

Diabetes:

**Co-morbidities and
Drug Therapy Problems in
Patients with Diabetes**

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Introduction

Diabetes is a leading cause of illness and death in our society. Significant dollars have been invested to positively impact this disease from its prevention to its treatment. Many different approaches have been taken to manage these patients. One common approach, at least for the past ten years, has been to develop disease state management programs and case management services which focus on the management of the illness. Despite these efforts, the expenditures for insulin therapies have tripled, while the annual expenditures for oral anti-diabetic medications have quadrupled to over \$8.0 billion.

A more recent approach, which focuses on the management of the medications involved in treating patients with diabetes, is the provision of comprehensive medication therapy management services. Comprehensive medication management is a patient-centered service based on a comprehensive evaluation of all the patient's medications and their impact on the patient's multiple medical conditions. This report describes the co-morbidities, the drug therapy problems identified and resolved, as well as the outcomes that can be achieved when qualified pharmacists who provide MTM services manage patients with diabetes.

Background

Comprehensive medication management services allow the pharmacist to play a more active role in helping to manage the patient with diabetes. Specifically, when these services are provided, the patient receives a standard patient care process focused on identifying, resolving and preventing drug therapy problems.

Each patient receives an assessment of all of his/her medications (prescription, non-prescription, alternative, nutritional supplements, traditional medicines, samples, etc.) to determine if any of the medications are inappropriate, ineffective, unsafe or inconvenient for the patient to take as intended. When drug therapy problems are identified, they are resolved by changing products, doses, or by educating the patient on how to maximize the effectiveness of the medication. A care plan is developed for each patient, including individualized goals of therapy for each medical condition. The practitioner then determines what needs to be done to optimize the patients' medication experience and to achieve the goals of therapy as soon as possible. The practitioner then follows-up with the patient to determine the actual outcomes experienced by the patient. Patients return for follow-up visits approximately three times each year.

Comprehensive medication management services identify and resolve drug therapy problems and this impacts patient outcomes.

Patient Sample

Although many different programs are available to manage patients with diabetes, very little is known about the drug-related needs and concerns of this group of patients. In an attempt to learn more, we studied a group of 22,694 patients who received medication therapy management services between April 1, 2006 and September 30, 2010.

Qualified pharmacists provided Medication Therapy Management Services to patients in ambulatory practice settings[1]. The qualifications of these individuals can be reviewed on the Minnesota Medicaid website (<http://www.dhs.state.mn.us/>). The majority of the practices were clinic-based and the service was provided in close proximity to, and in collaboration with, the prescribing physicians. A total of 263 different practitioners provided care to this sample of patients.

Data Documentation and Analysis

The Assurance System™ was used to record and analyze the data generated by these services. This system creates a state-of-the art Electronic Therapeutic Record™ and is designed to document all types of drug therapies. The Electronic Therapeutic Record™ allows the practitioner to associate all drug therapies with the patients' medical conditions, drug therapy problems, interventions, as well as clinical and economic outcomes (www.medsmanagement.com). It helps practitioners identify, track, and resolve a patient's drug therapy problems, create custom patient care plans, and document and report patient therapeutic goals over time. In doing so, practitioners can demonstrate both the clinical outcomes and economic benefits of the medication therapy management service.

The Assurance System™ is accessed through a secure Internet Citrix connection. Assurance System™ is compliant with all Health Insurance Portability and Accountability Act (HIPAA) requirements. This documentation system also automatically generates electronic bills for MTM services in any format required by various payers including Resource Based Relative Value Scale and conventional service invoices. Data from multiple practitioners can be stripped of patient identifiers and pooled for institutional level or network level service analyses.

The Assurance System™ produces an Electronic Therapeutic Record™ that can be combined across an entire network of practitioners.

Results

The data from 22,694 patients were analyzed. These patients were seen during 50,142 documented visits representing an average of 2.2 visits per patient. The sample consisted of 14,263 women (63%) and 8,427 men (37%). The average age of the sample was 63, varying from two to 102 years old. Starting with this population, we examined the drug-related needs of all patients with diabetes. This study sample consisted of 11,728 patients receiving drug therapy for diabetes. Their data were summarized for 27,803 medication management service encounters between April 1, 2006 and September 30, 2010. There were 7,011 (60%) female patients with diabetes and 4,717 (40%) male patients. Their ages varied from five years to 96 years with a mean age of 66 (median age = 68).

Patient Co-Morbidities

Patients with diabetes have a significant number of co-morbidities. This situation makes it difficult to focus only on the diabetes since many of the co-morbidities influence its management, either directly or indirectly. This is especially true as it relates to the medications being used by patients with diabetes.

Patients receiving comprehensive medication management services had an average of six medical conditions. The median number of medical conditions was four. There were patients who had as many as 35 different medical conditions. In fact, 49% of patients in this sample have ≥ 5 co-morbidities requiring drug therapy and as many as 19% have ≥ 10 other medical conditions. The sample included patients with one medical condition however this represented only 22% of the sample. Table 1 illustrates the most common co-morbidities in patients with diabetes.

Patients with diabetes used an average of 15 medications to treat or prevent six different medical conditions.

Table 1: Co-Morbidities in 11,728 Patients with Diabetes

MEDICAL CONDITION (CO-MORBIDITY)	% OF DIABETIC PATIENTS WITH THE CO-MORBIDITY
Hypertension	58%
Hyperlipidemia	54%
Prevention of stroke or MI	22%
Gastroesophageal reflux disease (GERD)	20%
Depression	18%
Osteoporosis	16%
Pain - generalized	14%
Allergic rhinitis	11%
Insomnia	10%
Asthma	9%

Over one-half of the patients experienced hyperlipidemia and hypertension along with diabetes. Approximately one-fifth of the patients experienced depression, pain, osteoporosis and GERD as well as prevention therapy for a stroke or myocardial infarction, in addition to diabetes. Clearly any or all of these medical conditions contribute to the complexity inherent in the patient with diabetes.

Medications Used by Patients

Patients experiencing this number of co-morbidities will be expected to be taking a large number of medications and this is certainly the case with these patients. The number of medications taken by patients varied from one to 67 different medications. This number includes all preparations being taken for therapeutic purposes; prescription medications, non-prescription products, food supplements, vitamins, herbal remedies, traditional medicine and alternative therapies. Medication therapy management requires all of the medications be evaluated for appropriateness, effectiveness, safety and compliance. The average number of medications being taken was 15, and the median number was 14. Ninety six percent of patients were taking five or more medications, 79% were taking 10 or more and 46% were taking 15 or more medications.

Fifty-seven percent of the sample (6,688 patients), was taking 47,192 different non-prescription products. Over half of these patients with diabetes were taking non-prescription products on a chronic basis. The majority of these drug products are not recorded in standard payer medical record systems. In addition, 175 of the patients were using 565 different “physician sample” products to manage their medical conditions. It should be noted that dispensing systems do not label samples or keep a record of their use, nor are non-prescription products included in the dispensing record.

Drug Therapy Problems Experienced by Patients

Patients taking medications have drug therapy problems[2]. This is the case in this patient sample as well. Eighty four percent of the sample had one or more drug therapy problems, while 44% had three or more and 29% had five or more drug therapy problems identified and resolved during the study period. These 9,873 patients with diabetes experienced 49,816 drug therapy problems in the four and one-half years studied. Table 2 describes the types of drug therapy problems experienced by these patients.

Table 2: Drug Therapy Problems

DRUG THERAPY PROBLEM CATEGORY	# OF PROBLEMS	% OF TOTAL
Unnecessary drug therapy	2,020	4%
Needs additional drug therapy	16,258	33%
Ineffective—different drug needed	3,259	6%
Dosage too low	13,500	27%
Adverse drug reaction	4,416	9%
Dosage too high	2,847	6%
Non-adherence/Noncompliance	7,422	15%
TOTAL	49,722	100%

As is illustrated in table 2, the most frequent category of drug therapy problem is that the patient is in need of additional drug therapy. The majority of these problems involved patients who required preventive aspirin,

ACE inhibitors, and/or oral calcium supplements to prevent long-term complications or immunizations. There were also 3,547 cases in which a patient on oral anti-diabetic therapy needed insulin to be added to their therapy to achieve the desired goals of therapy.

The second most common drug therapy problem category is that the dosage of the medication the patient is taking is too low to be effective. This is a very costly drug therapy problem since the patient continues to suffer and many medical problems are precipitated when the correct medication is selected, the patient is faithfully following the instructions, but the dosage is not sufficient to produce the desired goal of therapy. Drug therapy problems in patients with diabetes resulting from dosages that are assessed to be too low to produce the desired outcomes involve not only the patient’s anti-diabetic medications, but also commonly involved insufficient dosages of their statin medication, ACE inhibitors, or their medications to control chronic pain. Ineffective drug therapy is one of the most common and costly problems in today’s health care system.

It is especially interesting to note that a little over one third (39%) of all the drug therapy problems identified were associated with the patients’ diabetes therapies. The majority of these patients’ drug therapy problems were associated with the multiple co-morbidities (other than diabetes) experienced by the patient. Table 3 displays the differences in types of problems based on the relationship to diabetic medications.

Table 3: Drug Therapy Problems Associated with Co-Morbidities

DRUG THERAPY PROBLEM CATEGORY	# OF PROBLEMS ASSOCIATED WITH THE DIABETES MEDICATIONS (% OF CATEGORY)	# OF PROBLEMS ASSOCIATED WITH NON-DIABETES MEDICATIONS (% OF CATEGORY)
Unnecessary drug therapy	325 (16%)	1,695 (84%)
Needs additional drug therapy	5,538 (34%)	10,720 (66%)
Ineffective drug	988 (30%)	2,271 (70%)
Dosage too low	7,222 (53%)	6,278 (47%)
Adverse drug reaction	1,112 (25%)	3,304 (75%)
Dosage too high	1,309 (46%)	1,538 (54%)
Non-adherence/noncompliance	2,795 (38%)	4,627 (62%)
TOTAL	19,289 (39%)	30,433 (61%)

Pharmacist Interventions

It is encouraging to know that these drug therapy problems can be resolved by direct communication between the pharmacist and the patient in 87% of the cases. This means that the physician does not have to be interrupted or support staff be bothered except in a small portion of the situations (18%). This has significant ramifications for keeping the physician productive.

Patient Outcomes

In these patients with diabetes, only 67% of the diabetes measures were meeting the intended goal at the initial medication management assessment, while 90% of goals were being met at the follow-up after the practitioner intervened. This level of clinical success requires a comprehensive approach and a commitment to work with patients to identify and resolve drug therapy problems.

Evaluating the outcomes of drug therapy requires comprehensive documentation of related medications, laboratory values, and changes in clinical signs and symptoms over time. In the Assurance System™ practitioners can record changes in parameters used to evaluate the impact of drug therapy for each medication condition the patient has. As an example, to evaluate the outcomes that drug therapies are having on a patient with diabetes, you need to be able to evaluate glycemic control (blood glucose and Hemoglobin A1c), blood pressure control (<130/80 mmHg) and lipid lowering (LDL <100 mg/dl, 2.6 mmol/L). In order to fully evaluate the outcomes associated with drug therapies in patients with diabetes, all of these values (and more if the patient also has other co-morbidities) must be monitored, evaluated, and documented over time. Using the Assurance System™ practitioners providing care for patients with diabetes can track improvements or lack of improvement in all of these laboratory measurements over time. This allows the practitioners to easily evaluate the impact that the patient's drug regimens are having on the various surrogate endpoints and make necessary adjustment in drug selection or dosing to achieve the desired goals.

In 4,700 patients with diabetes, serial blood pressures were measured over time and documented in the patients' electronic therapeutic record. At their most recent visit, 95% of their values for diastolic blood pressure were at goal (\leq 80 mmHg). Systolic pressures were at goal in 71% of the most recent measurements (\leq 130 mmHg). In these same patients with diabetes, their glycemic control was evaluated by measuring their A1c values. As displayed in Table 4, their most recent A1c values were at goal (<8%) in 85% of patients with diabetes. Their most recent A1c values were at a more aggressive goal of <7% in 58% of cases. As described earlier, lipid control is also an important factor in reducing risk for patients with diabetes. Their most recent cholesterol (total) was at goal (<200 mg/dl, 5.2 mmol/L) in 88% of these patients with diabetes. In 77% their LDL was at goal (either <100 mg/dl, 2.6 mmol/L or <70 mg/dl, 1.8 mmol/L if indicated). Triglycerides were at goal in only 57% of these patients with diabetes indicating that many patients require individualized drug regimens, often combinations, in order to adequately control cholesterol and triglycerides.

Table 4: Outcome Data in Patients with Diabetes
Most Recent Value at GOAL

SYSTOLIC	DIASTOLIC	A1C<8%	A1C<7%	CHOLESTEROL	LDL
71%	95%	85%	58%	88%	77%

Economic Analysis

Health care costs avoided and money saved is documented in a number of different ways in the Assurance System™. Table 5 reports the cost saving events that occurred during this four and one half year time period. All of these measures are conservative in nature because of the stringent criteria applied to their reporting.

Table 5: Health Care Savings Associated with MTM Services

HEALTH CARE SAVINGS ASSOCIATED WITH MEDICATION MANAGEMENT SERVICES	# Of EVENTS FOR 11,7288 PATIENTS WITH DIABETES
Medical Clinic Visit Avoided	19,268
Specialty Office Visit Avoided	927
Employee Work Day Saved	386
Laboratory Service Avoided	375
Urgent Care Visit Avoided	633
Long Term Care Admission Avoided	2
Emergency Department Visit Avoided	1,683
Hospital Admission Avoided	75
TOTAL	23,349

Total health care savings = \$5,187,003 = 5.5:1 ROI

The comprehensive medication management services reported here resulted in an average savings of \$442 per patient. These health care savings documented at the time the service was provided are conservative and account for only those costs avoided for the next 90 days following these services. Health care savings were based on the U.S. National Averages for 2008 provided by the Agency for Healthcare Research and Quality – Center for Financing, Access and Cost Trends, 2010[3].

The return on investment (ROI), calculated in 2008 dollars was approximately 5.5:1. Therefore, for every \$1 invested in providing these services for patient with diabetes, over the next 90 days \$5.50 can be saved. It is quite safe to say that this figure will increase when other long-term factors are added into the equation including prevention of longer-term complications including renal, cardiovascular, retinopathy, or neuropathies resulting from poor glycemic, lipid, and blood pressure control.

Comprehensive medication management services resulted in \$442 in health care savings per patient with diabetes.

Discussion

Diabetes care is complex and requires that many drug therapy problems and challenges be addressed in order to ensure patients achieve all of their goals of therapy. Adequate glycemic control is desirable, but not sufficient to prevent acute complications and to reduce the risk of long-term complications. The 2007

guidelines describe the Standards for Medical Care in Diabetes[4-6]. These American Diabetes Association updated “Standards” call for the comprehensive evaluation and management of not only glycemic control, but also of the patient’s hypertension, dyslipidemia, medical nutritional status, as well as kidney, eye, nerve, thyroid, and liver functions. All of these risk factors must be adequately managed in order to provide patients with diabetes the optimal chance to avoid long-term end organ damage and improve their quality of life.

A comprehensive assessment of a patient’s medications is necessary whether the patient has diabetes and/or other medical conditions. Co-morbidities can create a challenging and uncertain environment in which to make isolated drug therapy decisions. It is important that a practitioner is focused on managing all of the patients’ drug therapies since the complexity of the case and the associated risks increase when the number of medications, number of co-morbid medical conditions and resulting drug therapy problems increase. In general, when the number of medical conditions increases, so too does the number of drug therapy problems.

78% of the patients with diabetes had at least one additional co-morbidity requiring drug therapy management.

Conclusions

Our experience indicates that patients with diabetes are often complex with an average of six medical conditions being treated or prevented with an average of 15 different drug products. The simultaneous application of multiple guidelines to manage multiple medical conditions can become confusing, complex, or even conflicting in some circumstances. Evaluating the outcomes of drug therapy requires comprehensive documentation of related medications, laboratory values, and changes in clinical signs and symptoms over time. Comprehensive medication management services provided by experienced pharmaceutical care practitioners can produce positive clinical outcomes in patients with diabetes including those with multiple medical conditions.

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