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A Pilot Evaluating Clinical Pharmacy Services in an Ambulatory Psychiatry Setting

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ABSTRACT ~ Objectives: *A pilot of clinical services provided by psychiatric clinical pharmacists in an outpatient clinic are described and evaluated. The primary objective was to evaluate the difference in change of Patient Health Questionnaire (PHQ)-9 and/or Generalized Anxiety Disorder (GAD) Questionnaire scores between the two groups. Secondary objectives were to assess time patients spent in clinic, time to target psychotropic medication dose, and patient self-reported medication adherence.* ***Experimental Design:*** *Data were collected from January 2014 to November 2015 for patients with depression and/or anxiety who had an appointment within an outpatient psychiatric clinic with either a provider (control) or both a provider and clinical pharmacist (case).* ***Principle Observations:*** *A total of 217 patients were included in the study; 117 patients served as controls and 100 patients received clinical pharmacist intervention. No statistical difference was detected in the primary outcome. However, patients in the case group had higher baseline PHQ-9/GAD scores, and the frequency of measured values was lower than anticipated, limiting power to detect a difference. All secondary outcomes achieved statistical significance. Both time in clinic and time to reach a stabilized psychotropic medication regimen were shorter in the control group. Patient self-reported adherence favored a higher adherence rate in the intervention group.* ***Conclusion:*** *While this study found no significant difference in the change in PHQ-9/GAD scores between groups, it demonstrated the need for enhanced utilization of measurement-based outcomes in the psychiatric setting. Pharmacists provide a range of services to patients and providers and can serve as key partners to enhance measurement-based care.* Psychopharmacology Bulletin. *2018;48(2):18–28.*

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Background

Of the 450 million people worldwide with mental illness, only a small minority receive proper treatment.[1] To improve the quality and cost of mental health care, national initiatives focus on providing evidence-based care and utilizing collaborative practice models.[2] Psychiatric pharmacists are uniquely trained in the use of psychotropic medications and have great potential to optimize patient care in the outpatient setting.[3]

With regard to pharmacotherapy, there are many barriers to successful treatment, including difficulties with adherence due to intolerable adverse effects, delayed clinical efficacy, and insufficient monitoring.[3–7] Studies have demonstrated pharmacists can significantly improve patient adherence to therapy, patient satisfaction, patient knowledge regarding pharmacotherapy, and overall produce cost savings.[3–5]

This study focuses on an outpatient psychiatric clinic, which includes a multidisciplinary team of psychiatrists, residents, nurse practitioners, social workers, and clinical pharmacists. The clinic was developed in early 2014 to provide medication management and psychotherapy for patients with mental illnesses, primarily depression and anxiety. The goal of this clinic is to stabilize patient mood symptoms and assist with identification of a long-term provider in the community within three months. This three-month time frame was established to allow the clinic to meet the high demand for access to psychiatry.

The clinic started with four half-days per week (16 hours/week). A board certified psychiatric pharmacist (BCPP) was incorporated into the clinic 4 hours/week, which was supported by the department of psychiatry, and a pharmacy fellow's time was donated and supported by her research mentor for an additional 4 hours/week. Over a 4-hour time period, a pharmacist attends the multidisciplinary team meeting and visits with a maximum of 6 patients via telephone. Pharmacists follow up with patients who are either 1) referred by their prescriber (e.g. individuals at risk for adverse effects, treatment non-adherence, or with suicidal ideation), or 2) discussed at the team meeting and subsequently a referral is requested by the pharmacist. With regard to the latter, pharmacists typically discuss with providers whether phone follow up is appropriate in patients with a medication change or with other complicating factors that could be addressed by the pharmacist. A BCPP and pharmacy fellow conduct the majority of follow-up phone calls with patients, with a few phone visits conducted by pharmacy residents with pharmacist supervision. T-codes are submitted for reimbursement with phone calls, however only a single payer provides payment for these services. Therefore, pharmacist support is largely provided by the department of psychiatry, as highlighted.

The primary goals of pharmacist follow-up are to ensure patients are clear on the treatment plan, identify any issues with tolerability, and assess efficacy prior to the patient's next clinic visit. During phone visits, pharmacists provide various services depending on individual patient needs. Services include evaluating side effects of newly initiated psychotropic medications or recent dose changes, tolerability, self-reported efficacy and adherence, affordability, mood, suicidality, and providing medication education. The phone visits typically range from 10 to 30 minutes and all patient care activities and recommendations are documented by the clinical psychiatric pharmacist in the electronic medical record (EMR) using a standard note template. In addition to follow-up phone calls, pharmacists provide other value-added services in clinic including medication recommendations, responding to drug information questions, medication reconciliation, education to psychiatry residents and other clinic staff, and scholarly activities.

Though current literature supports the incorporation of pharmacists into transitions of care and primary care clinics, few studies have examined the impact of pharmacists in an outpatient psychiatric clinic.[4,5,8] Due to the novelty of the psychiatric clinic described herein, there is a lack of data evaluating the value-added services provided by clinical pharmacists as part of the multidisciplinary team. In addition, the impact of pharmacists on anxiety and depression symptoms as measured by the Patient Health Questionnaire (PHQ)-9 and Generalized Anxiety Disorder (GAD) questionnaires has not been assessed thoroughly in the literature. The data depicted throughout this study serve as pilot data. The results of the study can help validate and better define the potential impact of pharmacists in the psychiatric outpatient setting while providing framework for future interdisciplinary outpatient psychiatric clinics.

Objectives

The primary objective was to describe pharmacy services in the outpatient management of psychiatric disorders and to determine if clinical improvement occurred in patients who received pharmacist intervention. The primary outcome was defined as difference in change of PHQ-9 and/or GAD scores between the two study groups, assessing scores obtained from the patient's initial clinic visit and scores obtained at the end of the patient's duration in clinic. The secondary objectives were time spent in clinic, time to target psychotropic medication dose, and patient self-reported medication adherence. The target psychotropic medication dose was defined as the dose that maximized efficacy and

minimized toxicity. The patient would continue on that dose after discharge from the clinic. Patients were considered either "adherent" or "non-adherent" based on whether or not they missed doses of one or more of their medications on a regular basis per self-report. For patients who spoke with a pharmacist, adherence was based on whether or not they had missed a single medication dose in the week prior to the phone call, which was often the period since the last clinic visit. Other aspects of adherence were assessed, including no shows, patients lost to follow-up, and patients engaged in psychotherapy.

Hypothesis

Patients receiving team-based care with a psychiatrist and a clinical pharmacist will experience a more significant change in PHQ-9 and GAD scores compared to the control group receiving the standard of care by a psychiatrist.

Methods

Study Setting. The study was conducted in an outpatient psychiatric clinic housed within a large academic medical center. The clinic provides services to patients with a variety of psychiatric disorders and serves as a training location for a broad range of disciplines, including medical and pharmacy residency/fellowship programs.

Study Design. This study is a retrospective cohort analysis including patients managed in clinic from January 2014 to November 2015. Patients were included in the study if they were 18 years or older, had a diagnosis of depression and/or anxiety (defined per corresponding International Classification of Disease Codes -9 and -10), underwent a psychotropic medication change (defined as dose titration, medication addition, medication discontinuation, or cross-taper/medication switch), and had at least one return visit to the clinic. This information was obtained from appointment records and the EMR. The study population was divided into two groups. The control group contained patients who visited only with a provider (psychiatrist, psychiatry resident, nurse practitioner), while the case group contained patients who visited in-person with a provider and via phone with the clinical pharmacist. The study was reviewed and approved by the University of Michigan Institutional Review Board and the research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Statistical Analysis. Sample size calculation was based on the primary outcome of change in PHQ-9 and/or GAD using a type one error (α)

of 0.05 and a power of 0.80 (1-β). Based on a published study,[9] 123 patients were needed for each group to detect a significant difference in change of PHQ-9 and/or GAD scores between the two study groups. Descriptive statistics were reported using mean, median, and range. Categorical data were analyzed using the Chi-square test or Fisher's exact test. The two-sample student's t-test and Mann-Whitney U test were used to analyze continuous data. JMP®, Version 12 (SAS Institute Inc., Cary, NC) was utilized for all statistical analyses.

For the primary outcome, an intent-to-treat analysis was conducted including all patients regardless of whether or not initial and final PHQ-9/GAD scores were available. For secondary outcomes, per-protocol analyses were conducted including only patients who had data available for each individual outcome. Therefore, sample sizes vary for each secondary outcome based on the number of patients who had data available for that outcome. Various sample sizes used for analyses and corresponding results can be found in Tables 3–5.

Results

In total, 217 patients met inclusion criteria; 117 patients served as controls and 100 patients received clinical pharmacy services. All baseline clinical characteristics were similar between the study groups (Tables 1–2). Patients in the pharmacist group had slightly higher initial PHQ-9 and GAD scores compared to patients in the control group. Notably, not all patients had initial and/or final scores obtained (Table 3).

During the study period, pharmacists made twenty recommendations to patients of which nineteen were verbally accepted by the patient and confirmed via pharmacist note documentation (95%). Recommendations included medication administration timing/instructions (32%), adherence or self-management education (21%), pharmacologic/non-pharmacologic therapy (21%), starting new medications (16%), and dose adjustments (10%). Pharmacists made fifty-seven recommendations to prescribers of which forty-three were accepted and confirmed per written/verbal response or chart review (75%). The majority of accepted recommendations included medication dose adjustment (dose increase, decrease, or schedule adjustment, 47%), ordering of future monitoring lab values (16%), and switch to alternative therapy (12%). Other accepted recommendations included medication initiation or discontinuation (9%), prescription refill (9%), future dose adjustment consideration (5%), and psychotherapy review (2%). Recommendations to providers that were not accepted included dose adjustments prior to the patient's next visit, change to an alternative therapy, select monitoring

TABLE 1

Patient Demographics

VARIABLE	CONTROL N = 117	CASE N = 100	*P-VALUE*
Age, years	40	42	0.37
Sex, no. (%)			0.51
Male	40 (34.2)	30 (30)	
Female	77 (65.8)	70 (70)	
Race, no. (%)			0.92
Caucasian	94 (80.3)	78 (78)	
African American	11 (9.4)	13 (13)	
Other	12 (10.3)	9 (9)	
Primary diagnosis, no. (%)			0.79
Depression	80 (68.4)	64 (64)	
Anxiety	35 (29.9)	34 (34)	
Other	2 (1.7)	2 (2)	
Number of Comorbidities, no. (%)			0.31
1	16 (13.7)	11 (11)	
2	30 (25.6)	15 (15)	
3	23 (19.7)	22 (22)	
4	13 (11.1)	23 (23)	
5	16 (13.7)	11 (11)	
6	9 (7.7)	11 (11)	
7	5 (4.3)	3 (3)	
8	3 (2.6)	3 (3)	
10	2 (1.7)	1 (1)	
Number of Psychiatric Comorbidities, no. (%)			0.47
1	50 (42.7)	37 (37)	
2	44 (37.6)	47 (47)	
3	19 (16.2)	15 (15)	
4	2 (1.7)	1 (1)	
5	2 (1.7)	0 (0)	
Medication Change, no. (%)			0.32
Start	14 (12)	8 (8)	
Titrate	27 (23.1)	21 (21)	
Switch	4 (3.4)	3 (3)	
Stop	2 (1.7)	0 (0)	
Start and titrate	44 (37.6)	42 (42)	
Start and switch	2 (1.7)	1 (1)	
Titrate and switch	6 (5.1)	11 (11)	
Titrate and stop	1 (0.9)	0 (0)	
Start, titrate, and switch	17 (14.5)	11 (11)	
Start, titrate, and stop	0 (0)	3 (3)	
Number of types of medication changes	1.8	1.9	0.40

TABLE 2

Baseline Characteristics

VARIABLE[a]	CONTROL N = 107	CASE N = 94	*P-VALUE*
Initial PHQ9	13.9	15.2	0.18
Depression Severity, no. (%)			0.88
Minimal (0–4)	5 (4.7)	4 (4.3)	
Mild (5–9)	25 (23.4)	20 (21.3)	
Moderate (10–14)	29 (27.1)	21 (22.3)	
Severe (15–19)	22 (20.6)	21 (22.3)	
Very severe (20–27)	26 (24.3)	28 (29.8)	
VARIABLE[b]	CONTROL N = 90	CASE N = 94	*P-VALUE*
Initial GAD	12.0	12.8	0.37
Anxiety Severity, no. (%)			0.65
Minimal (0–4)	10 (11.1)	12 (12.8)	
Mild (5–9)	23 (25.6)	18 (19.2)	
Moderate (10–15)	26 (28.9)	25 (26.6)	
Severe (15–21)	31 (34.4)	39 (41.5)	

Notes: Sample sizes determined using the following: [a]patients with initial PHQ-9 reported; [b]patients with initial GAD reported.
Abbreviations: GAD, generalized anxiety disorder questionnaire; no., number; PHQ-9, patient health questionnaire.

TABLE 3

PHQ-9 and GAD Reporting

VARIABLE[a]	CONTROL N = 115	CASE N = 100	*P-VALUE*
Final PHQ-9 reported, no. (%)	58 (50.4)	65 (65.0)	
VARIABLE[b]	CONTROL N = 58	CASE N = 65	
Appropriately obtained PHQ-9 (performed within 2 weeks of patient's last clinic visit), no. (%)	36 (62.1)	39 (60.0)	0.81
VARIABLE[c]	CONTROL N = 103	CASE N = 96	*P-VALUE*
Final GAD reported, no. (%)	43 (41.7)	65 (67.7)	
VARIABLE[d]	CONTROL N = 43	CASE N = 65	
Appropriately obtained GAD (performed within 2 weeks of patient's last clinic visit), no. (%)	26 (60.5)	38 (58.5)	0.84

Notes: Sample sizes determined using the following: [a]patients with diagnosis of depression; [b]patients with final PHQ-9 scores reported; [c]patients with diagnosis of anxiety; [d]patients with final GAD scores reported.

TABLE 4

Primary Outcome

	BASELINE MEAN (SD)	END CLINIC CHANGE MEAN (SD)	DIFFERENCE IN CHANGE	*P-VALUE*
PHQ9				
Control, n = 117	13.9 (6.1)	−4.1 (5.8)	0.2	0.87
Case, n = 100	15.2 (6.9)	−4.3 (6.0)		
GAD				
Control, n = 117	12.0 (5.8)	−3.7 (5.3)	0.4	0.75
Case, n = 100	12.8 (6.3)	−4.1 (6.1)		

recommendations (e.g. drug or vitamin D level), or an over-the-counter symptom management recommendation.

The PHQ-9 and GAD scores improved by an average of 4.1 points (SD 5.8) and 3.7 points (SD 5.3) in the control group and by an average of 4.3 points (SD 6.0) and 4.1 points (SD 6.1) in the pharmacist group (*P-values* = 0.87, 0.75). No statistical difference was detected in the primary outcome (PHQ-9 0.2, *P-value* = 0.87; GAD 0.4, *P-value* = 0.75).

Secondary endpoints of time spent in clinic and time to psychotropic medication target dose were significantly longer in the pharmacist group by about two and a half weeks (11.1 vs 13.5 weeks, *P-value* = 0.01; 6 vs 8.7 weeks, *P-value* = 0.003). Self-reported patient adherence was also statistically significant, favoring a higher self-reported adherence rate in the pharmacist group (64.6% vs 78%, *P-value* < 0.0001). No statistical differences were detected in other patient adherence aspects including

TABLE 5

Secondary Outcomes

	CONTROL N = 117	CASE N = 100	*P-VALUE*
Time in clinic (weeks)[a]	11.1; 1.0–39.5	13.5; 3.0–45.0	0.01
	CONTROL N = 98	CASE N = 82	
Time to target dose (weeks)[b]	6.0; 0.0–25.8	8.7; 0.0–32.0	0.003
	CONTROL, N (%) N = 79	CASE, N (%) N = 91	
Patient adherence[c]			
Self-reported	51 (64.6)	71 (78.0)	< 0.0001
# no shows	33 (28.2)	32 (35.2)	0.78
Lost to follow up	25 (21.4)	25 (27.5)	0.53
Engaged in psychotherapy	72 (61.5)	71 (78.0)	0.14

Notes: Sample sizes determined using the following: [a]all study patients; [b]patients achieving target dose within study period; [c]patients with adherence data available.

number of no shows, patients lost to follow-up, and patients engaged in psychotherapy (*P-value* = 0.78, 0.53, 0.14, respectively).

Discussion

There were no statistically significant differences in baseline characteristics between groups. However, differences in baseline PHQ-9 may have been clinically significant, as patients on average had baseline moderate depression in the control group compared to severe depression in the intervention group. It is possible for this difference to enhance bias in the study, as patients starting out with more severe depression may either be more difficult to treat or have greater room for improvement.

Pharmacist recommendations were generally accepted by providers. Many of those not accepted would be best categorized as future considerations of a psychotropic medication change, which may or may not be appropriate given a patient's fluctuating course of illness.

Results demonstrated a small, but non-statistically significant difference in the change in PHQ-9 and GAD scores. These results are consistent with other literature that has failed to show a statistically significant difference in the change in clinical outcomes related to depression and anxiety as a result of pharmacist intervention.[3–6] However, there were several limitations in the study to consider when interpreting this outcome. A substantial limitation of the study was the short follow-up period. With the short-term management goals of the clinic, it is possible the time frame was not long enough to demonstrate an additional impact made by pharmacists on clinical outcomes as measured by PHQ-9 and GAD scores. With the long time to reach peak effect of psychotropic medications, patients may not fully realize the benefits of medication changes made in clinic until they have transitioned out of clinic. Another limitation was reporting bias due to the retrospective nature of the study and the inherent challenge in isolating the pharmacist's impact. Determination of the primary outcome required consistent PHQ-9 and GAD obtainment. However, there was a significant proportion of patients in both groups that did not have final PHQ-9 and/or GAD scores reported, and an even greater proportion of patients that didn't have scores reported appropriately within 2 weeks of patients' final visits in clinic. This data highlights the need to enhance measurement-based care in the psychiatric setting. Given the relatively low completion rate of PHQ-9 and/or GAD scores, an additional opportunity for pharmacists in our clinic may be to take the lead to increase completion rates. Lastly, the study sample did not reach the desired sample size needed to achieve statistical power to detect a difference between groups. Studies summarized in the review article by Goldstone et al. mirror our results,

emphasizing limitations of similar studies, including small sample sizes. Larger, well-designed studies are required to accurately document the impact of psychiatric pharmacists on clinical outcomes.

The secondary outcomes of time spent in the outpaitient psychiatric clinic and time to reach a stabilized psychotropic regimen favored the control group. A longer duration in these measures may be a result of recommendations by pharmacists leading to a greater number of medication changes in the intervention group. However, the present study analyzed the types of medication changes that were made, rather than the total number of medication changes, so it is difficult to determine whether this was a factor in the differences in the secondary endpoints. Stratification based on number of return visits and medication changes could assist future studies in more clearly defining disease severity and the pharmacist's impact on patient outcomes.

Patient self-reported adherence was significantly greater in patients who spoke with a pharmacist compared to patients who did not receive pharmacist follow-up. This is consistent with previous literature that has shown increased medication adherence with pharmacist interventions.[10] However, it is possible that these differences can be more easily explained by documentation differences rather than differences in clinical interventions. Pharmacists are trained to assess adherence, and often have a built-in adherence assessment in their note templates, making it possible that they are reporting it more consistently than providers. In this pilot study, objective data such as refill histories or pill counting were not utilized to assess adherence, but a standardized method of measuring adherence should be considered in future studies.

Since the study's completion, the outpatient psychiatric clinic has supported additional pharmacist resources, including additional pharmacist's time spent in clinic from initially covering 10% of the clinical pharmacist's salary, to currently covering 40%. Future directions in the clinic include standardization of patient referral to the pharmacists to ensure prioritization, more consistent documentation of PHQ-9 and GAD scores, and exploration of incorporation of genetic testing to improve pharmacotherapy selection in this patient population. In addition to more consistently measuring clinical outcomes, evaluation of both provider and patient satisfaction and openness to clinical pharmacy services in a psychiatric setting are potential humanistic outcomes to be considered in the future.

Conclusion

This study serves as an initial stepping stone for continuous development and quality improvement of the pharmacist role in the clinic described.

The study institution plans to use this information to enhance the care provided within the current clinic as well as future interprofessional psychiatry clinics. This may include full comprehensive medication reviews assessing medication appropriateness beyond psychiatric disorders, and more rigorous assessment of clinical outcomes utilizing measurement-based care. Further, other institutions may use this data to assist in development and implementation of a psychiatric outpatient clinical service with a collaborative approach to patient care, involving a pharmacist providing similar services and interventions as described. As we move towards a measurement focused chronic care model and encourage patient self-management, pharmacy intervention may be particularly helpful with regards to patient view of self-efficacy, self-confidence, and patient ownership of their treatment. ✤

Abbreviations

BCPP, Board certified psychiatric pharmacist; EMR, Electronic medical record; PHQ-9, Patient Health Questionnaire-9; GAD, Generalized Anxiety Disorder.

Conflicts of Interest

None.

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