

**Registry-Managed Care Coordination and Education for Patients with Co-occurring
Diabetes and Serious Mental Illness**

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Abstract

Objective: Longitudinal changes in health outcomes of patients with serious mental illness and co-occurring diabetes were examined after introduction of an intervention involving electronic disease management, care coordination, and personalized patient education.

Methods: This observational cohort study included 179 patients with serious mental illness and diabetes mellitus type 2 at a behavioral health home in Chicago. The intervention employed a care coordinator who used a diabetes registry to integrate services; patients also received personalized diabetes self-management education. Outcomes included glucose, lipid, and blood pressure levels as assessed by glycosylated hemoglobin, low-density lipoprotein, triglycerides, and systolic/diastolic values from electronic medical records, and completion of specialty visits confirmed with optometrists and podiatrists. Interrupted time-series segmented random-effects regression models tested for level changes in the eight study quarters following intervention implementation compared with eight preimplementation study quarters, controlling for clinic site and preimplementation secular trends.

Results: Significant declines were found in levels of glucose, lipids, and blood pressure postimplementation. In addition, completed optometry referrals increased by 44% and completed podiatry referrals increased by 60%.

Conclusions: Significant improvement in medical outcomes was found among patients of a behavioral health home who had comorbid diabetes and mental illness after introduction of a multicomponent care coordination intervention, regardless of which clinic they attended.

HIGHLIGHTS

- To address disproportionately high levels of co-occurring serious mental illness and type 2 diabetes, a new intervention employed a care coordinator who used a diabetes registry to integrate services and generate personalized diabetes education for patients.
- With the intervention, significant improvement was observed in patients' blood sugar, cholesterol, and blood pressure indicators, and completion of recommended eye and foot care appointments also increased significantly.
- This combination of evidence-based intervention components, previously found effective for other populations, was associated with improvement in a population of individuals with co-occurring diabetes and serious mental illness.

Changes among Patients with Co-Occurring Diabetes and Serious Mental Illness using Registry-Managed Care Coordination, and Personalized Diabetes Education

The prevalence of diabetes among adults with serious mental illness is two- to threefold higher than the general population (1,2), yet only one-third receive a diagnosis and treatment (3), and care is often subpar (4,5). Although the benefits of integrated primary and behavioral health care for this population are acknowledged (6,7), less is known about how to integrate specialized diabetes care (8). Integration strategies tested in the general population include care coordination (9), use of electronic registries (10), and personalized diabetes self-management education (11). This study examined changes in patient-level outcomes among adults with diabetes and serious mental illness following introduction of an intervention incorporating these strategies.

Care coordination involves connecting patients with healthcare providers, monitoring their treatment plans, educating them about their conditions, and sharing information to enhance effective care (12,13). Studies show that introducing dedicated staff who coordinate health care for people with serious mental illness significantly improves the quality and outcomes of primary care (14). Recipients in one of care coordination utilized more preventive services and more evidence-based cardio-metabolic care (15), and those in another study saw significantly improved mean scores for their physical health after one year (16). Despite this promising evidence, care coordination for diabetes management among individuals with serious mental illness is rare.

Disease registries are electronic databases containing medical information for patients with specific types of chronic illnesses that is used to facilitate delivery of evidence-based care (17). Registries notify providers of abnormal test results and missed appointments, track the

progress of high-risk patients, and enable health outcomes management at individual and clinic levels (18,19). One study of a diabetes registry introduced to primary care clinics found significant reductions in glycosylated hemoglobin (A1c) test levels (20), and another study of a diabetes registry adopted by primary care practices found significant improvement in A1c, low-density lipoprotein (LDL), and blood pressure outcomes (21). These studies suggest the promise of registries in the delivery of integrated care for patients with co-occurring diabetes and serious mental illness.

Diabetes patient education is designed to increase understanding of the disease and enhance skills and motivation for successful self-management (22). Effective delivery involves personalizing the information and incorporating their needs, goals, culture, and life experiences (23). Research shows that people with co-occurring diabetes and serious mental illness seldom receive diabetes education (5,24,25), although evidence indicates its effectiveness for this population (26,27). However, there are few diabetes education programs geared toward the specific needs of people with mental illness.

Medical homes deliver primary care that is patient centered, comprehensive, team-based, coordinated, and focused on quality and safety (28). Behavioral health homes integrate this kind of general medical care with services for patients with mental illness (29,30). One type of behavioral health home involves colocating primary care providers in community behavioral health care settings (31,32), with advanced practice nurses often delivering care (33,34). Patients report high satisfaction with colocation (35,36), and studies have found significantly improved A1c, blood pressure, and LDL levels among patients using this model (37,38).

This study examined the medical outcomes of patients with type 2 diabetes mellitus at a behavioral health home with colocated primary care providers after introduction of a practice

enhancement program including care coordination, registry-managed care, and personalized diabetes education. We hypothesized: 1) that there would be significant improvement over time in patients' A1c, LDL, triglyceride, and blood pressure values, and 2) that significant increases would occur in proportions receiving dilated eye and comprehensive foot examinations.

METHODS

Research Setting

The behavioral health home consisted of two primary care clinics operated by the University of Illinois at Chicago (UIC) College of Nursing that were colocated in an outpatient mental health program called Thresholds on the north and south sides of Chicago (39). Serving over 900 patients annually (40), each clinic was staffed by two or three advanced practice registered nurses authorized to provide primary care services without oversight of a medical doctor in the state of Illinois. A medical assistant performed clerical duties, such as reception and scheduling, and clinical functions, such as taking vital signs and drawing blood (41). Clinics used a team approach to care, rather than individual patient assignments.

Patients with diabetes were asked to keep daily logs of their blood sugar levels, but this occurred inconsistently. They often missed appointments or did not follow through on prescribed treatments and referrals. Even with colocation, the electronic health record (EHR) used by clinic staff was separate from that used by the mental health program, and the former required specialized programming to generate automated reports for patient tracking and clinic management. Thus, a registry was requested to bridge this gap. The latest audit prior to study inauguration found that 24% of diabetes patients with co-occurring hypertension had uncontrolled blood pressure and 33% did not meet the clinics' standard for glycemic control. This presented an ideal situation for introduction of care coordination using an electronic

registry, dedicated care manager, and personalized educational materials.

Study Population.

The study included 179 clinic patients with a diagnosis of diabetes mellitus type 2. Time since diagnosis ranged from 6 months to 20 years, and patients had high rates of co-occurring hypertension, coronary artery disease, kidney disease, and obesity. Most were covered by Medicaid (N=104, 58%) or Medicare (N=57, 32%), 5% (N=9) had private insurance, and 5% (N=9) were uninsured. At study inauguration, 89% (N=159) of clinic patients were prescribed metformin, 65% (N=116) ACE inhibitors, 28% (N=50) insulin, 32% (N=57) glitazones, and 19% (N=34) sulfonylurea. Study procedures were approved by the UIC Institutional Review Board.

Intervention

The *registry* contained EHR information specific to diabetes management, including diagnoses of general medical and mental health conditions, laboratory results, appointment data, referrals for specialty care, and lifestyle factors (e.g., smoking and diet). Registry data were used to generate specialized reports for patients, providers, and administrators. For providers, patient-specific reports generated before each visit summarized recent lab values and test results, and flagged out-of-range values for further attention. For patients, user-friendly “report cards” showed trends over time in A1c, LDL, and blood pressure, and included reminders for upcoming eye or foot exams. Reports for administrators summarized patient outcomes and appointment attendance by clinic and across clinics.

A *care coordinator* split work time to 50% at each clinic and was tasked with linking behavioral and primary care providers via email and telephone, enhancing communication between the two groups, and sorting out glitches in appointment scheduling and transportation.. She also populated the registry with lab values and appointment information, and generated all

reports. Direct patient contact included reminding patients by telephone of appointments, accompanying patients to specialty care visits, discussing report card results, and providing diabetes education. The coordinator also facilitated specialty care by negotiating specific blocks of appointment time with university outpatient eye and podiatry clinics, arranging transportation with mental health case managers, and scheduling appointments with eye and foot specialists willing to conduct examinations onsite.

University researchers worked with the coordinator, primary care providers, mental health program staff, people with lived experience of diabetes and mental illness, and medical students to develop *patient self-management education materials*. These were packaged as an online Diabetes Education Toolkit of didactic information linked to care standards and related podcasts for use with patients in the clinic. A central part of the Toolkit was a “library” of one-page information sheets. These were written at a grade-school level to accommodate low levels of health literacy and numeracy (the patient’s ability to interpret and act on quantitative and probabilistic health information in making effective health decisions) commonly found among people with serious mental illness (42,43,44). The library covered a variety of topics linked to treatment regimens, co-occurring conditions, and strategies for diabetes self-management. To personalize education for each patient, the coordinator selected topics based on out-of-range lab values, poor health indicators, or clinical goals for that patient. Attaching educational materials to patient-specific reports prompted medical providers to review them with patients and send them home for sharing with family and other supporters. The same materials were sent by the coordinator to case managers with reminders to review them at the patient’s next behavioral health visit. Behavioral healthcare provider participation included reviewing and reinforcing diabetes education and treatment regimens, providing transportation to specialty appointments,

and sharing treatment plans with the care coordinator and clinic medical staff.

Study Design

Because of the highly vulnerable nature of the patient population, random assignment was not considered practical or ethical. Instead, we used a one-group pre-post interrupted time-series design, one of the strongest quasi-experimental designs (45). For this approach, data on all participants are collected at equally spaced time points (in this case quarterly) before and after an intervention is implemented (46). The main objective is to examine whether data patterns observed postimplementation are different from those observed preimplementation by using segmented regression analysis (45,47). The preintervention segment acts as a control for secular trends in outcomes that may occur and that are unrelated to the intervention (45,48).

Measures. Registry data were extracted for all patients with type 2 diabetes served in the eight quarters prior to intervention implementation (April 1, 2010 through March 31, 2012) who also had one or more lab values in the eight quarters following implementation (April 1, 2012 through March 31, 2014), with extraction ending March 31, 2014. Values were grouped by study quarter; when there were multiple measures in a quarter, the last measure in the quarter was used. Values included A1c, LDL, triglycerides, and systolic and diastolic blood pressure. Occurrence of eye and foot examinations was verified with patients' podiatry and optometry providers and calculated as the proportion completed annually per American Diabetes Association (ADA) guidelines (49).

Analysis

Standard descriptive analysis was conducted to examine the distributions and measures of central tendency of all variables. The characteristics of each clinic's patients were compared and tested for significant differences. Next, paired t-tests were computed to assess change following

intervention implementation by using the approach of Fesseha and colleagues (50) in which baseline A1c was defined as the final measure during the preimplementation period and compared to the nadir A1C which was defined as the single lowest postimplementation measurement. Use of nadir LDL, triglyceride, and blood pressure values also followed published analyses (51-53). Multivariable interrupted time-series segmented random-effects regression models were used to examine changes in values over 16 quarters of data (eight pre- and eight-post implementation). The models accounted for autocorrelation of repeated measures using first-order autoregressive covariance structures, and controlled for study site to adjust for differences in clinic populations, and for number of outcome measurements. Potential seasonal effects on outcomes were accounted for by use of 4 years of data with equal seasonal exposures before and after the intervention (54). We posited an impact model that would show no significant preintervention trends in outcome measures and a statistically significant postintervention level change in outcomes. To measure change in specialty eye and foot care we calculated the percentage completing each examination during the 12-month period at the end of the first eight quarters (April 1, 2011 through March 31, 2012) and the end of the second 8 quarters (April 1, 2013 through March 31, 2014). Analyses were conducted in IBM SPSS Statistics, version 25, and SAS, version 9.4.

RESULTS

Table 1 presents the background characteristics of 179 patients, in total and by clinic location. Around two-thirds were male, and the average age was 51.2. Approximately a third (31%) did not complete high school. Most had primary diagnosis of schizophrenia (38%, N=68) or schizoaffective disorder (24%, N=43), 19% had bipolar disorder, and 19% had major depressive disorder. Clinic patient populations were highly similar, except for significantly

higher proportions of African American patients at the south location and Whites at the north location, reflecting the racial makeup of their surrounding communities. When this group of 179 was compared with the 48 patients excluded because they lacked lab values in the postimplementation period, no significant differences ($p < 0.05$) in age, gender, race, education, or psychiatric diagnosis were found.

Table 1 also presents patient medical outcomes. The mean A1c level for the sample was 7.4 ± 2.2 , which exceeded the recommended level of < 7 in the 2010 ADA standards in effect at baseline (49,54). The average LDL level was 96.2 ± 34.1 , which is below the recommended level of < 100 in the standards. The average triglycerides level was 134.7 ± 81.2 , which is below the recommended level of < 150 . The average systolic blood pressure was 124.0 ± 14.8 , and the average diastolic was 81.4 ± 8.5 , which exceed the recommended level at baseline of $< 130/80$ for the diastolic value but not the systolic value. The only significant difference by clinic concerned triglycerides, which were higher at the north clinic (154.5 ± 91.8), exceeding the recommended level.

Table 2 presents paired t-tests of the change in medical outcomes between pre- and postimplementation periods. Compared with their final preimplementation value, individuals' nadir measurements after intervention implementation were significantly lower for A1c (average decline = -0.68 ± 1.16 , $t = 7.55$, $df = 168$, $p < 0.001$), for LDL (average decline = -9.31 ± 24.73 , $t = 4.89$, $df = 168$, $p < 0.001$), for triglycerides (average decline = -16.79 ± 56.35 , $t = 3.73$, $df = 156$, $p < 0.001$), and for systolic and diastolic blood pressure (average systolic decline = -12.65 ± 10.54 , $t = 15.59$, $df = 168$, $p < 0.001$; average diastolic decline = -9.20 ± 7.14 , $t = 16.75$, $df = 168$, $p < 0.001$).

Table 3 presents the results of multivariable interrupted time-series random-effects regression analyses. Significant post-implementation level decline was found in A1c (-0.75 ± 0.35 ,

p=0.032), LDL (-19.75 ± 8.07 , p=0.015), triglycerides (-47.88 ± 22.75 , p=0.037), and blood pressure $\geq 130/80$ (-2.07 ± 0.71 , p=0.004). No significant secular trends occurring in outcomes prior to the intervention were noted, with the exception of blood pressure, which showed a small preintervention decline (-0.12 ± 0.04 , p=0.001). Also, no significant differences were found in outcomes associated with study site, except for blood pressure, which was lower at the north than at the south clinic (-0.74 ± 0.24 , p=0.002).

Finally, we examined changes in the proportions of patients who completed specialty care appointments for monofilament foot and dilated eye examinations. Results (not shown) revealed significant increases in the proportion completing eye exams, from 23% (N=40 of 173) preimplementation to 34% postimplementation (N=58 of 173) ($\chi^2=4.46$, N=173, df=1, p=0.023), as well as increases in the proportion completing foot examinations, from 17% (N=30 of 174) to 28% (N=48 of 174) ($\chi^2=5.35$, N=174, df=1, p=0.014).

DISCUSSION

Following introduction of a multicomponent intervention designed to improve patient outcomes and adherence to diabetes care standards, significant improvement was noted in glucose, lipid, and blood pressure indicators. In addition, patient completion of optometry referrals increased by 44% and completion of podiatry referrals increased by 60%. Ours is the first study to show that this combination of evidence-based intervention components, previously found effective for other populations, was associated with improvement in a population of people with co-occurring diabetes and serious mental illnesses.

More limited success was achieved with specialty care outcomes, despite extensive planning with the directors of university eye and podiatry clinics. Accommodations included setting aside special dates and times for appointments, provision of transportation, telephone

reminders, and support from the project's care coordinator who "hung out" with patients in clinic waiting areas providing magazines and healthy snacks. This speaks to persistent barriers to receiving care outside the health home when patients are required to travel to unfamiliar treatment locations. The patient appointment no-show rate for the on-site clinics was a noteworthy 24%, so keeping off-site appointments at university outpatient clinics remained particularly challenging.

The care coordinator devoted considerable effort to engaging behavioral health staff in an understanding of each patient's diabetes management goals. In particular, sharing patients' report cards and individualized education materials with mental health staff, along with reminders to discuss them at the next meeting, helped provide a consistent message to patients about self-managing their diabetes. The report card motivated patients by visually illustrating how their medical test results were improving, remaining stable, or worsening over time. Dedicating the time of the care manager to maintaining the registry and generating specialized reports helped fill a gap in information that clinics' nursing staff and management had identified as problematic.

The Diabetes Education Toolkit was used in several ways. Although primary care providers were well educated about diabetes, they expressed appreciation for being able to access a variety of handouts written at a level their patients could understand. Because behavioral health staff were not well educated about diabetes or diabetes self-management strategies, they used the Toolkit to increase their own and their clients' awareness of diabetes basics, available treatments, common co-morbidities, and self-management strategies. As such, the Toolkit helped both sets of staff to deliver easily understandable and consistent messages to patients about how to better manage their diabetes. This Toolkit is updated annually and can be accessed along with a simple

diabetes tracking spreadsheet in Microsoft Excel at

<https://www.center4healthandsdc.org/diabetes-education-toolkit.html>.

Approximately 55% of clinic patients reported being current smokers, which may have interfered with their achievement of targeted health outcomes. Although nurses reported that they encouraged smoking cessation at every visit, coordinated efforts to engage patients in accessible, evidence-based smoking cessation classes might have helped improve their diabetes and overall health outcomes (56,57). Similarly, 49% of patients were obese, and another 14% were overweight. Although nurses encouraged weight loss, patients did not have access to evidence-based weight management classes that were welcoming to people in mental health recovery (58).

Some caveats apply to our findings. First, our study population came from a single behavioral health home and was not a nationally representative sample, which may limit the generalizability of our findings. Second, our data came from EHRs and the reports of podiatrists and optometrists regarding specialty visit completion. Data gathered directly from patients would have shed light on their reactions to the educational materials and their satisfaction with primary care services. Third, in the absence of a randomized controlled trial, we cannot attribute the positive changes we observed to the intervention itself. Finally, use of a single care coordinator may also limit the generalizability of findings regarding this role's impact.

CONCLUSIONS

Comorbid mental illness and diabetes are associated with poor quality of life, low treatment adherence, inferior glycemic control, frequent use of emergency department and inpatient care, and high medical costs (6, 59). Costs for patients with co-occurring psychiatric and endocrinal disorders are twofold or even higher (depending on treatment setting) compared

with costs incurred by patients with endocrinal disorders alone (1). To address these formidable obstacles, our findings and those of others can be used to create interventions that incorporate additional evidence-based practices. These include proven weight reduction strategies (60), smoking cessation models (61), and substance use treatment (62) that address the needs of lower-income populations with limited health literacy and additional general medical and behavioral health comorbidities. Finally, research using rigorous designs will be required to further develop these types of interventions and evaluate their feasibility and effectiveness.

Table 1: Baseline characteristics of study participants with co-occurring diabetes and serious mental illness (N=179)

Characteristics	Total (N=179)		North Clinic (N=88)		South Clinic (N=91)	
	N	%	N	%	N	%
Gender						
Male	119	66.4	60	68.2	59	64.8
Female	60	33.5	28	31.8	32	35.2
Race						
Black	107*	61.8	40	46.5	67	77.0
White	49*	28.3	36	40.9	13	14.9
Hispanic	5	2.9	1	1.2	4	4.6
Asian	4	2.3	3	3.5	1	1.1
Other	8	4.6	6	7.0	2	2.3
Age (M±SD)	51.2± 9.8		52.5± 9.6		50.0± 9.8	
Education						
< High School	48	30.9	18	25.3	30	35.8
High School Graduate	65	41.9	36	50.7	29	34.5
Some College	30	19.4	11	12.5	19	22.7
College Graduate	12	7.8	6	8.4	6	7.2
Diagnosis						
Schizoaffective Disorder	43	24.0	16	18.2	27	29.7
Schizophrenia	68	38.0	37	42.0	31	34.1
Bipolar Disorder	34	19.0	16	18.2	18	19.8
Depressive Disorder	34	19.0	19	21.6	15	16.5
Baseline Medical Outcomes (M, SD)						
A1c	7.36	2.20	7.24	1.90	7.47	2.46
LDL	96.15	34.06	99.98	33.15	93.70	36.12
Triglycerides	134.74*	81.25	154.46	91.81	120.83	72.33
Blood Pressure						
Systolic	123.96	14.84	125.94	16.30	120.64	13.36
Diastolic	81.35	8.53	80.59	9.12	82.64	8.47

*p < .05 in chi-square or independent t-tests

Table 2. Changes in diabetes-related medical outcome measures from pre-to postimplementation of the intervention

Medical Outcomes	Change from pre- to post-implementation		Test Statistic ^a	Df	P
	M	SD			
A1C	-0.68	1.16	t=7.55	168	<.001
LDL	-9.31	24.73	t=4.89	168	<.001
Triglycerides	-16.79	56.35	t=3.73	156	<.001
Blood pressure: Systolic	-12.65	10.54	t=15.59	168	<.001
Blood pressure: Diastolic	-9.20	7.14	t=16.75	168	<.001

^a Paired t-tests compared the final value from the preimplementation period with the nadir value from the postintervention period (p<.001 for all comparisons)

Table 3. Interrupted time-series random-effects regression models of postimplementation changes in medical outcomes^a

Medical Outcome	Estimate	SE	p	95% CI
A1C				
Intercept	7.01	0.16	<.001	6.70, 7.31
Site ^b	-0.20	0.18	.267	-0.55, 0.15
Pre-Intervention Secular Trend	-0.03	0.02	.117	-0.07, 0.01
Post-Intervention Level Change	-0.75	0.35	.032	-1.43, -0.06
Number of observations	0.07	0.04	.092	-0.12, 0.16
LDL				
Intercept	97.61	3.71	<.001	90.32, 104.91
Site ^b	-1.09	4.09	.791	-9.17, 7.00
Pre-Intervention Secular Trend	-0.51	0.49	.306	-1.48, 0.47
Post-Intervention Level Change	-19.75	8.07	.015	-35.62, -3.89
Number of observations	1.03	1.32	.433	-1.55, 3.62
Triglycerides				
Intercept	130.34	9.82	<.001	110.98, 149.69
Site ^b	14.30	9.62	.140	-4.77, 33.37
Pre-Intervention Secular Trend	-0.97	1.55	.534	-4.05, 2.11
Post-Intervention Level Change	-47.88	22.75	.037	-92.83, -2.93
Number of observations	3.60	4.49	.422	-5.23, 12.44
Blood Pressure ^c				
Intercept	-0.87	0.24	<.001	-1.34, -0.41
Site ^b	-0.74	0.24	.002	-1.22, -0.27
Pre-Intervention Secular Trend	-0.12	0.04	.001	-0.19, -0.05
Post-Intervention Level Change	-2.07	0.71	.004	-3.46, -0.68
Number of observations	0.02	0.08	.822	-0.13, 0.17

^a The analysis controlled for preimplementation trends, clinic site, and number of observations among patients.

^b 1= North clinic, 0 = South clinic.

^c $\geq 130/80 = 1$, $< 130/80 = 0$.

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