intervention-related medical decreased $42.98 PPPM in the post-intervention period, yielding an estimated $204,583 savings during the post-intervention period. Therefore, the total estimated savings for this intervention is $207,190.

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