2015

Justifying the Implementation of a Collaborative Drug Therapy Management (CDTM) Protocol in an Outpatient Psychiatric Clinic: A Retrospective Chart Review

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Thesis title Justifying the Implementation of a Collaborative Drug Therapy Management (CDTM) Protocol in an Outpatient Psychiatric Clinic: A Retrospective Chart Review

Intended date of commencement 05/09/2015

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For Honors Program use:

Level of Honors conferred: University Magna cum laude

Departmental Honors in Pharmacy

Justifying the Implementation of a Collaborative Drug Therapy Management (CDTM) Protocol in an Outpatient Psychiatric Clinic: A Retrospective Chart Review

A Thesis

Presented to the Department of Pharmacy

College of Pharmacy and Health Sciences

and

The Honors Program

of

Butler University

In Partial Fulfillment

of the Requirements for Graduation with Honors

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PharmD Candidate, Butler University

April 22, 2015

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ABSTRACT

Objective

To identify opportunities where pharmacists could intervene and justify the benefits of outpatient clinical pharmacy services through a CDTM protocol within Gallahue Mental Health Center by assessing current antipsychotic monitoring

Methods

A retrospective chart review was performed of patients visiting an outpatient psychiatric clinic over 14 months. A review was also completed of patients followed at two primary care clinics within Community Health Network. Patients were at least 18 years old and had at least one active antipsychotic prescription. A standardized data collection sheet was used to document monitoring frequency and appropriateness as recommended by the 2004 American Diabetes Association consensus statement. Demographic information was also collected.

Results

Of those primarily followed in Gallahue, only 1% had any documented fasting blood glucose or lipid panel, 23% had any documented blood pressure, and 53% had any documented weight. This differed greatly from the primary care clinics' results of 63%, 100%, and 92%, respectively. The majority of providers did not adequately document reasons for not performing recommended monitoring.

Conclusion

Substantial discrepancies exist between current and guideline-recommended monitoring practices of patients on antipsychotics, thereby supporting CDTM between clinical pharmacy specialists and providers as a possible solution to improve evidence-based patient care.

INTRODUCTION

Schizophrenia, Antipsychotic Medications, and Beyond

Of the various afflictions to the human body, psychiatric disorders, namely schizophrenia, have eluded a clear defining and thereby understanding of etiology. The term "schizophrenia" was first introduced to the medical community by Swiss psychiatrist Eugen Bleuler in 1908, a break from a long-standing diagnosis of "dementia praecox" that gave all patients with psychosis an unavoidably poor prognosis.[1] Schizophrenia as a disease state, therefore, rose from opposing opinions on how diagnosed patients would progress rather than from an exact matter of pathophysiology. Such grey area in psychiatry persists today, with the fifth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5) placing schizophrenia as a diagnosis on the continuous schizophrenia spectrum.[2] Understanding a patient's psychosis is relative at best, relying heavily on the process of differential diagnosis.

That elusive understanding of psychosis has come in closer reach with the advent of antipsychotic agents. The first typical antipsychotic chlorpromazine was introduced in the early 1950s, followed by the first atypical antipsychotic clozapine in the late 1960s and over 60 other antipsychotic agents at some point in time worldwide.[3] Biomedical researchers have suggested excess dopaminergic transmission as the cause for diseases like schizophrenia, since all antipsychotic drugs to date have some degree of dopamine blockade.[4] This is likely not the complete story, however: none of these agents fully alleviate all symptoms associated with schizophrenia, and some atypical antipsychotic

agents have seemingly been just as or even more effective for disease states outside of the schizophrenia spectrum, such as bipolar disorder and major depressive disorder.[5,6] No matter the lack of clarity, though, antipsychotic medications remain an important component of therapy for patients with psychiatric disorders.

Antipsychotic Medications' Inherent Risks

While demonstrating efficacy in controlling psychiatric disorders, antipsychotic medications are not without significant short- and long-term risks. Typical, or "first-generation," antipsychotic agents are shown to cause a significant degree of extrapyramidal side effects (EPS) and other neurologic adverse drug reactions, thought to be associated with their potent blockade of D2 receptors that induces a neurochemical imbalance as seen in Parkinson's disease.[7,8] Atypical, or "second-generation," antipsychotic agents are believed to cause a lesser degree of EPS, though their long-term use is associated with an increased risk of metabolic syndrome.[9,10] The American Heart Association and National Heart, Lung, and Blood Institute have defined metabolic syndrome as at least three of the following risk factors: large waistline ($\geq$40" in men and $\geq$35" in women); high triglyceride level ($\geq$150 mg/dL); low HDL cholesterol level (<40 mg/dL in men and <50 mg/dL in women); high blood pressure ($\geq$130 mmHg systolic or $\geq$85 mmHg diastolic); or high fasting blood sugar ($\geq$100 mg/dL).[11] The causal relationship between atypical antipsychotics and metabolic syndrome is unclear and likely multifactorial. Proposed mechanisms of this relationship have included impaired tissue glucose uptake due to 5-HT_{2A} receptor antagonism;

impaired insulin gene expression by pancreatic beta-cells due to inhibition or induction of various enzymes; and impaired activity of leptin, a hormone involved in appetite control, due to 5-HT_{2C} receptor antagonism.[12]

Psychiatric and Cardiovascular Disease

To build upon the risks associated with atypical antipsychotic use, a review of the literature suggests that patients with psychiatric disorders are predisposed to cardiovascular disease. A 2011 selective review for epidemiological, morbidity, and mortality data on the relationship between psychiatric disorders and physical illnesses concluded that individuals with severe mental illness were more likely to have hypertension, dyslipidemia, or diabetes mellitus; to be overweight or obese; and to smoke.[13] While lifestyle habits and access to primary care are surely contributing factors, this overarching trend across various populations may indicate a link to the disease process itself.

A Call for Closer Clinical Monitoring

A national probability sample survey of office-based physician practices to evaluate antipsychotic use trends in the United States found that antipsychotic-related office visits increased from 4.6 million in 1998 to 8.6 million in 2002, a change of 187%.[14] With the continued discovery of new antipsychotic drugs and their expanding use in unique disease states since 2002, practice guidelines and guidance documents were developed to help clinicians monitor the safety of the increased number of patients using these agents.

The 2002 Mount Sinai Conference, an assembly of expert psychiatry-focused research groups, created a summary document that included

recommended monitoring frequencies for different types of antipsychotic medications. The document's recommendations included annual monitoring, at minimum, for tardive dyskinesia and EPS using a standardized tool such as the Abnormal Involuntary Movement Scale (AIMS).[15] A copy of this scale, which includes standardized monitoring for EPS, can be found in Appendix A.

As more literature came to light involving the close association between atypical antipsychotics and cardiovascular disease, the American Diabetes Association (ADA), along with the American Psychiatric Association, the American Association of Clinical Endocrinologists, and the North American Association for the Study of Obesity, published a consensus statement conveying recommendations for atypical antipsychotic monitoring practices. Monitoring measures recommended in this document included personal and family history of metabolic syndrome risk factors, weight, waist circumference, blood pressure, fasting plasma glucose, and fasting lipid profile.[16] These measures would allow the psychiatrist or other provider to initiate appropriate therapy for the comorbidity, or refer the patient to another health care professional knowledgeable about the disease state. A copy of this monitoring protocol for atypical antipsychotics is found in Appendix B.

Continuing Gaps in Patient Care

Although published over a decade ago, available research suggests that actual clinical practices have been slow to adopt ideal monitoring recommendations. A 2012 systematic meta-analysis of both inpatient and outpatient studies analyzing routine screening practices in patients taking

antipsychotics found that blood pressure and triglycerides were the only parameters measured at a rate above 50%; the nine studies that directly examined monitoring before and after guidelines implementation only found a statistically significant improvement in fasting blood glucose testing at 15.4% (RR 1.47, 95% CI 1.13-1.9, p=0.005).[17] More so, it has been estimated that at least 20 minutes are necessary for metabolic syndrome screening in addition to a standard psychiatric consultation.[18] The anecdotal estimate for length of a follow-up visit within Gallahue Mental Health Center is 15 minutes. While psychiatrists and other behavioral health providers have the literature to understand these medication-related issues, they may not have enough time in an individual's follow-up visit to address such monitoring.

Collaborative Drug Therapy Management

As pharmacists have gained more experience in specialty areas of medicine, clinical practice has evolved to allow them greater autonomy to affect patient care positively. The American College of Clinical Pharmacy (ACCP) published a position statement in 2003 regarding collaborative drug therapy management (CDTM), defined as the following:

> "a collaborative practice agreement between one or more pharmacists working within the context of a defined protocol [that] are permitted to assume professional responsibility for performing patient assessments; ordering drug therapy-related laboratory tests; administering drugs; and selecting, initiating, monitoring, continuing, and adjusting drug regimens"[19]

Such work has grown rapidly throughout the past decade, with 47 states (including Indiana) and the District of Columbia allowing some degree of CDTM as of early 2013.[20] The majority of these agreements have been in the practice

areas of infectious disease, anticoagulation, parenteral nutrition, pain management, cardiovascular health (*e.g.* heart failure, dyslipidemia, hypertension), and diabetes mellitus.[21]

Psychiatric Pharmacists' Qualifications

Clinical pharmacy specialists have the opportunity to target psychiatry as their field of expertise through additional training beyond a Doctor of Pharmacy degree. The American Society of Health-System Pharmacists (ASHP) offers accredited residency programs in psychiatric pharmacy, which seek to develop multidisciplinary team skills and improve pharmacotherapy knowledge related to behavioral health disorders.[22] Pharmacy fellowships are also available for additional training, though only one psychiatry-focused fellowship has been accredited by ACCP.[23] The Board of Pharmacy Specialties (BPS), an autonomous division of the American Pharmacists Association (APhA), provides pharmacists with the opportunity to become board-certified in psychiatric pharmacy, demonstrating their ability to assess patients, monitor drug responses, recognize drug-induced problems, and recommend appropriate treatment plans.[24] In addition to formalized training and certifications, the College of Psychiatric and Neurologic Pharmacists (CPNP), a professional pharmacy organization, offers a platform for clinical pharmacy specialists to consult colleagues on unique challenges that arise in their practices.[25] Through residency or fellowship training, board certification, and the support of professional organizations, psychiatric pharmacists are well-qualified to make significant contributions to the ongoing, chronic care of their patients.

Psychiatric Pharmacists within CDTM

While plenty of literature is available supporting CDTM's impact on patient care outcomes for cardiovascular and endocrine disease states, information regarding CDTM practices in psychiatry-specific populations is limited. Some of the published literature has involved safety-net clinics and indigent populations, cases that are hard to generalize to other care centers.[26,27] Other pharmacist-run psychiatric services have been started within the Department of Veterans Affairs, a health system that is difficult to extrapolate to private sector practices due to its long-standing history of giving expanded prescribing rights to pharmacists.[28,29] Furthermore, almost all psychiatric pharmacists serving these clinics were funded at least in part by a university, making the setup of such clinics less financially feasible in a non-teaching health system.[18,26,27,29,30] A meta-analysis of the literature from 1972 to 2003 found significant improvements in the use of psychotropic drugs when clinical pharmacists acted as treatment consultants and patient educators, despite the lack of large-scale studies.[31] Until such studies are completed, site-specific studies are critical in proving the value of psychiatric pharmacists in mental health clinics.

Community Health Network

Community Health Network is a non-profit, non-teaching health system with more than 200 patient care sites throughout central Indiana.[32] The health system also acts as the largest provider of behavioral health for central Indiana, with more than 19,000 outpatient client visits each year provided to pediatric, adult, and geriatric populations.[33] Gallahue Community Support Services

(GCSS), one of several outpatient psychiatric clinics within the health system's Gallahue Mental Health Center, was the primary location involved in this study. Eastside Medical Center and Jane Pauley Primary Care Clinic, the secondary locations involved in this study, are outpatient primary care clinics for the health system. These primary care clinics already have clinical pharmacists on staff acting within collaborative practice agreements; however, they are similar to GCSS by their geographical location and high proportion of Medicaid-insured patients, allowing for appropriate comparison in this study.

Project Scope

A clinical pharmacy specialist in psychiatry currently spends approximately 20 hours each week at GCSS, informally seeing patients in an effort to improve their long-term medication monitoring. A previous pharmacy-driven study within Community Health Network worked on establishing psychiatrist-pharmacist relationships and determining an appropriate means of billing for the psychiatric pharmacist.[34] This study will build upon that foundation, adding a clinical backing to these pharmacoeconomic dimensions. The presented thesis focuses on the information obtained from the retrospective chart review phase of this overall initiative and was completed to fulfill the Doctor of Pharmacy degree graduation requirements for the author.

OBJECTIVES

The primary objective of this study was to demonstrate the need for pharmacy staff and to justify the benefits of implementing outpatient clinical pharmacy services through a CDTM protocol at Gallahue Mental Health Center in Indianapolis, Indiana. A parallel objective was to collect, analyze, and present data on current antipsychotic monitoring practices at an outpatient psychiatric clinic, specifically in relationship to evidence-based guidelines and to monitoring practices at two primary care clinics within Community Health Network.

HYPOTHESIS

Considering the literature on current antipsychotic monitoring trends, it was hypothesized that monitoring practices at GCSS would fall short of those recommended by the 2002 Mount Sinai Conference and the 2004 ADA consensus statement. It was also predicted that more frequent monitoring would be documented for those patients primarily followed at a primary care clinic, since these providers are more commonly focused on hypertension, dyslipidemia, and diabetes mellitus.

METHODS

Project Timeline

The study was approved by the Community Health Network Institutional Review Board in October 2014 in conformity with the Declaration of Helsinki's research principles.[35] Additionally, as required by Butler University and

Community Health Network policies, the Collaborative Institutional Training Initiative (CITI) Program covering human subject research was completed prior to starting the project.[36] Data collection began in early November 2014 and concluded in early January 2015. Statistical analysis of the data took place throughout February and March. Study findings were presented in April at the Butler University Undergraduate Research Conference.

Inclusion and Exclusion Criteria

Patients were included in the study if they were at least 18 years old and had at least one active prescription for an antipsychotic medication. Patients were excluded if they did not meet the age requirement or did not attend at least one follow-up visit at their clinic site.

Data Source

A possible subject list was created by pulling the medical record number (MRN) from the Epic® electronic medical record system of patients who visited one of the study sites from November 1, 2012, to December 31, 2013, and were prescribed a medication in the therapy class of "psychotherapeutic drugs." The start date was chosen based on when Epic® was fully implemented within the Community Health Network sites of interest, and the 14-month timespan was chosen to capture one year's worth of baseline and follow-up visits for included subjects. The generated list was narrowed to include only those patients prescribed an antipsychotic medication. The data collection phase of the study utilized this revised list.

Data Collection Sheet

A data collection sheet was developed prior to the study's beginning that incorporated monitoring parameters from both the 2002 Mount Sinai Conference and the 2004 ADA consensus statement. In addition to demographic information, data on currently and previously prescribed antipsychotics, indication, other active medications, comorbidities, social history, and time between clinic visits was gathered to get a better account of overall clinic practices. Images of this data collection sheet can be found in Appendix C.

Statistical Analysis

The primary means of study analysis for baseline subject characteristics and other nominal data was descriptive statistics. Due to the small volume of documented values, information on monitoring for tardive dyskinesia, EPS, and metabolic syndrome was converted to nominal data where feasible for ease of analysis. Most of the demographic information was analyzed for significant differences with a Chi-square test or a Fisher's exact test, with the exception of an ANOVA test for ethnicity, an ANOVA test for antipsychotic indication, and an unpaired t-test for age. In addition, a Chi-square test or Fisher's exact test analyzed number of documented visits, specific antipsychotic use, and whether or not monitoring was completed at the various clinic sites. A p-value < 0.05 was set as the threshold for statistical significance for all of these tests.

For quantitative monitoring results, mean values were calculated for weight, systolic blood pressure, diastolic blood pressure, fasting blood glucose, total cholesterol, triglycerides, HDL cholesterol, and LDL cholesterol. An unpaired

t-test was used to compare the calculated means of GCSS and of the two primary care clinics, with a p-value < 0.05 set as the threshold for statistical significance. Statistical tests were not run for tardive dyskinesia and EPS monitoring due to a lack of documented results from the two primary care clinics.

All statistical tests mentioned above were run using the Microsoft Excel 2010 Analysis ToolPak Add-In.

RESULTS

Study Size and Demographics

Of the patients that were prescribed a "psychotherapeutic drug," two-hundred fifty individuals were receiving an antipsychotic medication. Following the completion of data collection, two-hundred four subjects were found to be eligible for inclusion in study analysis: 88% (n=180) from GCSS and 12% (n=24) from the two primary care clinics. A diagram detailing the exact number of subjects from each clinic included and excluded is shown in Appendix D.

Most of the GCSS subjects were female at 54% (n=98), with the same percentage of females present in the primary care clinics (n=13). The majority of GCSS subjects were Caucasian and black at 52% (n=93) and 45% (n=81), respectively. This ethnicity trend was inverted at the primary care clinics, with 42% (n=10) being Caucasian and 54% (n=13) being black. The mean age for GCSS subjects was 44.9 ± 12.9 years, which was lower than the primary care clinics' mean age of 49.1 ± 19.5 years. Hypertension, hyperlipidemia, and obesity were the most common comorbidities in all subject groups, with obesity as the

most frequently reported in 52% (n=93) of GCSS subjects and 54% (n=13) of primary care clinic subjects. Hyperlipidemia was the only comorbidity with a statistically significant difference, being found in 24% (n=43) of GCSS subjects and 58% (n=14) of primary care clinic subjects (p=0.0004). Hypertension ($p<0.05$), diabetes mellitus (p=0.0084), and CAD (p=0.0066) were significantly more present in the family histories of GCSS subjects. Tobacco, alcohol, and illicit drug use were frequent, with 44% (n=79) of GCSS subjects and 33% (n=8) of primary care clinic subjects having documented tobacco use.

While not statistically significant, some perhaps clinically significant differences were found between study groups concerning antipsychotic indication and use history. The most common indications for antipsychotic use at GCSS were schizophrenia at 49% (n=89) and schizoaffective disorder at 23% (n=42), in contrast to rates of 13% (n=3) and 0% respectively at the primary care clinics. The most common indication at the primary care clinics was major depressive disorder (MDD) at 29% (n=7). In addition, 27% (n=48) of GCSS subjects had some documented history of antipsychotic use, whereas only 8% (n=2) of primary care clinic subjects had a documented history. More details about these differences and demographic information are captured in Table 1.

Clinic Visits by Subjects

GCSS subjects had more frequent follow-up during the study timeframe than those at the primary care clinics. Only 21% (n=5) of primary care clinic subjects visited their provider more than five instances in the 14-month period, in contrast to 59% (n=106) of GCSS subjects. The average length of time between

clinic visits was 7.1 ± 4.13 weeks for GCSS subjects, while the average time for the primary care clinic subjects was 14.7 ± 12.5 weeks ($p<0.05$).

An inverse relationship was seen between study site and how often the scheduling of follow-up clinic visits was documented in clinic notes. GCSS providers only documented about follow-up in 58% (n=662/1150) of total subject visits, notably lower than the 88% (n=99/112) of instances seen with the primary care providers ($p<0.05$). Table 2 shows specific information about clinic visits for each of the study groups.

Antipsychotic Medication Use

Atypical antipsychotics were used more frequently as a class in this study than their older, typical antipsychotic counterparts. Of the total instances of **unique antipsychotic use for a given study site's subjects**, atypical antipsychotics were prescribed in 82% (n=214/262) of GCSS instances and 88% (n=22/25) of primary care clinic instances. The only atypical antipsychotics prescribed to subjects at GCSS and both primary care clinics were quetiapine at 22% (n=40) and 46% (n=11), respectively, and aripiprazole at 19% (n=34) and 21% (n=5). While typical antipsychotics were prescribed in both study groups, the large majority were used at GCSS, being prescribed in 18% (n=48/262) of GCSS instances and 12% (n=3/25) of primary care clinic instances. The most commonly prescribed of the typical antipsychotics was haloperidol for 17% (n=35) of study subjects overall.

GCSS providers had unique prescribing trends compared to their primary care counterparts. No subjects at the primary care clinics received a long-acting

antipsychotic injection as part of their medication regimen, compared to 44% (n=79) of subjects at the outpatient psychiatric clinic ($p<0.05$). Twenty-nine percent (n=53) of GCSS subjects were prescribed multiple antipsychotics at one time, compared to only 4% (n=1) of primary care clinic subjects (p=0.0061). Twenty-seven percent (n=48) of GCSS subjects were started on a new antipsychotic at some point during the study timeframe, while 46% (n=11) of subjects were at the primary care clinics. A detailed breakdown of antipsychotic use by study group is shown in Table 3.

Tardive Dyskinesia and Extrapyramidal Side Effects Monitoring

No standardized scales were used to monitor for EPS at any site, and tardive dyskinesia monitoring with AIMS was only performed at 2.8% (n=32/1150) of GCSS subject visits. Of these 32 structured assessments, thirty AIMS scores were "0" and two AIMS scores were "1." Specific items were often unreported, with providers usually documenting a total AIMS score in their clinic note rather than using the AIMS scoring system available in Epic®.

Metabolic Syndrome Monitoring

Monitoring of weight, blood pressure, fasting blood glucose, and fasting lipid panels was significantly better at the two primary care clinics than the outpatient psychiatric clinic. These respective measures were checked at 96%, 100%, 30%, and 25% of study visits at the primary care clinics, contrasting with respective frequencies of 14%, 6%, 0.2%, and 0.3% of study visits at GCSS ($p<0.05$). Family history monitoring took place at 57% of primary care clinic visits

and 53.7% of GCSS visits, though this was not a statistically significant difference. An exact count of monitoring instances is listed in Table 4.

With the limited amount of continuous data obtained, the only statistically significant differences between GCSS and the two primary care clinics were weight and blood pressure. The mean weights for these study groups were 94.4 kilograms and 168.1 kilograms, respectively ($p<0.05$). The mean systolic blood pressures were 130.5 mmHg and 121.6 mmHg ($p=0.00064$), and the mean diastolic blood pressures were 84 mmHg and 74 mmHg ($p<0.05$). While statistically insignificant, a large difference of means was found in measured triglycerides on fasting lipid panels, being 193.3 mg/dL for GCSS and 126.8 mg/dL for the primary care clinics ($p=0.11422$). Waist circumference was not measured or documented at any study visit. A complete analysis of continuous data is provided in Table 5.

DISCUSSION

Outpatient Psychiatric Clinic Practices

According to the 2002 Mount Sinai Conference, patients on atypical antipsychotics should be monitored annually for tardive dyskinesia and EPS despite their lower risk of developing these symptoms as compared to patients on typical antipsychotics.[15] Only 27 of the 180 subjects followed during this 14-month period at GCSS had an AIMS score documented, suggesting possible gaps in tardive dyskinesia and EPS monitoring.

It has been deduced in the literature that atypical antipsychotic monitoring for metabolic syndrome has not improved substantially since the 2004 ADA consensus statement. A review of administrative claims data from major health insurance plans in the United States from 2001 to 2006 suggested that 75% of patients on antipsychotics received no baseline glucose testing and 90% received no baseline lipid panel by the end of 2005.[37] According to electronic medical record documentation, rates within Gallahue Mental Health Center were seemingly worse than these reports.

Furthermore, nearly one-third of subjects at this clinic experienced antipsychotic polypharmacy, increasing the risk of side effects from these medications. Documentation providing medical necessity for the use of multiple antipsychotics was not provided in the medical records for most subjects.

Primary Care Clinic Practices

None of the subjects followed at the primary care clinics had documented monitoring for tardive dyskinesia or EPS. This suggested lack of monitoring could reflect a lesser appreciation in non-psychiatry settings for the neurologic risks associated with antipsychotic medications.

In regards to metabolic syndrome risk factor monitoring, the primary care clinics were highly effective at monitoring weight and blood pressure, checking these values at almost every clinic visit. Frequency was lower for fasting blood glucose and lipid panels, though this was significantly higher than monitoring practices at the outpatient psychiatric clinic. However, such practices could

reflect the primary care treatment of cardiovascular and endocrine disease states rather than conscious monitoring of the long-term effects of antipsychotic use.

Differences in Monitoring Results

It is unclear why such a drastic difference in measured weights existed between GCSS and the primary care clinics, particularly since no major outliers were present and comorbidity differences at baseline were insignificant. Regardless of statistical significance, this information about weight should be interpreted with caution, since height data was not collected to allow for body mass index (BMI) calculations of patients. Waist circumference is a monitoring parameter recommended by the 2004 ADA consensus statement, since abdominal obesity and body fat distribution changes have been possibly linked to insulin resistance and dyslipidemia.[16] No waist circumference measurements were documented at GCSS and the primary care clinics, and a weight outside of context is not as helpful in preventative monitoring for metabolic syndrome.

The significant difference in measured blood pressures seems more logical, since the primary care clinics completed this monitoring at every follow-up visit. GCSS subjects' mean blood pressure values of 130.5 mmHg systolic and 84 mmHg diastolic were also around the metabolic syndrome risk factor threshold of $\geq$130/85 mmHg.[11] This finding could suggest better control of comorbid hypertension by primary care providers, and it could also support the theory that individuals with schizophrenia spectrum disorders are at a greater baseline risk for cardiovascular disease.[13]

No strong inference can be drawn from fasting blood glucose and fasting

lipid panel, since these two labs combined were only completed in five instances at GCSS altogether. While one would not expect these more extensive labs at every clinic visit, fasting blood glucose should be checked at least annually according to the 2004 ADA consensus statement, meaning this parameter should have been documented for the majority of subjects over the 14-month period.[16]

A Place for Pharmacy Expertise

Along with being well-qualified as medication management experts by their extensive education and training, pharmacists are ideal health care professionals for identifying how to act upon monitoring results appropriately. In previously described CDTM practices within psychiatry, the clinical pharmacist acted as the connection between the many other health care team members. Following an assessment, dosage changes, and medication counseling, a psychiatric pharmacist at a fluphenazine decanoate clinic was able to consult the psychiatrist, clinic nurse, or social workers as required for the patient's needs.[28] Clinical pharmacists' recommendations were also well-received by providers in the available literature, being accepted >90% of instances at an outpatient psychiatric pharmacy clinic for indigent populations and at a safety-net clinic.[26,27] As health care continues to advance its understanding of the pathophysiology of psychiatric disease states such as schizophrenia, antipsychotic use will likely become even more of a therapeutic cornerstone. Having a psychiatric pharmacist closely involved with the care of clinic patients through a CDTM protocol will ensure that these medications are utilized safely and effectively.

Study Limitations

First, it is possible that monitoring rates were higher than study findings at all study sites due to a lack of standardized documentation in clinic notes. While psychiatrists at GCSS were likely checking for signs of tardive dyskinesia and EPS at most clinic visits, the lack of AIMS score documentation did not capture these instances in the study. Providers also may have reviewed labs performed at other outpatient clinics rather than completing them in office, though this was not consistently documented for most subjects.

In addition, the study author was not always able to identify the precise initiation date of a subject's antipsychotic medication, making it difficult to assess adherence to monitoring recommendations of the ADA from baseline onward as shown in Appendix B. Because the Epic® electronic medical record system went online just prior to the starting point of this study, it was hard to locate and interpret clinic history from the previous system. While the monitoring parameters in the ADA consensus statement are based upon number of weeks since initiating an antipsychotic medication, the study author opted to look for parameters at every follow-up visit due to the large amount of unknown start dates for subjects' antipsychotics.

Finally, small sample sizes in the chosen primary care clinics limited the power of this study to detect actual practice differences. The initially generated list of patients receiving a "psychotherapeutic drug" within Community Health Network likely missed a substantial number of possible subjects, perhaps also due to the relatively recent implementation of Epic® in the health system.

CONCLUSION

The objective of this study was to demonstrate the need for a CDTM protocol within Gallahue Mental Health Center that would allow a clinical pharmacist to bring antipsychotic monitoring practices into closer alignment with the most recent guidelines from the ADA, other professional organizations, and expert panels. Analyzing the clinic visits of patients on antipsychotics over a 14-month period showed significant gaps in both performing and documenting such interventions. The results of this study, in conjunction with current literature on the collaboration of psychiatric pharmacists in outpatient clinics, could justify CDTM implementation as a feasible means of strengthening the holistic care of those receiving antipsychotics for behavioral health disorders.

ACKNOWLEDGEMENTS

The author would like to acknowledge members of the Community Health Network clinical pharmacy team that took part in this research project: faculty advisor Laura Ruekert, PharmD, BCPP, CGP; PGY-2 psychiatric pharmacy resident Kelly Banker, PharmD, BCPS; and psychiatric pharmacist Cheen Lum, PharmD, BCPP. All provided a high degree of guidance and support that made the work of this honors thesis possible, as well as encouraged him to continue pursuing a passion for psychiatric pharmacy. The author would also like to thank Veronica Vernon, PharmD, BCPS, BCACP for reading and providing feedback on an earlier draft of this honors thesis.

Furthermore, the author would like to give recognition to some of the psychiatrists within Community Health Network: Elizabeth Cunningham, DO; Frank Covington, MD; and Syed Khan, MD. These individuals offered valuable insight on appropriate study design and abstract work, showing their dedication to the exploration of evidence-based, interdisciplinary health care.

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APPENDICES

Appendix A (AIMS+EPS)

AIMS-PLUS EPS

(ABNORMAL INVOLUNTARY MOVEMENT SCALE-PLUS EXTRAPYRAMIDAL SIDE EFFECTS SCALE)

Instructions: Rate highest severity observed. Rate movements that occur upon activation one less than those observed spontaneously.

Code: 0 = None; 1 = Minimal, may be extreme normal; 2 = Mild; 3 = Moderate; 4 = Severe (circle the appropriate rating below).

TARDIVE DYSKINESIA (Do not Include Tremors)

1. **Muscles of facial expression** _____ 0 1 2 3 4
   e.g., movements of forehead, eyebrows, periorbital area, cheeks; include frowning, blinking, smiling, grimacing
2. **Lips and perioral area** _____ 0 1 2 3 4
   e.g., puckering, pouting, smacking
3. **Jaw** _____ 0 1 2 3 4
   e.g., biting, clenching, chewing, mouth opening, lateral movement
4. **Tongue** _____ 0 1 2 3 4
5. **Upper extremities** (arms, wrists, hands, fingers) _____ 0 1 2 3 4
   Include choreic movements (i.e., rapid, objectively purposeless, irregular, spontaneous), athetoid movements (i.e., slow, irregular, complex, serpentine)
6. **Lower extremities** (legs, knees, ankles, toes) _____ 0 1 2 3 4
   e.g., irregular lateral knee movement, irregular foot or heel movements
7. **Trunk movements** (neck, shoulders, hips) _____ 0 1 2 3 4
   e.g., irregular rocking, twisting, squirming, or pelvic gyrations

TD Total: _____

EXTRAPYRAMIDAL SIDE EFFECTS

1. **Dystonia** _____ 0 1 2 3 4
   e.g., persistent spasm usually of the eyes, face, neck or back muscles (this results in persistent abnormal positioning of one or more extremities or of the face, neck, or trunk)
2. **Parkinsonism** _____ 0 1 2 3 4
   e.g., bradykinesia (decreased movement), shuffling gait, masklike facies, resting tremor, drooling
3. **Akathisia** _____ 0 1 2 3 4
   e.g., restlessness, pacing, rocking, inability to sit still
4. **Rigidity** _____ 0 1 2 3 4
   e.g., increased muscle tone with continuous passive resistance to movement, cog-wheel rigidity
5. **Parkinson tremor** _____ 0 1 2 3 4
   e.g., slow, rhythmic, present at rest (pill rolling)
6. **Akinesia** _____ 0 1 2 3 4
   Decreased motor movements often associated with weakness, decreased spontaneous movements and paresthesias

EPS Total: _____

COMMENTS:

Examiner: _____ Date: ___/___/___

Appendix B (2004 ADA Consensus Recommended Monitoring)

	Baseline	4 wks	8 wks	12 wks	3 mos	Annual	5 yrs
Personal/family history of metabolic syndrome risk factors	X					X	
Weight	X	X	X	X	X		
Waist circumference	X					X	
Blood pressure	X			X		X	
Fasting plasma glucose	X			X		X	
Fasting lipid profile	X			X			X

Table derived from the 2004 ADA consensus statement[10]
*More frequent assessments may be warranted based on clinical status

Appendix C (Data Collection Sheet)

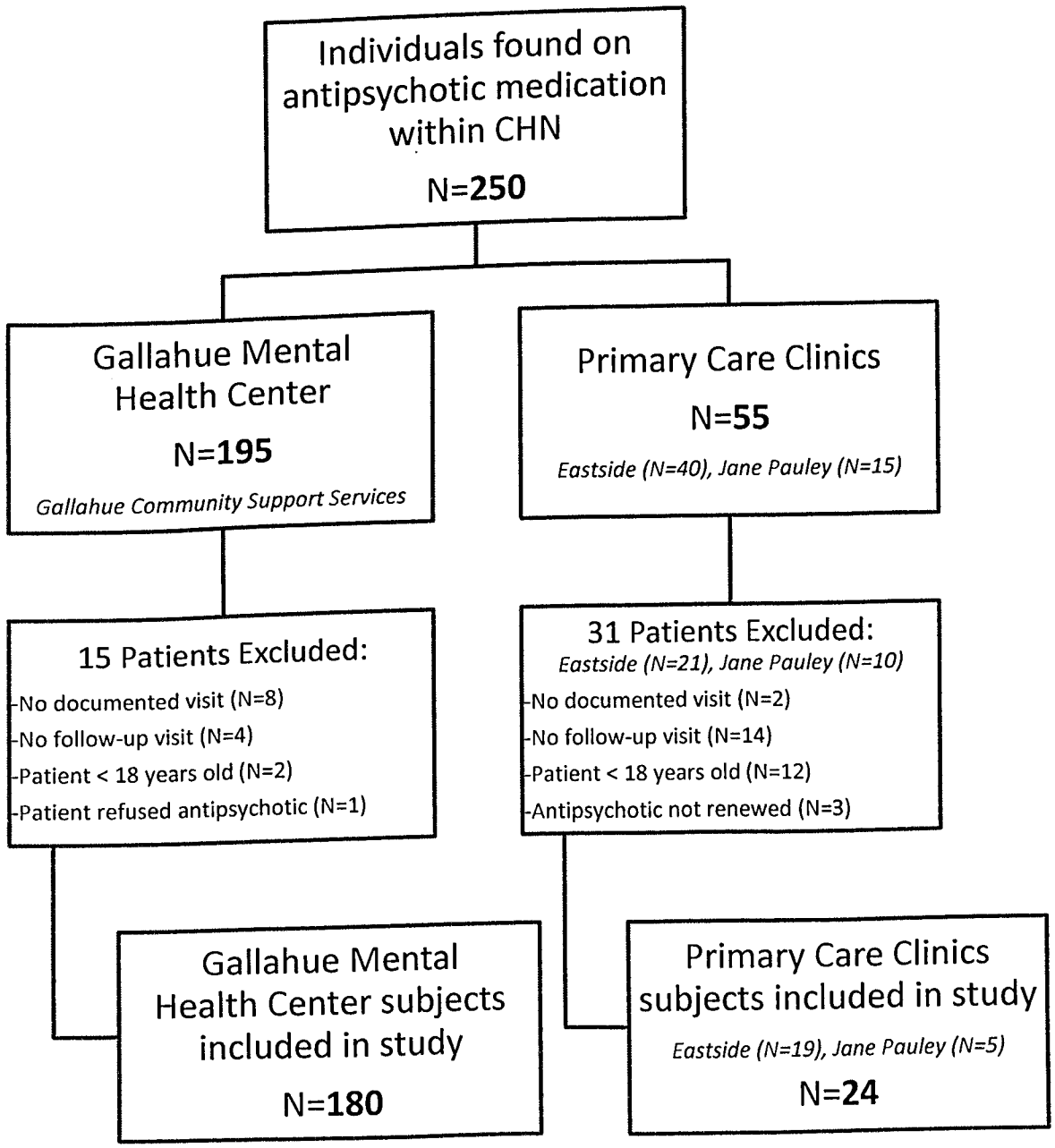
GALLAHUE MENTAL HEALTH CENTER (CHN) – DATA COLLECTION SHEET

Demographics				Information at clinic visit								
SUBJECT #	SEX	ETHNICITY/ALLERGY	VISIT	AGE	LAST VISIT	AP INDICATION	PREVIOUS AP	COMORBIDITIES	OTHER MEDS	SH	RX	F/U

Antipsychotic use							Tardive dyskinesia						
AP	STRENGTH	FREQUENCY	TOTAL	PROB	AWC		TOTAL	FACE	LIPS	JAW	TONG	UE	LE	TRUNK
							0							
							0							
							0							

Extrapyramidal side effects								Metabolic syndrome								
TOTAL	DYSTON	AKATHIS	RIGID	TREMOR	GAIT	SALIV		WT	WAIST	SBP	DBP	FBG	TC	TG	HDL	LDL	FH	WHY NOT ASSESSED
0																		
0																		
0																		

Appendix D (Subject Inclusion and Exclusion)



TABLES

Table 1 (Subject Demographics)

Documented Demographics of Subjects Included in Study			
	Gallahue Mental Health Center N=180	**Primary Care Clinics** N=24	**P-Value**
Sex			
Male	82 (45.6%)	11 (45.8%)	0.9795
Female	98 (54.4%)	13 (54.2%)	
Ethnicity			
Caucasian	93 (51.7%)	10 (41.7%)	0.16383
Black	81 (45%)	13 (54.2%)	
Hispanic	4 (2.2%)	1 (4.1%)	
Asian	2 (1.1%)	0	
Mean Age	44.9 (SD=12.9)	49.1 (SD=19.5)	0.16598
Comorbidities			
Hypertension	74 (41.1%)	11 (45.8%)	0.6594
Hyperlipidemia	43 (23.9%)	14 (58.3%)	0.0004
Diabetes Mellitus	42 (23.3%)	7 (29.2%)	0.5298
CAD	12 (6.7%)	3 (12.5%)	0.3938
Obesity	93 (51.7%)	13 (54.2%)	0.818
Family History			
Hypertension	16 (8.9%)	11 (45.8%)	5.25×10^{-7}
Hyperlipidemia	3 (1.7%)	2 (8.3%)	0.1065
Diabetes Mellitus	23 (12.8%)	8 (33.3%)	0.0084
CAD	27 (15%)	9 (37.5%)	0.0066
Social History			
Tobacco Use	79 (43.9%)	8 (33.3%)	0.3260
Alcohol Use	17 (9.4%)	3 (12.5%)	0.7121
Illicit Drug Use	19 (10.6%)	3 (12.5%)	0.7288
AP Indication			
Schizophrenia	89 (49.4%)	3 (12.5%)	0.085
Schizoaffective	42 (23.3%)	0	
Bipolar I	25 (13.9%)	4 (16.6%)	
Bipolar II	3 (1.7%)	3 (12.5%)	
MDD	7 (3.9%)	7 (29.2%)	
Psychosis NOS	11 (6.1%)	0	
Other*	3 (1.7%)	7 (29.2%)	
Previous AP Use			
Typical AP's	16 (8.9%)	0	0.2257
Atypical AP's	32 (17.8%)	2 (8.3%)	0.3818

*Other indications included insomnia, autistic disorders, and Alzheimer's dementia

Table 2 (Clinic Visit Information)

Quantity of Patient Follow-Up at Clinic Sites			
Number of Documented Visits	**Gallahue Mental Health Center**	**Primary Care Clinics**	**P-Value**
2	5 (2.8%)	5 (20.8%)	0.0025
3	19 (10.6%)	5 (20.8%)	0.1715
4	24 (13.3%)	5 (20.8%)	0.3496
5	26 (14.4%)	4 (16.7%)	0.7608
6	33 (18.3%)	0	0.0168
7	14 (7.8%)	1 (4.2%)	1
8	18 (10%)	1 (4.2%)	0.7059
9	19 (10.6%)	0	0.1369
10	13 (7.2%)	1 (4.2%)	1
11	5 (2.8%)	2 (8.3%)	0.193
12	1 (0.6%)	0	1
13	1 (0.6%)	0	1
14	1 (0.6%)	0	1
15	0	0	
16	0	0	
17	1 (0.6%)	0	1
Average Weeks Since Last Clinic Visit	7.1 (SD=4.13)	14.7 (SD=12.51)	2.37×10^{-8}
Follow-Up Clinic Visit Scheduled (of total visits)	57.6% (662/1150)	88.4% (99/112)	1.95×10^{-10}

Table 3 (Antipsychotic Medication Use)

Actively Prescribed Antipsychotic Medications			
	Gallahue Mental Health Center	**Primary Care Clinics**	**P-Value**
Atypical AP's			
Aripiprazole	34 (18.9%)	5 (20.8%)	0.7858
Asenapine	7 (3.9%)	0	1
Clozapine	11 (6.1%)	0	0.3685
Iloperidone	0	0	
Lurasidone	12 (6.7%)	0	0.3672
Olanzapine	13 (7.2%)	2 (8.3%)	0.6914
Paliperidone	44 (24.4%)	0	0.0029
Quetiapine	40 (22.2%)	11 (45.8%)	0.0214
Risperidone	49 (27.2%)	2 (8.3%)	0.0467
Ziprasidone	4 (2.2%)	2 (8.3%)	0.1482
Typical AP's			
Chlorpromazine	4 (2.2%)	0	1
Droperidol	0	0	
Fluphenazine	3 (1.7%)	0	1
Haloperidol	34 (18.9%)	1 (4.2%)	0.086
Loxapine	0	0	1
Perphenazine	6 (3.3%)	1 (4.2%)	0.5894
Pimozide	0	0	
Thioridazine	0	1 (4.2%)	0.1176
Thiothixene	1 (0.6%)	0	1
Use of Long-Acting Injections	79 (43.9%)	0	5.67×10^{-6}
Antipsychotic Polypharmacy	53 (29.4%)	1 (4.2%)	0.0061
Subjects Starting New AP	48 (26.7%)	11 (45.8%)	0.0588

Table 4 (Completion of Monitoring at Clinic Visits)

Completion of Recommended ADA Monitoring Practices					
	Gallahue Mental Health Center*		Primary Care Clinics+		P-value
	YES	NO	YES	NO	
Family History	617	533	64	48	0.4792
Weight	163	987	107	5	2.3×10^{-89}
Blood Pressure	65	1085	112	112	3.27×10^{-114}
Fasting Blood Glucose	2	1148	33	79	8.14×10^{-35}
Fasting Lipid Panel	3	1147	28	84	4.37×10^{-28}

*1150 individual clinic visits recorded at the Gallahue Mental Health Center clinic
+112 individual clinic visits recorded at the two primary care clinics

Table 5 (Metabolic Syndrome Monitoring Results)

Metabolic Syndrome Monitoring Results			
	Gallahue Mental Health Center	**Primary Care Clinics**	**P-value**
	Mean (Standard Deviation)		
Weight (kg)	94.4 (30.34)	168.1 (64.45)	4.83×10^{-29}
Blood Pressure			
Systolic BP	130.5 (21.78)	121.6 (12.67)	0.00064
Diastolic BP	84 (14.9)	74 (11)	7.68×10^{-7}
Fasting Blood Glucose	96.5 (12)	120.1 (61)	0.59384
Fasting Lipid Panel			
Total Cholesterol	184 (30.27)	181.4 (49.64)	0.93018
Triglycerides	193.3 (27.21)	126.8 (69.28)	0.11422
HDL Cholesterol	36.7 (16.86)	48 (12.47)	0.15637
LDL Cholesterol	109 (21.7)	108 (42.57)	0.96973