PATIENT CENTRIC MODEL

PILOT DATA ANALYSIS REPORT

PREPARED FOR THE ALLIANCE FOR PATIENT MEDICATION SAFETY

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INTRODUCTION

The effectiveness of prescribed pharmaceuticals depends on a patient's adherence to them. Failure to take medications can result in negative health outcomes and wasted health care resources.

This report describes an analysis of data collected before and after implementation of a program called the Patient Centric Model. The "Patient Centric Model" (PCM) is a system of patient care designed to change the way a pharmacist practices. The PCM seeks to improve patient medical outcomes more efficiently and effectively than the traditional community practice model. The key ingredient in the PCM is prescription synchronization. By synchronizing all patient prescriptions to be refilled on the same day of the month, many of the problems associated with refilling prescriptions are reduced or eliminated.

Patients are assigned a day of the month to pick up all prescriptions. Prior to the appointment day, patients are contacted with a single call to clarify what prescriptions need to be filled and picked up. By simplifying the refill process, it is hypothesized that patients will adhere better with their prescribed medications.

Pilot pharmacies are asked to enroll 10 to 20 patients who are taking multiple, on-going prescriptions for chronic conditions. This enrollment is not random, so the patients are part of what is called a convenience sample. Convenience samples are common in pilot studies where the goal is exploratory research.

The following analysis measures patient persistence with refilling their medications. Medication persistence can be measured in various ways including pill counts, patient self-report, and electronic devices that measure the opening of prescription bottles. This analysis will use the most common method in researching persistence in pharmacy claims data – Gaps Between Refills (Sikka R, Xia F et al. 2005).

Gaps Between Refills measures the amount of time between when a prescription should be filled based upon the amount of drug dispensed and the actual time the prescription is filled. This method assumes that patients may have perfectly good reasons for not always refilling medications when predicted, so they are given a specified grace period to obtain an additional refill. This grace period begins at the end of the supply of the previous prescription and is equal to one-half of the days' supply of 1 prescription. For a 30 day prescription, the grace period would be 15 days. A patient is classified as "persistent" if the prescription is refilled before the end of the grace period. A patient's is "non-persistent" if the refill gap exceeds the grace period. This measure is categorical in that it consists of only two categories of compliance: persistent or non-persistent.

PRELIMINARY PATIENT AND PRESCRIPTION DATA

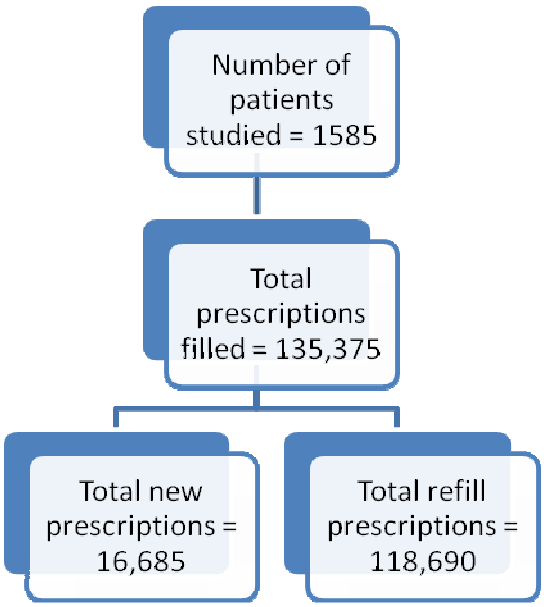

Figure 1: Patient and Prescription Data Used in the Analysis

A preliminary analysis of the data on 1585 patients was conducted in late 2010 to explore patient persistence in the study population (Figure 1). The preliminary analysis found patients to be highly persistent prior to the intervention – approximately 84% had at least 80% their medications filled on time each month. The analysis also showed non-persistence most often for the drugs listed in Table 1 below. This table shows many agents used in chronic disease states where non-persistence can lead to adverse outcomes. But it also includes agents whose persistence is hard to classify like drugs commonly used on an as-needed basis (i.e., ibuprofen, meloxicam, famotidine) and medications with variable dosing schedules such as insulin aspart and warfarin. Consequently, a decision was made to focus the analysis on agents commonly used to treat chronic disease conditions.

Ibuprofen	Folic Acid	Pregabalin
Lorazepam	Metformin HCl ER	Insulin Glargine
Fluticasone/Salmeterol	Ranitidine	Furosemide
Warfarin Sodium	Clonazepam	Alprazolam
Insulin Aspart	Topiramate	Famotidine
Metoclopramide	Glimeporide	Fluoxetine
Pantoprazole	Hydrochlorothiazide	Hydralazine
Ibandronate	Meloxicam	Gabapentin
Alendronate		

Table 1: Medications With the Highest "Non-Persistence"

STUDY DESIGN

A "market basket" of drugs was evaluated according to drug class. Namely, these included angiotensin-converting enzyme (ACE) inhibitors)/Angiotensin II receptor blockers (ARBs), thiazide diuretics, beta blockers, dihydropyridine calcium channel blockers, statins, metformin, sulfonylureas and Selective serotonin reuptake inhibitors (SSRIs)/Serotonin–norepinephrine reuptake inhibitors (SNRIs). The classes were chosen based on the chronic nature of the conditions for which drugs in the class are used, and the high frequency of use these medications in the dataset. The drugs that comprise these medications represent approximately one-third of all types of drugs recorded.

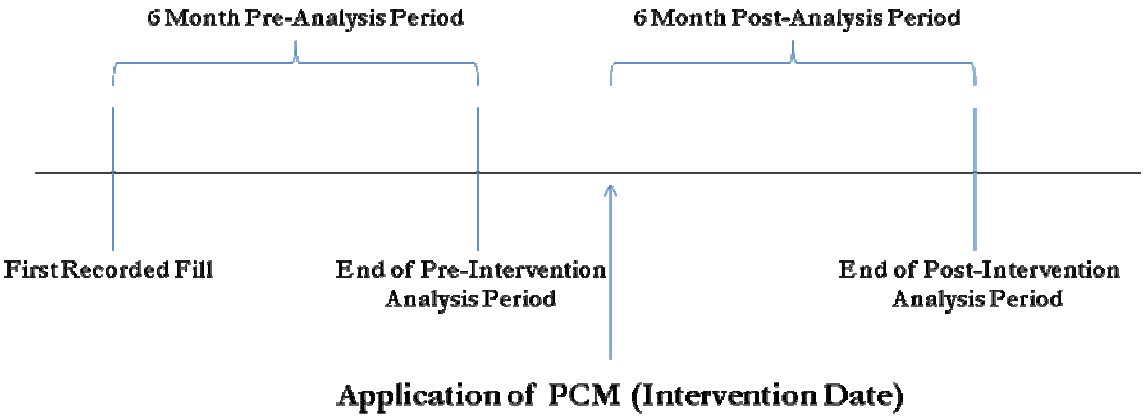

Figure 2: Study Design

Persistence during the pre-intervention and post-intervention periods was analyzed separately for each drug class – meaning that persistent rates before and after the intervention were calculated independently of each other. To be included in the pre-intervention group, patients must have had the first prescription filled at least 6 months (180 days) prior to the intervention date (See Figure 2). These patients were followed for 6 months from the first fill to evaluate persistence. To be included in the post-intervention group, patients must have had at least one prescription within the drug class filled within 15 days of the intervention date. These patients were followed for 6 months after the intervention date.

Some of these individuals were followed for an additional six months allowing a 12-month analysis of patient persistence. To avoid confusing the six-month cohort with the 12month cohort, we examined patients who continued to take their medications in months 8 through 12 regardless of their persistence status in months 1 through 6. Month 7 was not examined in order to create a "buffer" period because the "6-month only" patients did not have an exact 180 days of follow-up (i.e., 185, 190, etc.). The median time to non-persistence for patients in months 8 to 12 represents the time to non-persistence from month 8.

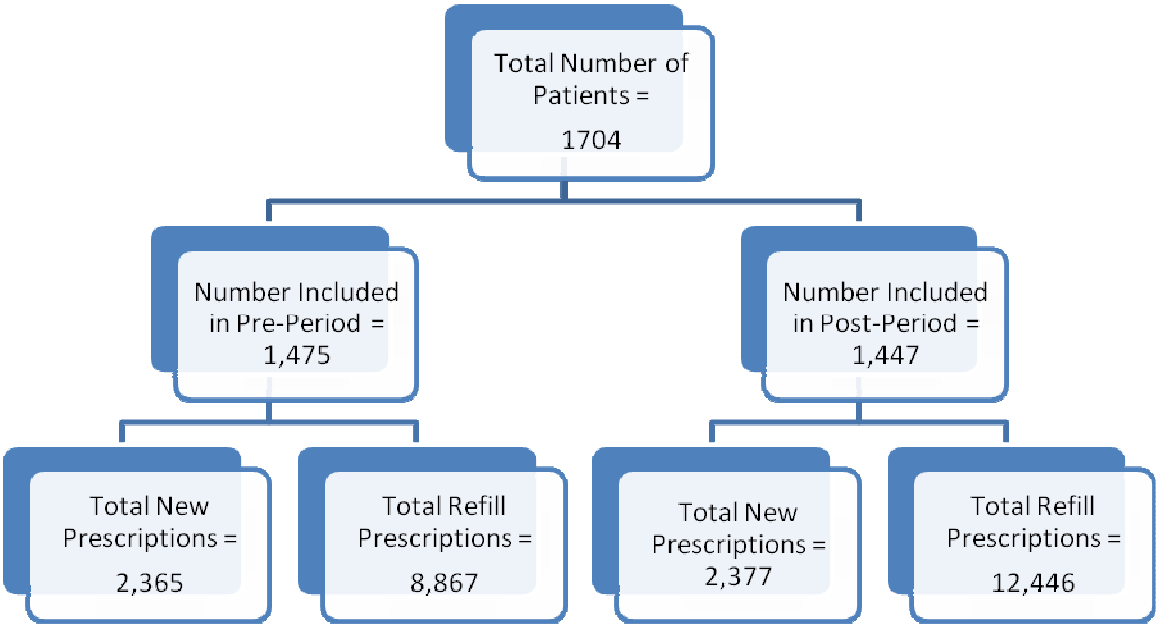

Figure 3: Patient and Prescription Data Used in the Analysis

The final dataset used in the analysis contained a total of 1,704 patients and 20,563 new prescriptions. From that dataset, a total of 1,474 met the criteria for inclusion in the pre-intervention, and 1,447 patients met the criteria for inclusions in the post-intervention group. Each group represented approximately 85% of the patients in the dataset.

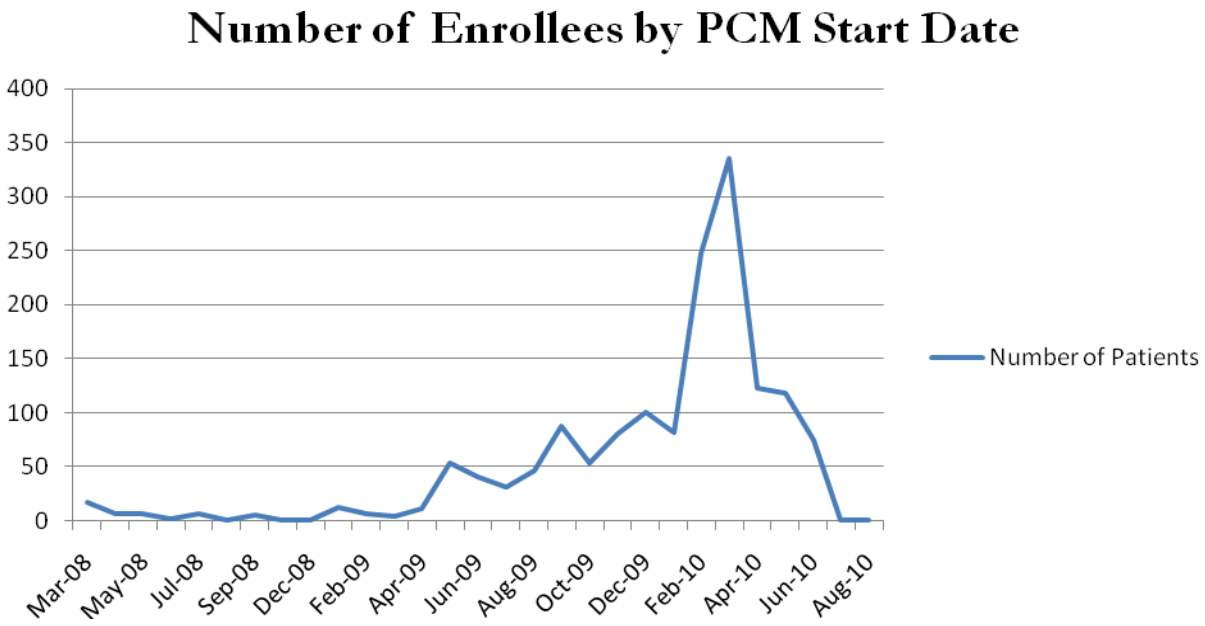

Figure 4: Number of Enrollees by PCM Start DAte

Enrollment from March 2008 through April 2009 was relatively flat over time with an average enrollment of 6 patients per month. After this period, there was a steady increase in enrollment from May 2009 through January 2010 with an average enrollment of 64 patients per month. A spike in enrollment was observed in the months of February 2009 and March 2009 with an average enrollment of 180 patients per month and a sharp subsequent decrease in enrollment in the following months.

PERCENT OF NON-PERSISTENT PATIENTS

Drug Class	Total Number of Patients	Percent of Non-Persistent Patients	Median Time to Non-Persistence (Days)
ACEIs / ARBs			
Pre	932	33%	58
Post (Mos. 1 – 6)	863	25%	84
Post (Mos. 8 – 12)*	419	24%	63
Beta-blockers			
Pre	751	36%	59
Post (Mos. 1 – 6)	733	28%	75
Post (Mos. 8 – 12)	365	24%	65
Dihydropyridine CCBs			
Pre	376	37%	56
Post (Mos. 1 – 6)	350	22%	84
Post (Mos. 8 – 12)	166	25%	67
Thiazide Diuretics			
Pre	484	40%	58
Post (Mos. 1 – 6)	431	30%	86
Post (Mos. 8 – 12)	200	30%	67
Statins			
Pre	739	37%	60
Post (Mos. 1 – 6)	704	29%	80
Post (Mos. 8 – 12)	336	24%	60
Metformin			
Pre	364	40%	61
Post (Mos. 1 – 6)	342	33%	67
Post (Mos. 8 – 12)	161	25%	70
Sulfonylureas			
Pre	278	37%	63
Post (Mos. 1 – 6)	255	25%	85
Post (Mos. 8 – 12)	118	31%	76
SSRIs/SNRIs			
Pre	549	38%	31
Post (Mos. 1 – 6)	506	32%	65
Post (Mos. 8 – 12)	231	25%	62

Table 2: Percent of Non-Persistent Patients

Among the drug classes evaluated, ACEIs and ARBs were prescribed most often, followed by beta blockers and statins (Table 2). Patient non-persistence was lower for all of the drug classes after the PCM intervention at both six months and 12 months. For patients who eventually became non-persistent, all patients took longer to become non-persistent in both the six-month and 12-month post-intervention periods than in the pre-intervention period.

DISCUSSION

Prior to the intervention, non-persistence within each of the classes of medications ranged from 33% to 40%. After the intervention, non-persistence was consistently lower for each drug class at both 6 months and 12 months. At six months, non-persistence ranged from 22% to 32%. Persistence at 12 months was similarly improved compared to the pre-intervention group. Furthermore, these data suggest that patients stay persistent for a longer period of time while enrolled in the patient centric model than before they were enrolled in the program. These finding are very positive for the effectiveness of the PCM program in improving patient persistence.

Nevertheless, these results are not conclusive due some of the limitations of the research design. No causal relationship between the PCM program and persistence rates can be made because no control group was established to account for time-related factors such as a natural increase in persistence rates that might coincide independently with the application of the program.

Selection of patients was also a limitation. Each pharmacy chose the patients to be enrolled in the program, so there was some selection bias in which individual received the program. Indeed, the preliminary analysis found that persistence rates prior to the PCM program were unusually high. In addition, not all the patients in the pre and post-intervention groups were the same due to individuals dropping out of the program or being lost to follow-up. As shown in Table 2, the post-intervention group is comprised of fewer patients than the pre-intervention group. It is possible that some individuals most likely to benefit from the PCM program were not represented in the post-intervention group because they dropped out prior to its implementation.

Key findings

Non-persistence was consistently lower for each chronic drug class after implementing the Patient Centric Model.

Patients were found to stay persistent for longer periods of time while enrolled in the patient centered model.

This analysis was unable to account for switching between medication classes because it was difficult to know whether the switch was due to non-persistence or a therapeutically appropriate switch from one drug class to another (e.g., from thiazide diuretic to ACE inhibitor). However, it was possible to avoid any misclassification due to switching between drugs within the drug class, since these switches were analyzed at the drug-class level.

Finally, patient level factors such as age, gender, co-morbidities, or other factors may influence the results. These were not included in the dataset, but would be ideal when analyzing persistence. While some information regarding medical conditions was included in the dataset, it was recorded inconsistently for each patient, thereby precluding its use in any analysis.

SUMMARY

Despite the limitations of the data, this study provides preliminary evidence that the PCM program can increase persistence in patients. In fact, it was impressive that improvements in persistence could be identified given the high persistence levels seen in individuals prior to the program. It would be useful to see how well it influences less persistent patient populations.

Future assessments of the PCM program or other initiatives could be improved with some modifications of the dataset. First, data fields need to be standardized in a way where medication names are consistently recorded. The current free text descriptions of dispensed medication resulted in misspelled drug names and missing information. In addition, inconsistencies occurred in the salt name documented and in whether the brand name or generic name was recorded. Standardizing the data can avoid the loss of information and make analysis easier. Another recommendation is to provide some way of indicating if patients have completed follow-up (such as adding a check box) to differentiate them from individuals who are non-persistent or drop-out. This can help in properly classifying patients.

DEFINITIONS

Refill Gap = difference between 'days between refill' and 'days' supply' for a given prescription

Grace period = each individual has a certain grace period to obtain an additional refill. This grace period commences at the end of the supply of the previous prescription and is usually equal to one-half the days' supply of a prescription (*Sikka R, Xia F et al. 2005*).
For example, one-half of 30 days is 15 days of grace period

Non-persistent = if a patient's refill gap exceeds the predetermined grace period, that patient is considered non-persistent at that point in time, for that prescription refill.

> *For example*, if days' supply = 30 days; then the grace period is one-half of 30 days—i.e., 15 days.
> If the refill gap = 10 days (< 15), then the patient is Persistent. And, if the refill gap = 18 (> 15) days, then the patient is Non-Persistent.

References

Sikka R, Xia F, Aubert R. Estimating Medication Persistency Using Administrative Claims Data. *Am J Manag Care*. 2005; 11: 449-457

ADDENDUM TO FINAL REPORT

For this analysis, we were interested in looking at patients with data for all drugs both 12 months before and 12 months after the intervention. To be included in the cohort, patients must have had at least 3 refills before and 3 refills after the intervention date. For this particular analysis, persistence was defined as having at least 80% of all refills filled on time.

We looked at both "persistent" and "non-persistent" groups prior to and after the intervention, although our primary interest was the non-persistent patients. The final sample included 1,460 patients, representing a total of 18,176 new prescriptions with at least 1 subsequent refill and a total of 158,901 prescription refills. There were 236 patients comprising the non-persistent cohort and 1,224 patients comprised the persistent cohort. Of the total number of prescriptions, 87.8% were persistent before the intervention and 88.2% were persistent after the intervention. Of the 1,224 patients comprising the persistent cohort, 89.5% continued to remain persistent. Of the 236 patients in the non-persistent cohort, 56.8% became persistent after the intervention.

The percentage of persistent refills among the non-persistent cohort significantly increased from 59% prior to the intervention to 76% after the intervention ($t = 10.98$, $p < 0001$, 95% Confidence Interval = [13.3%, 19.1%]). In the persistent cohort, the percentage of persistent refills decreased by 2.3% from 93% to 91%, respectively ($t = -8.25$, $p < 0.0001$, 95% Confidence Interval = [2.0%, 3.2%]).

Increases in overall persistence rates were minimal, but increases among non-persistent patients were more pronounced. This analysis provides evidence that the intervention is effective in increasing persistence rates among patients who are non-persistent, although the design of the study does not permit a conclusion of causality. The design does not control for unmeasured patient-level variables including age, gender, income, insurance status, severity of illness, and geographic location.