

Co-morbidities and Drug Therapy Problems in Patients with Diabetes

Robert J. Cipolle, Pharm.D., Linda M. Strand, Pharm.D., Ph.D., Mike J. Frakes, Pharm.D.

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 medication therapy management services (MTM). MTM 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 patients with diabetes are managed by qualified pharmacists who provide MTM services.

Background

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

MTM services identify and resolve drug therapy problems and this impacts patient outcomes.

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 that are being experienced by the patient. Patients return for follow-up visits approximately 3 times each year.

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 1122 patients who received medication therapy management services between January 1, 2003 and December 31, 2004.

Qualified pharmacists provided Medication Therapy Management Services to patients in ambulatory practice settings. 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 18 different practitioners provided care to this sample of patients.

Data Documentation and Analysis

The Assurance Pharmaceutical Care System™ was used to record and analyze the data generated by these MTM 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. 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 Pharmaceutical Care System™ produces an Electronic Therapeutic Record™ that can be combined across an entire network of practitioners.

The Assurance Pharmaceutical Care System™ is accessed through a secure internet Citrix connection. Assurance™ 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 CMS 1500 forms and conventional service invoices.

Data from multiple MTM practitioners can be stripped of patient identifiers and pooled for institutional level or network level service analyses. This report summarizes MTM services provided by 18 individual pharmaceutical care practitioners.

Results

The data from 1122 patients were analyzed. These patients were seen during 2787 documented visits representing an average of 2.5 visits per patient. The study sample consisted of 640 women (57%) and 482 men (43%). The average age of the sample was 64, varying from 21 to 91 years old.

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 with diabetes used
an average of 13
medications to treat or
prevent 8 different medical
conditions.*

Patients receiving MTM had an average of 8 medical conditions. The median number of medical conditions was 7. There were patients who had as many as 23 different medical conditions. In fact, 78% of patients in this sample have ≥ 5 co-morbidities requiring drug therapy and as many as 29% have ≥ 10 other medical conditions. The sample included patients with 1 medical condition however this represented only 4.3% of the sample. Table 1 illustrates the most common co-morbidities in patients with diabetes.

Table 1 Co-morbidities in Patients with Diabetes

Two thirds of the patients experienced hyperlipidemia and hypertension along with diabetes. A fourth 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 1 to 34 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 13, and the median number was 10. Ninety percent of patients were taking 5 or more medications, 57% were taking 10 or more and 29% were taking 15 or more medications.

Seventy-seven percent of the sample (860 patients), was taking 3,590 different non-prescription products. Three out of every four 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, 10% of the patients were using 277 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. This is the case in this patient sample as well. Seventy-seven percent of the sample had 1 or more drug therapy problems, while 39% had 3 or more and 17% had 5 or more drug therapy problems identified and resolved during the study period. These 1122 patients experienced 2892 drug therapy problems in the two years studied. Table 2 describes the types of drug therapy problems experienced by these patients.

Table 2 Drug Therapy Problems

DRUG THERAPY PROBLEMS	# of PROBLEMS (% of total)
Unnecessary Drug Therapy	125 (4%)
Needs Additional Drug Therapy	1060 (37%)
Ineffective Drug	218 (8%)
Dosage Too Low	674 (23%)
Adverse Drug Reaction	180 (6%)
Dosage Too High	166 (6%)
Noncompliance	469 (16%)
TOTAL	2892 (100%)

As is illustrated in the table, 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. 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. 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 less than half (49%) 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 PROBLEMS	# of PROBLEMS Associated with DIABETES MEDICATIONS (% by category)	# of PROBLEMS Associated with OTHER MEDICATIONS (% by category)
Unnecessary Drug Therapy	21 (17%)	104 (83%)
Needs Additional Drug Therapy	513 (48%)	547 (52%)
Ineffective Drug	87 (40%)	131 (60%)
Dosage Too Low	406 (60%)	268 (40%)
Adverse Drug Reaction	65 (36%)	115 (64%)
Dosage Too High	70 (42%)	96 (58%)
Noncompliance	241 (51%)	228 (49%)
TOTAL	1403 (49%)	1489 (51%)

Pharmacist Interventions

It is encouraging to know that these drug therapy problems can be solved by direct communication between the pharmacist and the patient in 77% of the cases. This means that the physician does not have to be interrupted or support staff bothered except in a small portion of the situations (23%). This has significant ramifications for keeping the physician productive.

Patient Outcomes

Perhaps most importantly, only 67% of the diabetes measures were meeting the intended goal at the initial MTM 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.

Economic Analysis

Health care costs avoided and money saved are documented in a number of different ways in the Assurance System. Table 4 reports the cost saving events that occurred during this two year time period. All of these measures are conservative in nature because of the stringent criteria applied to their reporting.

Table 4 Health Care Savings Associated with MTM services

Health Care Savings Associated with MTM Services	# of Events (1122 Patients) with Diabetes
Medical Clinic Visit Avoided	934
Specialty Office Visit Avoided	215
Employee Work Day Saved	40
Laboratory Service Avoided	51
Urgent Care Visit Avoided	8
Emergency Department Visit Avoided	16
Hospital Admission Avoided	1
Total	1265

Total Health Care Savings = \$619,002

ROI = 3:1

The Medication Therapy Management services reported here resulted in an average savings of \$551 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 MTM services.

***MTM services resulted in \$551
in health care savings per
patient with diabetes.***

The return on investment (ROI), calculated in 2007 dollars was approximately 3:1. Therefore, for every \$1 invested in providing MTM services for patient with diabetes, over the next 90 days \$3 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.

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 (Diabetes Care, volume 30, January 2007). These American Diabetes Association updated “Standards” call for the comprehensive evaluation and management of not only glycemia, 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.

96% of the patients with diabetes had at least 1 additional co-morbidity requiring drug therapy management.

Conclusions

Our experience indicates that patients with diabetes are often complex with an average of 8 medical conditions being treated or prevented with an average of 13 different drug products. The simultaneous application of multiple guidelines to manage multiple medical conditions can become confusing, complex, or even conflicting in some circumstances. MTM services provided by experienced pharmaceutical care practitioners can produce positive clinical outcomes in patients with diabetes including those with multiple medical conditions.