Community Pharmacy Foundation Grant
FINAL REPORT

Evaluation of Outcomes in Community-based Disease State Management Programs: Asthma and Diabetes

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Results

The enrollment period for the diabetes and asthma DSM programs began in April 2004 and ended June 2005. The diabetes DSM program enrolled 70 patients (43 experimental and 27 control) at eight pharmacies in California. Twenty-eight patients (18 experimental and 10 control) were assessed the entire 12 months of the program. Forty-two participants withdrew during the study period. The asthma DSM program originally enrolled 11 patients by January 2005, well below the projected number of 130. A majority of these patients were withdrawn due to the pharmacist at the San Diego site leaving the VONS company, and no one being able to continue the operation of the program. Along with the lack of enrollment at other sites, it was decided to shut down the asthma DSM program at VONS, and continue the evaluation of the diabetes DSM program. Therefore, the results of the study will encompass only the diabetes DSM program.

Description of the entire sample at baseline:

Table 1: Baseline Characteristics

Independent t-test for continuous variables; chi-square for categorical data

	Experimental (n=43)	**Control (n=27)**	**p-value**
Mean Age (yrs)	58.43	63.94	
Gender			0.605
Male	22	7	
Female	21	9	
Ethnicity:			0.746
Caucasian	28	9	
African American	1	1	
Hispanic	10	5	
Asian/Pacific Islander	5	1	
Other	1	0	
Years with Diabetes			0.274

< 1 year	4	1	
1-5 years	21	6	
5-10 years	7	5	
> 10 years	12	11	
Other Medical Conditions:			
Hypertension	25	11	
Hyperlipidemia	21	10	
CHD[a]	11	4	
Retinal Disease	8	4	
Depression/Anxiety	3	2	
Thyroid Disorder	5	0	
Eye exam within last year	37	13	0.730
Foot exam within last year	23	6	0.198
Smoker	27	13	0.495
Alcohol Use			0.894
< 1 drink per week	7	3	
1-7 drinks per week	4	1	
> 7 per week	1	0	
Quit	6	0	
Family History of Diabetes	26	11	0.755
Physical Activity:			0.789
< 3 days per week	8	1	
≥ 3 days per week	16	7	
Diabetes Medications:			
Sulfonylurea	22	11	
Biguanide	26	12	

Thiazelidinedione	18	5	
Meglitinide	0	1	
α-glucosidase inhibitor	1	0	
Insulin	12	2	
Aspirin Use	14	8	

[a] Coronary Heart Disease

Clinical Outcomes

Data analysis was conducted only for the evaluables or "completers" for whom we had pre and post data. An initial analysis revealed that the primary indicators (HbA1c, SMBG, BP, TC, HDL, LDL) were not significantly different between the experimental and control groups. As Table 2 shows, mean HbA1c for the diabetes DSM management group was 6.66% at the initial visit and 6.63% at the final visit, although the visits in between did show variation of up to 1%. The change in HbA1c from initial to final visit was not significant (p=0.916). Also, patients in the DSM management group had a mean, average monthly self-monitored blood glucose of 154 mg/dL at the initial visit and 127 mg/dL at the final visit, which was an improvement but not statistically significant (p=0.284). Usual care (Control group) patients had a mean, average monthly self-monitored blood glucose of 132 mg/dL at the initial visit and 124 mg/dL at the final visit, again not statistically significant (p=0.284).

A paired t-test comparison between indicators at first and last visit again found no significant differences, although in most cases the trend was in the direction of improvement. However, further analysis showed that these trends barring the BMI, were not significant. Finally, an ANCOVA confirmed that there were no differences between pre and post, controlling for baseline as a covariate.

Diabetes knowledge test indicated that patients scored higher on the knowledge test after the education than before, however, the difference was not statistically significant.

Table 2: Paired comparisons: (n=18 for Experimental; n=10 for Control)

	Experimental Pre (mean)	Experimental Post (mean)	p-value	Control Pre (mean)	Control Post (mean)	p-value
HbA1c	6.7	6.6	0.916	7.0	6.8	0.677
SMBG	154	127	0.132	147	134	0.999
Mean BP	133/84	130/72	0.901	143/82	140/80	0.981

	mmHg	mmHg		mmHg	mmHg	
BMI	34.35	31.33	0.815	29.5	24.0	0.395
TC	180	155	0.317	191	168	0.584
HDL	49	48	0.338	51	48	0.769
LDL	104	84	0.253	111	89	0.419
TG	155	108	0.272	173	146	0.616
Diabetes knowledge	26.6	27.7	0.143	24.6	27.0	0.280

Economic Outcomes:

Our community partner, VONS revealed that they had established relationships with physicians who had intended to participate (signed off on participation) by providing access to data (i.e., ER visits, hospitalizations etc.). However, as the study progressed, VONS was unable to deliver the data due to physician unwillingness. Hence it was challenging to estimate costs tied to the study. On another note, VONS has had a Pharmaceutical Care Program for a few years, hence there were no set up costs.

The pharmacist (Outcomes fellow) in charge of data collection for the current study informed us that there were no reported ER visits or hospitalizations and almost no recommendations for changes in pharmacotherapy that were necessary with the patients. This is not completely surprising in view of the low average HbA1C of our sample. Several inferences could be made from the points mentioned above. 1) In studies similar to the current one, a significant effect can be/has been detected if the baseline HbA1C is higher and there is more potential for improvement. 2) The efforts of the treating physician and pharmacist could help maintain the patient's health throughout the year with no additional pharmacotherapy modifications. Since there were no reported ER visits or hospitalizations, and medication adherence rate was above 80% in more than 90% of the sample, it appears that our sample was reasonably under diabetes control and motivated to follow regimens.

In addition to these points, the primary issue of low sample size and the resultant lack of statistical significance in our results precluded the value of cost data estimation.

Humanistic outcomes

The other indicators we evaluated were patient satisfaction with the service, and generic (SF-36) as well as disease specific quality-of-life (D-39).

Patient satisfaction analysis revealed that on a scale of 3, the pharmacists conducting the clinic were rated higher than 2.7 on each of the 5 components; which is a very positive outcome. However there were no differences between the experimental and control groups, in effect, the control (C) group averages were higher than the experimental (E) group for each component of patient satisfaction. This may be a factor of truly higher satisfaction from the control group who could have pharmacists answer their questions. For those who were in the experimental group, this could indicate that their expectations had been raised at the beginning and they were now evaluating the pharmacist based on that higher level of expectation.

Table 2: Patient satisfaction

Question	Experimental group	Control group	p-value
Availability of pharmacist	2.93	3.00	0.336
Friendly and approachable	2.93	3.00	0.334
Time spent	2.93	3.00	0.334
Quality of care	3.00	3.00	Could not be computed
Confidence in managing disease	2.71	2.80	0.727
Increase awareness	2.81	N/A	

The health status of our experimental sample (compared to national US norms by the SF-36) was at or around the 50th percentile for most domains[1]. For most of the mental health scales (SF, RE, MH), the scores were higher than national norms. Our C group was higher than mean national norms in all domains.

Further analysis of the health status assessments revealed some mixed results. There were no differences between E and C groups at baseline (except general health which was lower for the E group). The end of study scores for the D-39 were significantly higher for the E group than the C group for 4 of 5 domains, and this was a positive and welcome outcome. The domains where E was higher were: Anxiety & Worry, Social Burden, Sexual Functioning and Emotion & Mobility. These were repeated at end of study for the

SF-36 domains of general heath, vitality and social functioning. Within the E group, there were no significant differences between baseline and end of study for D-39 or SF-36, the trends were in the correct direction (end of study being higher than baseline) for about half of the domains (Diabetes Control, Anxiety & Worry, Social Burden, Physical Functioning, Bodily Pain, General Health). Paired comparison between baseline and end of study for the C group revealed no differences in most domains.

Table 3: Paired comparisons: (n=17 for Experimental; n=7 for Control)

	Experimental Pre (mean)	Experimental Post (mean)	p-value	Control Pre (mean)	Control Post (mean)	p-value
D39 – Diabetes Control	34.87	37.25	0.593	29.25	23.81	0.289
D39- Anxiety and Worry	40.76	40.96	0.959	23.47	18.88	0.289
D39-Social Burden	16.39	17.73	0.280	9.59	8.37	0.407
D39 – Sexual functioning	32.44	30.06	0.691	31.75	9.52	0.196
D39 – Energy and Mobility	38.91	38.01	0.764	19.80	16.66	0.369
SF-36: Physical Functioning	52.81	58.17	0.380	86.20	79.17	0.105
SF-36: Role Physical	57.35	52.94	0.083	75.00	66.66	0.363
SF-36: Bodily Pain	55.35	66.23	0.121	88.57	81.86	0.275
SF-36: General	48.12	54.65	0.168	73.85	81.00	0.290

Health						
SF-36: Vitality	54.80	51.18	0.245	73.57	76.43	0.413
SF-36: Social Functioning	75.00	69.85	0.322	94.64	92.86	0.689
SF-36: Role Emotional	66.66	66.66	--	83.33	72.22	0.465
SF-36: Mental Health	74.12	73.65	0.869	80.00	83.33	0.462

Comparison between completers vs non-completers:

A t-test comparison between these groups showed no significant differences for the E group; however, for the C group, there were differences in about half of the variables – demographic, clinical as well as humanistic. Furthermore among the C group, the completers had better baseline characteristics than the non-completers. This may point to a degree of self-selection bias, i.e. those with better health status wanted to continue the study, possible explanation being they are more proactive/motivated. However, there were no significant differences between baseline and end of study outcomes in these patients – which could indicate that this group may have benefited from pharmacist intervention OR the small sample size had an effect on the results.

Discussion

As mentioned in Results, very few of the results were significant statistically; although the trends were in the right direction. As we discuss below, sample size was our primary issue. We had estimated a much higher sample size (130 in both groups) at a power of 80%, since we were able to retain only half that number, power was affected (60% at best and for some indicators with missing post-data, only 34%) and hence the possibility of detecting significant differences between the control and experimental groups was also reduced.

The results were better for humanistic indicators than for the clinical ones, and this is evidence that the entire effort had some merit. In the literature and in personal experience, humanistic indicators are better received if corroborated with clinical outcomes, however, in the case of our study, both patient satisfaction and quality of life seemed to have had positive outcomes for our patients. We count this as a proxy and partial measure of the effectiveness of the clinic.

Since there was a lack of utilization data and we had a small sample size in our study, cost estimates on utilization were not provided. In previously published literature on pharmacist impact on outcomes such as the Asheville project[2,3], there was a significant cost savings estimated at $2,750 per patient during the first year of the program seen based on reduced rate of ER visits, hospitalizations, lab tests, prescription drug costs and diabetic supplies and improved productivity (less absenteeism – mean total healthcare costs were reduced by $918 (10.8%) per patient per year from the employers projected expenditures).

Limitations

A major limitation of both the diabetes and asthma DSM programs was enrollment. Several reasons may have contributed to the lack of participation in each program. Recruitment methods included flyers in the stores, physician collaboration, and phone calls to customers who received asthma or diabetes medications at the pharmacy sites. In recruiting asthma patients, candidates seemed to be uninterested in the management sessions because they only occurred once every 3 months and felt no benefit with the long gap between interventions. Others may have felt their asthma condition encompassed mild symptoms therefore; they did not think they would benefit from these sessions with pharmacists. Also, most asthmatics were younger and felt they did not have the time to come to the pharmacy for regular visits unlike older patients who have less busier schedules.

Although enrollment for the diabetes DSM program was better than the asthma program, there was still difficulty in recruiting diabetes patient into the study. Several factors may have contributed to slow enrollment rates. At several pharmacy sites, we relied on the pharmacists to recruit patients. Most of these pharmacists were unable to attract customers to the program primarily due to busy workflow. Some kind of compensation may have helped motivate the pharmacists to seek more enrollees. A significant number of patients enrolled in the study did not complete the program. Several of these patients seem to believe they were knowledgeable about their condition before finishing the program and decided to no longer participate. Others were absent to their appointments even after several reminders and rescheduling of sessions. Recruiting newly diagnosed diabetic patients into the program may have improved participation

and completion of the study. Newly diagnosed patients may be more motivated to seek assistance in managing their diabetes and obtaining education from pharmacists. Also, offering better incentives to participate in the study could have increased recruitment and reduced the number of withdrawals. All participants in the diabetes DSM program were offered a complimentary glucometer, but most patients already had a glucometer and were satisfied with their current model.

Another limitation of the study was the collection of patients HbA1c values. It was difficult for the pharmacists to obtain lab values from the patient or physician in a timely manner resulting in the inability to manage the patient appropriately. The use point-of-care monitoring of HbA1c at the pharmacy sites would have provided more effective diabetes management. Pharmacists could evaluate patients properly and make recommendations regarding drug therapy and lifestyle modifications.

Monthly average of self-monitored fasting blood glucose levels did not provide an adequate assessment of a patient's diabetes. Patients had been checking their blood sugar levels inconsistently from month to month and between patients check at different intervals from one another. Therefore, these are comparisons of random glucose levels, which do not have a recommended goal level to obtain when managing diabetes. A monthly average of fasting glucose levels would have provided a more effective mans of evaluating the management of someone's diabetes with the ADA recommending a fasting blood glucose range for type 2 diabetics to achieve. Also, this would allow patients to have different rates of testing but require at least a daily fasting reading.

Conclusion and Lessons Learnt

The diabetes (and asthma) clinic was ridden with patient enrollment, recruitment and retention issues; some of which may have been alleviated by an incentive; however, there were others that were beyond the control of the pharmacists on site and the PI and researchers off site. The successes of this project were not as big in terms of patient clinical improvements as we had originally planned and expected. However, patient reported outcomes were more positive in nature. Furthermore, the primary indicators such as HbA1C remained reasonably steady and within range, which is encouraging from a provider perspective. Since sample size was half of that estimated for testing significant differences, it is not possible to make inferences with confidence.

The project was a major learning experience for the Outcomes Fellow and the researchers, in terms of the pitfalls and challenges of practice based research, and in trying to implement and sustain a patient-focused service within the constraints of an active, busy chain store pharmacy.

From the perspective of the pharmacist, a service such as this one is a challenge to implement in terms of time and staffing barriers, without an added incentive. Furthermore, it may rest on the motivation of one or two individuals, who spearhead the service, but sustenance, translation and implementation of that motivation is a major challenge. Another point for improvement in similar programs is continuous and aggressive monitoring of patient progress.

For the patient, it seems worthwhile in the beginning but sustaining and returning to clinic each month may be tiresome, without the presence of an incentive to show up, and without an extrinsic reward to practice positive lifestyle and medication behavior.

There was initial willingness from the physician's end but no follow through and this is an area of challenge that is not unique to our study but needs more attention as we move our profession towards collaborative therapy management.

To summarize, the issues that made this study challenging and eventually, less of a success than expected, were systemic and not unique to this study. For that very reason, future attempts need to focus on addressing these constraints. As proposed by Bodenheimer, Wagner and Grumbach in their 6-component Chronic Care Model, establishing and sustaining a disease management effort needs concerted and coordinated planning from the community, the health care system, the providers, and alignment of incentives in order to provide self-management support and positive outcomes[4]. A very recent publication indicates that collaborative community health centers seemed to improve processes of care in diabetes but there was no impact on outcomes[5]. However since the condition is chronic in nature, long term evaluation is necessary and so far, the impact of disease management on long term outcomes is also inconclusive. As recognized by Bodenheimer et al above, sustaining a disease management program and its intermediate and long term outcomes is a challenge that requires consistent and persistent effort.

References:

1. Ware JE Jr., Snow KK, Kosinki M, Gandek B. SF-36 Health Survey: manual and interpretation guide. Boston, MA: The Health Institute, New England Medical Center, 1993.

2. Garrett, Daniel G., and Benjamin M. Bluml. Patient Self-Management Program for Diabetes: First-Year Clinical, Humanistic, and Economic Outcomes. Journal of the American Pharmacists Association. Vol. 45, No.2. March/April 2005.

3. Cranor, Carole W., Bunting, Berry A., and Dale B. Christensen. The Asheville Project: Long-Term Clinical and Economic Outcomes of a Community Pharmacy Diabetes Care Program. Journal of the American Pharmaceutical Association. Vol. 43, No.2. March/April 2003.

4. Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness: the chronic care model, Part 2. *JAMA*. 2002 Oct 16;288(15):1909-14.

5. Landon BE, Hicks LS, O'Malley AJ et al. Improving the management of chronic disease at community health centers. *NEJM* 2007, 356: 921-934.

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