APPOINTMENT-BASED MODEL (ABM) DATA ANALYSIS REPORT

PREPARED FOR THRIFTY WHITE PHARMACY

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EXECUTIVE SUMMARY

Prescribed pharmaceuticals are only effective when taken in sufficient quantities to achieve a therapeutic response. Failure to take medications in a consistent, continuous manner can lead to negative health outcomes and wasted health care resources.

The Appointment Based Model (ABM) program at Thrifty White Pharmacy seeks to improve patient adherence by synchronizing all of a patient's chronic fill medications to come due on a single day of the month. By simplifying the refill process, it is hypothesized that patients will adhere better with their prescribed medications. This report describes the impact of implementing the ABM on patient adherence and persistence to medications as compared to controls without the ABM.

Data for this study was collected retrospectively from the Thrifty White prescription claims database. Data was collected over a 12 month period between 2011 and 2012. There were two arms of the study (intervention ABM and control). Study patients were selected based on having at least two fills for one of 6 chronic medication classes (ACEIs/ARBs, beta blockers, dihydropyridine calcium channel blockers (CCBs), thiazide diuretics, metformin, and statins) after enrollment into the ABM program. Patients must have had at least 2 fills of the chronic medication on or after enrollment, with at least one fill occurring within the 30 day period preceding the enrollment date.

This analysis indicated significant improvements in adherence and persistence for the ABM patients when compare to control patients for all of the chronic medication classes. Adherence, as measured by proportion of days covered (PDC), was significantly higher for the ABM patients. *Depending on the drug class, patients enrolled in the program had 3.4 to 6.1 times greater odds of adherence as controls* during the evaluation period. Non-persistence was measured by calculating the likelihood that patients would stop taking their medicine. C*ontrol patients had a 52% to 73% greater likelihood of becoming non-persistent* compared to the ABM group, depending on drug class.

In conclusion, the results of this study indicate that the ABM program at Thrifty White Pharmacy was associated with improved patient adherence and reduced the likelihood of non-persistence.

INTRODUCTION

Prescribed pharmaceuticals are only effective when taken in sufficient quantities to achieve a therapeutic response. Failure to take medications in a consistent, continuous manner can lead to negative health outcomes and wasted health care resources.

The Appointment Based Model (ABM) program at Thrifty White seeks to improve patient adherence through a prescription synchronization program, which synchronizes all of a patient's chronic fill medications to come due on a single day of the month.
The ABM program is a system of patient care designed to change the process by which pharmacist serve patients on chronic care medicines. By synchronizing all patient prescriptions to be refilled on the same day of the month, many of the problems associated with refilling prescriptions can be addressed by the pharmacist.

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.

All patients enrolled in this study come from Thrifty White, a chain of employee-owned pharmacies located in rural Midwest locations in Minnesota, North Dakota, Iowa, Montana and Wisconsin. Patients taking multiple, on-going prescriptions for chronic conditions (ACEIs/ARBs, beta blockers, dihydropyridine calcium channel blockers (CCBs), thiazide diuretics, sulfonylureas, metformin, and statins) were recruited at Thrifty White pharmacies at numerous locations. This enrollment was not random, so the patients were part of what is called a convenience sample. Convenience samples are common in practice-based studies where random selection of patients is not possible.

The outcomes of interest in this study are adherence and non-persistence. In the literature, adherence is defined as "the extent to which a patient acts in accordance with the prescribed interval and dose of a dosing regimen".[1] Adherence in this study was measured using proportion of days covered (PDC) at the patient level for each chronic medication which is calculated by the following ratio: [2]

$$\frac{\text{number of days covered by the prescription fills}}{\text{time between first fill of the medication \& the end of study period}}$$

The PDC ratio ranges from 0 to 1 with larger proportions equaling greater adherence. A PDC of 80% or higher for the chronic medications in this study was considered to exceed the threshold for achieving most of the therapeutic benefit.[2] For example, a patient who received 310 days of metformin during a 365 day study period would have a PDC of 85% and be classified as "adherent" to this medication.

Persistence is defined as "the duration of time from initiation to discontinuation of therapy."[1] Therefore, non-persistence describes the time at which patients stop taking their medications. A survival model (Cox proportional hazards regression) was used to measure the different medication discontinuance likelihood between the ABM and control groups. Survival models permit group comparisons of the time that passes before discontinuance.

METHODS

Time Period:

The time period for enrollment ranged from June 30, 2011 through October 31, 2012. Prescription fill data were obtained until October 31, 2012.

Selection of Study Patients:

Study patients were selected based on having at least two fills for one of 6 chronic medication classes after enrollment into the ABM program. Patients must have had at least 2 fills of the chronic medication on or after enrollment, with at least one fill occurring within the 30 day period preceding the enrollment date. The first fill within 30 days of enrollment was considered the "start date" for the medication being evaluated. Because data only up to October 31, 2012 were available, patients with start dates after November 1, 2011 were excluded to allow for a full 12 months of observation for all patients. Patients with less than 2 fills after the start date and those with fills with a days-supply less than 30 were excluded.

Only six of the original seven proposed chronic medication classes were evaluated in this study -- angiotensin-converting-enzyme inhibitors or angiotensin-receptor blockers (ACEIs/ARBs), beta blockers, dihydropyridine calcium channel blockers (CCBs), thiazide diuretics, metformin, and statins). Sulfonylureas were excluded from the analysis because of low sample sizes after matching (n = 22 in controls, and n = 22 among study patients).

Selection of Controls:

Controls for patients for each drug class were selected if the control patient had a fill within the time period of enrollment (June 30, 2011 through October 31, 2012). The first occurring prescription fill for the drug class within this period was selected as the start date for controls. Patients were then matched to study patients based on age, gender, region, and start date (+/- 15 days).

This means that each ABM patient was similar to control patients in age, gender, region of the country, and filling of medication. Other potential confounding variables relating to the patient's health, complexity of therapy, or engagement in their therapy were not controlled for.

Analytical Approach:

We compared the proportion of days covered (PDC) and persistence among study patients enrolled in the ABM program compared to control patients, matched 1:m (m = 1, 2, or 3 matched controls) by age and sex with up to 3 controls per study patient. Patients with a PDC of at least 80% were considered to be adherent.[2] Overlapping days were credited towards the PDC. The time frame for the analysis was 365 days after the initial fill for the medication (i.e., start date).

Differences in adherence to medications between patients in the ABM program and matched controls were evaluated using proportion of days covered (PDC). The Friedman test (used to detect statistically significant differences in treatments using data that is not normally distributed) was employed in this analysis. A univariate conditional logistic regression was used to evaluate the likelihood of adherence by group. Logistic regression permits us to predict the odds that patients in the ABM group will be adherent in comparison to the matched control group.

To compare persistence between the ABM and control patients, a univariate conditional Cox proportional hazards regression was performed. Cox proportional hazards regression model a type of survival model used in epidemiology to permit group comparisons of the time that passes before discontinuance. Often used to compare differences in mortality over time, we used it to identify the time at which patients discontinue the medicine. Because no program drop-out date was provided, we assumed that patients continued in the program whether they did or not. This assumption is common based upon the intention-to-treat principle. A p-value < 0.05 was considered statistically significant.

RESULTS

The final sample sizes for control and study patients and the associated PDCs are listed in Table 1. Of note, the mean PDC for study patients is significantly greater than controls in each of the drug classes.

Table 1: Proportion of Days Covered (PDC) by Drug Class

Drug Class	Control			Study Patients			
	n	Mean PDC	SD	n	Mean PDC	SD	p-value*
ACEIs/ARBs	537	0.61	0.318	278	0.87	0.216	< 0.0001
Beta blockers	415	0.61	0.312	202	0.84	0.227	< 0.0001
CCBs	196	0.63	0.306	106	0.82	0.255	< 0.0001
Thiazide diuretics	100	0.58	0.328	59	0.80	0.269	0.001
Metformin	87	0.62	0.295	47	0.86	0.233	0.001
Statins	564	0.62	0.289	281	0.84	0.248	< 0.0001

*p-value, determined from Friedman test using median values

The proportion of patients who are considered adherent (i.e., PDC of 0.8 or greater) and associated odds ratios for each of the drug classes are listed in Table 2. The percentage of patients considered adherent was significantly greater for study patients compared to controls. Depending on the drug class, patients enrolled in the program had 3.4 to 6.1 times greater odds of adherence as controls during the evaluation period.

Table 2: Percent of Patients Adherent and Odds Ratios from Univariate Logistic Regression

	% Adherent (n)				
Drug Class	Control	Treatment	OR*	95% CI	p-value
ACEIs/ARBs	40.8	79.5	6.1	4.2 to 9.0	< 0.0001
Beta blockers	38.3	71.8	4.7	3.1 to 7.1	< 0.0001
DCCBs	40.3	68.9	3.8	2.2 to 6.7	< 0.0001
Thiazide diuretics	37.0	66.1	3.4	1.6 to 7.5	0.0017
Metformin	40.2	76.6	4.8	2.0 to 11.5	0.0003
Statins	37.4	76.2	5.8	4.0 to 8.4	< 0.0001

*OR = Odds ratio obtained from univariate conditional logistic regression models. This represents the odds of adherence for study patients compared with the control group. An OR > 1 favor the study group.

The percent considered non-persistent according to group is displayed in Table 3. Hazard ratios, associated 95% confidence intervals and p-values are also listed. Compared to patients in the program, patients who were not enrolled in the ABM program had a 52% to 73% higher likelihood of non-persistence, depending on drug class.

Table 3: Rates of Non-Persistence and Hazard Ratios

	% Non-Adherent				
Drug Class	Control	Treatment	HR*	95% CI	p-value
ACEIs/ARBs	70.0	33.8	0.27	0.20 to 0.35	< 0.0001
Beta blockers	71.6	38.1	0.30	0.22 to 0.41	< 0.0001
CCBs	67.4	43.4	0.48	0.32 to 0.71	0.0003
Thiazide diuretics	74.0	47.5	0.38	0.22 to 0.66	0.0006
Metformin	73.6	34.0	0.37	0.20 to 0.68	0.0013
Statins	72.5	41.6	0.39	0.31 to 0.50	< 0.0001

*HR = Hazard ratio obtained from univariate conditional Cox proportional hazard regression models. This represents the probability of non-persistence for study patients compared to controls. An HR < 1 favors the study group.

Study Limitations

Several limitations to the measures and study design are present in this research. This analysis did not control for all factors affecting adherence to medications. Some factors not addressed in the study design include the insurance status of the patient, the complexity of the patient's medication regimen, the severity of the patient's condition(s), and the level of patient motivation and engagement in their health care.

In addition, a convenience sample was used to select participants in the ABM program. This makes it possible that, prior to the start of the program, patients in the ABM group differed from the control group even after matching. Use of convenience samples is often unavoidable in this type of practice-based research because random assignment of interventions is impractical and unethical.

Another limitation is that patients labeled as “adherent” and “non-persistent” may not really be so. "Adherent" patients may be getting their prescriptions filled but not taking them as directed. "Non-persistent" patients may have been directed by the physician to discontinue therapy or they may have simply switched pharmacies. The ability to address this limitation is outside the scope of this study.

CONCLUSIONS

The results of this study indicate that the ABM program at Thrifty White was associated with improved patient adherence and reduced the likelihood of non-persistence. Although this research was unable to control for all potential confounding factors that may have influenced the results, the results are very promising.

Reference List

(1) Cramer JA, Roy A, Burrell A et al. Medication compliance and persistence: terminology and definitions. *Value Health* 2008;11(1):44-47.

(2) PQA Endorsed Measures. *Pharmacy Quality Alliance* 2012;Available at: URL: http://pqaalliance.org/measures/default.asp.