

Medication Adherence: Improved Results with Comprehensive Medication Therapy Management Services

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

Introduction

The lack of medication adherence is seen as the cause of treatment failures, serious adverse reactions, even deaths. Physicians, pharmacists, nurses, payers as well as policy makers have all placed medication adherence at the top of any list of solutions to drug related morbidity and mortality. However, a large number of different approaches have been suggested and tried and in spite of all of these attempts, the levels of non-adherence in ambulatory patients have not changed significantly since Sackett first discussed noncompliance behavior in the 1970s. In fact, figures indicate that patients can experience non-adherence levels of up to 75%, depending on the patient's age, complexity of medical needs and medication regimen, the method of measuring non-adherence, the cost of the medication, as well as many other confounding variables. (Osterberg, L. and Blaschke, T. Adherence to Medication. N Engl J Med 2005;353:487-97.)

Many different methods have been used to increase adherence, some of them successful but most of them successful only in the short term. A more recent approach, which focuses on the management of all of a patient's medications, 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 high levels of adherence that can be realized, as well as the positive outcomes that can be achieved when patients are managed by qualified pharmacists who provide comprehensive MTM services.

Background

MTM services allow the pharmacist to play a more active role in helping to increase adherence to medications. Specifically, when MTM services are provided, the patient receives a standard patient care process focused on identifying, resolving and preventing drug therapy problems which may be responsible for a patient's decision not to take a medication as intended.

MTM services identify and resolve drug therapy problems and this impacts patient adherence as well as clinical 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. (Cipolle, R., Strand L, Morley, P. Pharmaceutical Care Practice: The Clinician's Guide. McGraw-Hill, New York, NY, 2004)

Medication therapy management, as described above, is a rational thought process which approaches the evaluation and care of a patient and his/her medications in a logical, systematic, and comprehensive manner. First, the appropriateness of each medication is evaluated. This is necessary because if unnecessary medications are being taken, they can be discontinued thereby resolving many future drug therapy problems. Secondly, the effectiveness of the medication is evaluated. It must be determined that a medication is appropriate and effective before it can be assessed for safety. And then, only after each medication has been determined to be appropriate, effective and safe, does the pharmacist evaluate the patient's adherence to the intended regimen. When this process occurs, the data indicate that very different levels of non-adherence occur, suggesting that when problems with appropriateness, effectiveness and safety are solved, patients are quite willing and able to take medications as intended.

Patient Sample

Although many different programs have been introduced to increase adherence, very little is known about the medication taking behavior of individual patients, from the start of a medication through to measuring actual outcomes. In an attempt to learn more, we evaluated the data from practice for 2620 patients who received medication therapy management services between January 1, 2003 and December 31, 2004. The data which are analyzed and reported here are the same data that are available to all practitioners who provide MTM services and who use the Assurance System.

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 24 different practitioners provided care to this group 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 includes all medications (prescription, non prescription, herbals, traditional, food supplements) from all prescribers and all sources and 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 24 individual pharmaceutical care practitioners.

Results

The data from 2620 patients who were seen in MTM practices were analyzed. These patients were seen during 6090 documented visits representing an average of 2.35 visits per patient. The study sample consisted of 1712 women (65%) and 908 men (35%). The average age of the sample was 66, varying from 20 to 95 years old.

An understanding of the patients, their medical conditions, and the medications being taken is first necessary in order to evaluate the patients' medication taking behavior.

Patient have Multiple Co-Morbidities

Patients seldom experience a single medical condition, especially as a person ages. This is true in this ambulatory sample.

Patients used an average of 13 medications to treat or prevent an average of 7 different medical conditions.

Patients receiving MTM had an average of 7 medical conditions. The median number of medical conditions was also 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 26% have ≥ 10 other medical conditions. The sample included patients with 1 medical condition however this represented only 5% of the sample. This high level of co-morbidities will make adherence to multiple medications difficult and perhaps confusing. Table 1 illustrates the most common medical conditions in these patients.

Table 1

MEDICAL CONDITION	% of Patients with Condition
Hypertension	63 %
Hyperlipidemia	57 %
Diabetes	43 %
Pain-generalized	32 %
Osteoporosis	32 %
Gastroesophageal reflux disease GERD	28 %
Depression	26 %
Allergic Rhinitis	24 %
Prevention of Stroke or MI	22 %
Arthritis pain	17 %

Clearly any or all of these medical conditions contribute to the complexity inherent in a patient's efforts to be adherent to medication directions.

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 0 to 35 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 11, and the median number was 10. Ninety four percent of patients were taking 5 or more medications, 74% were taking 10 or more and 16% were taking 15 or more medications.

Seventy-eight percent (78%) of the sample (2040 patients), was taking 9322 different non-prescription products. The majority of these drug products are not recorded in standard payer medical record systems or pharmacy dispensing systems. In addition, 10% of the patients were using 563 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. Sixty-seven percent (67%) of the sample had 1 or more drug therapy problems, while 29% had 3 or more and 12% had 5 or more drug therapy problems identified and resolved during the study period. These 2620 patients experienced 5235 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	285 (5%)
Needs Additional Drug Therapy	1730 (33%)
Ineffective Drug	466 (9%)
Dosage Too Low	1097 (21%)
Adverse Drug Reaction	418 (8%)
Dosage Too High	311 (6%)
Nonadherence	928 (18%)
TOTAL	5235 (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. 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.

Special attention should be paid to the level of non-compliance or non-adherence. It should be noted that this is the level without intervening specifically for the purpose of increasing adherence. This is the level of non-adherence when pharmacists provide a comprehensive assessment of all of a patient's medications in a logical, systematic, and comprehensive manner. The pharmacist is obligated to solve all the problems of inappropriateness, ineffectiveness and safety, before he/she can assess the patient's medication taking behavior. Eliminating these problems makes it possible for a large percentage of patients to take their medications as intended.

Causes of Non-Adherence

The most frequent cause of patients being unable or unwilling to take medications as intended is that the patient cannot afford to purchase the medication or cannot afford the co-payment required to obtain the prescription. The next most frequent reason identified for non-adherence is that the patient did not understand the instructions. These include both verbal and written instructions for prescription and/or non-prescription products. Vague instructions including "as directed" and "as needed" are often associated with non-adherence problems. Table 3 below lists the causes of non-adherence in order of frequency.

Table 3

CAUSES OF NONADHERENCE DRUG THERAPY PROBLEMS	# of PROBLEMS (% of total)
Cannot Afford Drug Product	473 (51%)
Does Not Understand Instructions	214 (23%)
Patient Prefers Not To Take	111 (12%)
Patient Forgets To Take	94 (10%)
Drug Product Not Available	27 (3%)
Cannot Swallow or Administer Drug	9 (1%)
TOTAL	928 (100%)

Medical Conditions Most Commonly Associated with Non-Adherence

The medical conditions involved in non-adherence problems are described in Table 4. Chronic conditions requiring patients to take medications on a daily or multiple times each day are most frequently involved in non-adherence problems. The list of medical conditions associated with noncompliance problems is similar to the list containing all of the medical conditions being treated or prevented with drug therapy in the entire patient group (see Table 1 above).

Table 4

MEDICAL CONDITION	Medical Conditions Associated with Nonadherence
Diabetes	27 %
Hypertension	15 %
Hyperlipidemia	14 %
Osteoporosis	12 %
Depression	6 %
Gastroesophageal reflux disease GERD	5 %
Asthma	5 %
Allergic Rhinitis	4 %
Pain-generalized	3 %
COPD/Emphysema	3 %

Medications Associated with Non-adherence

Non-adherence drug therapy problems involve both prescription and nonprescription drug products. The drug class most frequently involved in non-adherence problems is the statins. Even though the statins are the most frequently involved class of drugs, they represent only 7% of the total 928 non-adherence drug therapy problems. The next most frequently involved medications were thiazolidinediones-pioglitazone-rosiglitazone (4%), proton pump inhibitors (3%), selective serotonin reuptake inhibitors-SSRI (2%), beta blockers (2%), aspirin (2%), and ACE inhibitors (2%).

Resolution of Non-Adherence Problems

It is especially interesting to note that for 92% of all the drug therapy problems associated with non-adherence, the pharmacist was able to resolve the problem directly with the patient. The pharmacist worked directly with the physician in only 8% of the problem situations. This saves physician time and makes them more effective at their work. It also suggests that when pharmacists are engaged they are able to make a significant difference in their patients' drug therapies, health, and lives in general. The

majority of these patients' drug therapy problems were associated with the multiple comorbidities experienced by the patient.

Pharmacist Interventions

Most non-adherence drug therapy problems can be solved by direct communication between the pharmacist and the patient (92 % of the cases). Table 5 lists the types of interventions the pharmacist and the patient agreed upon to resolve the non-adherence problems. Note that in addition to personalized patient education, reinitiating drug therapy that the patient had previously discontinued taking, was a common intervention to resolve non-adherence drug therapy problems.

Table 5

Collaboration with Patient: Interventions to Resolve Nonadherence Problems	# (%) of Events (537 Nonadherent Patients)
Patient education to clarify instructions and remove barriers	793 (65%)
Reinitiated drug therapy	138 (11%)
Changed product	90 (7%)
Initiated monitoring plan	78 (6%)
Provided patient with a pill reminder device	58 (5%)
Discontinued drug therapy	30 (2%)
Changed dosage	19 (2%)
Not resolvable	19 (2%)
Total	1225 (100%)

**92% of interventions to resolve nonadherence
problems required direct involvement of the patient**

The vast majority of non-adherence problems was resolved between the pharmacist and the patient. This means the physician does not have to be interrupted or support staff bothered except in a small portion of the situations (8%).

Table 6

Collaboration with Physician: Interventions to Resolve Nonadherence Problems	# of Events (537 Nonadherent Patients)
Changed Drug Product	43
Reinitiated Drug Therapy	35
Discontinued Drug Therapy	11
Changed Dosage	8
Initiated Monitoring Plan	4
Not resolvable	2
Total	103

**Only 8% of interventions to resolve
nonadherence problems required direct
involvement of the physician**

Table 6 above list the types of interventions agreed upon between the pharmacist and the physician in order to resolve a patient’s non-adherence drug therapy problem.

Patient Outcomes

Perhaps most importantly, when looking at the patient population with non-adherence problems, 44% of these patients’ medical conditions that were not at goal when MTM services were initiated improved through the identification and resolution of their non-adherence problem. This improvement in achieving goals of therapy was evaluated 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 7 reports the cost saving events that occurred during this two year time period for the entire sample of 2620 patients. All of these measures are conservative in nature because of the stringent criteria applied to their reporting.

Table 7 Health Care Savings Associated with MTM services

Health Care Savings Associated with MTM Services	# of Events (2620 Patients)
Medical Clinic Visit Avoided	1501
Specialty Office Visit Avoided	249
Employee Work Day Saved	62
Laboratory Service Avoided	73
Urgent Care Visit Avoided	19
Emergency Department Visit Avoided	26
Hospital Admission Avoided	2
Total	1932

Total Health Care Savings = \$915,993

Average Savings per Patient = \$349

The medication therapy management services reported here resulted in an average savings of \$349 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.

***MTM services resulted in \$349
in health care savings per
patient.***

The return on investment (ROI), calculated in 2007 dollars was approximately 3:1. Therefore, for every \$1 invested in providing MTM services for patient, over the next 90 days \$3 can be saved. This figure is conservative because it does not account for factors including prevention of longer term complications such as strokes, myocardial infarcts, and other long term consequences to chronic medical conditions.

Discussion

Patient non-adherence to medication regimens can cause any number of problems for the patient and the health care system. However, non-adherence involves so much more than determining if the patient is complying with prescribed directions. When MTM is provided in the manner described here, the pharmacist first understands the patient’s medication experience. This helps the pharmacist to understand what is

important to the patient, how the patient makes decisions about his/her drug therapy, and, how the patient is actually taking the medication.

It is common knowledge that patients frequently change the manner in which they take their medication (frequently without informing the prescriber). If this change is producing the desired results, than is it logical to change the regimen? The practice of MTM as described here takes all of this information into account. In addition, the pharmacist solves all the patient's drug therapy problems related to the medication before assessing the patient's behavior so that the pharmacist knows the patient is taking appropriate, effective, and safe medication before the pharmacist encourages the patient to be adherent. This is perhaps the practice process that everyone should follow so that when we encourage patients to be adherent, we are sure to be helping the patient and not contributing to the patient's problems. This is especially important since the statistics from this practice indicate that one out of two patients has a drug therapy problem with one or more of the medications he/she is taking at any time.

Patients have lower levels of non-adherence when drug therapy problems are identified and resolved.

Conclusions

The provision of MTM services by a qualified pharmacist can have a significant impact on the level of non-adherence. In addition, a comprehensive documentation system can make it easier to determine the causes of the non-adherence so specific solutions can be defined in a timely manner. Patients have lower levels of non-adherence when the drug therapy problems of appropriateness, effectiveness, and safety are solved before the patient's medication taking behavior is evaluated. The practice described here and the results generated from the practice also suggest that it is effective to engage the patient in the process of solving the non-adherence problem.