THE EFFECTS OF INTEGRATED CARE ON PATIENT OUTCOMES IN A PRIMARY AND BEHAVIORAL HEALTH CARE INTEGRATED SYSTEM

By

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A capstone project proposal submitted to the School of Nursing The State University of New York at Buffalo In partial fulfillment of the requirements for the degree of Doctor of Nursing Practice

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DNP Capstone Project Approval Form

This is to certify that Joanne Coppola

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successfully defended his/her Capstone project entitled:
The Effects of Integrated Care on Patient Outcomes in a Primary and Behavioral Health Care Integrated System

on December 13, 2018.

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*If applicable
Abstract

Problem under investigation: The mortality and cost of patients with chronic health conditions who also have mental illness are estimated to be 75% higher than patients in the general population and has constituted 10.4% of the global burden of disease. The integration of Primary and Behavioral Health Care (PBCHI) has been shown in some settings to improve mental and physical outcomes, however they have not been comprehensively evaluated.

Objective: The objective of this capstone project is to determine whether the integration of primary and behavioral health care will improve health outcomes of its participants.

Background literature review: Review of the literature found no consensus on whether PBCHI had an effect on health outcomes.

Theoretical Framework: General Systems Theory and its subset Complex Theory was used to explain the variability in outcomes.

Methods: A quasi-experimental design which used a retrospective chart review was used to collect eleven biologic markers collected from 180 patients enrolled in a PBHCI in Syracuse, New York. Data was collected at six-month intervals over a one-year period of time.

Data Analysis: Descriptive statistics, and RM-ANOVA was used to determine statistical significance in the difference in each biologic marker over time.

Results: The variable carbon monoxide (CO) was the only variable to show a difference over time as noted between the first and last data collection points. No other variables demonstrated statistical change.

Conclusion: More research is required over longer periods of time and to control for confounding factors.

Keywords: Integrated care, collaborative care, chronic illness, diabetes.
Introduction

People with mental and substance abuse disorders often die from chronic conditions that are preventable and can be treated successfully in primary care. The mortality of patients with conditions such as diabetes and hypertension that also have mental illness far exceeds that of patients in the general population (Substance Abuse and Mental Health Services Administration, 2017) (SAMHSA). In addition, people living with mental illness die earlier than the general population and have more co-occurring health conditions, which makes them more complex and costlier to care for. SAMHSA (2017) estimated that 68% of adult patients with mental illness also have chronic physical conditions such as type two diabetes. Moreover, the cost to care for patients who have chronic health disorders and mental illness is estimated to be 75% higher than those without mental health problems and those with chronic health disorders such as diabetes who have a mental health diagnosis cost the health care system four times more than those who have diabetes alone (SAMHSA, 2017).

The Primary and Behavioral Health Care Integration (PBHCI) program was developed by the Substance Abuse and Mental Health Services Administration (SAMHSA) in conjunction with the Health Resources and Services Administration (HRSA) to improve the health of patients with mental illness. The goal of the PBHCI program was to improve the mental and physical health of clients with mental illness as well as those who are at risk for developing or have a co-occurring chronic disease (SAMHSA, 2017). Integrated health care systems such as the combination of Behavioral and Primary health care are thought to be a solution to the challenges of health care delivery. Benefits to an integrated health system are thought to include: cost effectiveness (based on the efficiency of shared resources within the practice), client-oriented
care which includes taking care of the whole person instead of just focusing on one health problem, and equitable access to other programs (World Health Organization, 2008).

The U.S healthcare system is known to be fragmented, complex and inequitable (Hwang, Chang, LaClair & Paz, 2013). Policymakers have been charged with re-structuring delivery systems to fill some of those gaps, which has led to the development of integrated health care. The integration of mental health and primary care has emerged as a potential to streamline care for chronic conditions that are exacerbated by mental illness, however in an extensive review of the literature searching for the support of their effectiveness, there has been a lack of consensus.

Healthcare must continuously adapt to meet the needs of the diverse nature of the US population. The National Institute for Mental Health (NIMH) (2015) created several large surveys to study mental health care in the US. Studies included the Collaborative Psychiatric Epidemiology Surveys (CPES), National Co morbidity Survey Replication (NSC-R), National Survey of American Life (NSAL) and the National Latino and Asian American Study (NLAAS). Surprisingly, findings from these studies did not reveal great variation in prevalence of mental illness but that there are great variations in care, concluding that the challenge for all populations is health equity and optimal care (Insel, 2010).

**Capstone Objective**

In consideration of the need for further investigation of the effectiveness of PBHCIs as well as reducing the health care burden of people who have both mental illness and chronic co-occurring conditions, the intention of this capstone project was to further investigate whether the PBHCl was effective at improving health outcomes of patients with chronic diseases who also have mental disease, as evidenced by a change in biologic markers.
Literature Review

A search of the databases was conducted in Cochrane, Pubmed, PsychINFO, Ovid Health Star, CINAHL, and Medline. Key words included diabetes, chronic illness, mental illness, integrated care or collaborative care and related combinations. Studies included were limited to research on integrated health care programs for patients with mental illness and who had chronic illnesses such as diabetes.

Literature was reviewed to explore relevance to current health standards, studies were included if they were conducted within the past five years. Older randomized control studies that investigated the effect of integrated care systems but had no metabolic outcome measures (such as HbA1c), were numerous. More recent literature tends to combine the results of the previous studies therefore rendering multiple systematic reviews or building on findings of previous studies. There seems to be a relative lack in the literature of more recent evidence that includes metabolic outcomes. This is surprising considering the constant changing of health care delivery systems.

Studies included in this review had variability of methods and design. In the mixed methods study by Busetto, Ger Luijxkx and Vrijhoef (2014), a literature review provided a background of program implementation and context while quantitative data was extracted from two Dutch integrated practices that measured HbA1c levels in patients. The intention of this study however was to report on practice implementation as opposed to patient outcomes (which were measured as secondary findings), but which helped to define success in the program. In addition, the Care of Mental Health, Physical and Substance-use Syndromes (COMPASS) initiative also attempted to define a model of care that would result in the measurement of health outcomes to include HbA1c endpoints as well as other outcomes such as reduction of depression.
and patient satisfaction (Coleman et al., 2017). Similar in outcome goals, was a quality improvement (QI) project that was included because of its pre and post treatment evaluation that matches a phase II trial. The project discovered a 1.4% decrease in HbA1c levels in patients enrolled in an integrated practice, but the actual design of the program studied interventions such as case conferences and levels of depression (Doherty et al., 2016). Most of the studies did show a modest to low level of improvement of HbA1c in diabetic patients enrolled in the integrated programs however, no clear interventions were defined as having the most prominent impact. Many of the studies included both a qualitative as well as a quantitative method to their design.

Three large systematic reviews provided qualitative data although one of them also included a meta-analysis of the studies included. This was a common finding amongst all the articles initially reviewed as many studies collected data on patient and provider satisfaction as well as tools that measured levels of depression such as the nine item Patient Health Questionnaire (PHQ-9). Studies that used this qualitative data to control for variables in patients were included in this review however, qualitative outcomes were excluded as the focus of this review was to measure metabolic outcomes (biologic markers). Two quasi-experimental, two cross-sectional and one retrospective study provided quantitative low to moderate evidence of program effectiveness on HbA1c with the exception of a large quasi-experimental design that examined comparative effectiveness amongst integrated programs compared to control groups. This study revealed reduction in metabolic and physical outcomes such as diastolic blood pressure and total cholesterol levels, the study reported no reduction however in other measures including BMI and HbA1c levels (Scharf et al., 2013). The findings from this study became the basis for the final report generated by the RAND Corporation on evaluation of the Substance Abuse and Mental Health Services Administration (SAMHSA) Primary and Behavioral Health
Care Integration (PBHCI) grant program. Lack of quantitative improvement in these biologic markers may impact future funding of integrated programs, however, there are multiple design flaws to consider.

Amongst the limitations found were lack of randomization in the QI project (Doherty et al., 2014) as well as the large quasi-experimental study used by SAMHSA as a final report. Integration programs in the SAMHSA study were assigned to control practices, but this designation was thought to create some form of bias in which the results may not be applicable to the general population as it was too tightly controlled (Scharf et al., 2013). Variability in confounding elements were also noted as limitations in most of the studies. For example, the COMPASS initiative was reviewed by Rossom et al., (2017) who found that Black, Hispanic and patients on Medicaid had lower levels of HbA1c reduction compared to Caucasian counterparts raising further questions about the influence of health disparities. Other limitations included findings of different levels of integration as described by Hwang, Chang, LaClair and Paz (2013). Furthermore, Tepper et al., reported an inability to control for variables due to lack of an integrated electronic medical record system that combined both mental health as well as primary care (2017). The limitation in this case stems from a larger system issue. Despite the variability and limitations found within each study, all the studies concluded that evidence-based knowledge about integrated health care programs is insufficient, thus making generalization to other settings difficult.

Further review of the literature examined the success of integrated care. These studies included three systematic reviews conducted by: Lyngso, Godtfredsen, Host and Frolich, (2013); Ovretveit, 2011; and Oelke, Suter, Dias da Silve lima, Vliet-Brown, (2015). There was also one meta-analysis prepared by Butler and colleagues (2008), and a quasi-experimental design.
published by the Department of Health and Human Services (2013). All of the studies attempted to measure the effectiveness of integrated care, however they all examined different aspects of integration or used different methods for measurement. For example, the systematic review by Lyngso, et al. (2013) measured elements of the organization by focusing on the level of integration between practices. The success of an integrated system was the primary outcome measurement for this study. Oelke, et al (2015) also examined the success of an integrated practice however this study measured principles of comprehensive care, patient focus, geographic coverage, interdisciplinary teams, management and information technology.

Two of the studies evaluated models of integrated care to determine if a particular design created improved outcomes. Strategies such as information technology and reimbursement were the subject of comparison in the meta-analysis by Butler and colleagues (2008) in contrast to the systematic review done by Ovretveit (2011), which assessed models that focused on prevention of hospital readmission, disease and case management and chronic health prevention. Common to all of the studies was a large variety of tools used for measurement as well as stated difficulty determining the best measurement tool to measure program success.

Small sample size, lack of randomization, provider bias, system factors, and lack of control of variables are all cited as limitations and most of the studies suggested more research needs to be conducted to determine whether integrated systems are successful in improving health outcomes of their participants. Since inadequate access to care and increased burden of disease cost the health care system an estimated 1.24 trillion dollars (Dankwa-Mullan et al., 2010) the significance of this intervention rests upon the ability of integrated care systems to streamline healthcare for vulnerable populations such as patients with mental health illness and chronic disorders to help alleviate such health inequities and reduce premature death.
Gaps in practice reflect the gaps also found in the review of the literature. Examples are:

- Determining whether improvement in health outcomes are a result of the practice integration or care on the part of the clinicians;
- Identification of the elements within the integration that produce better outcomes.
- Identification of psychiatric disorders that influence a participant’s adherence to the program;
- Potential influence of health disparities such as populations of race, economic status and language barriers.

It is clear that further research regarding the effectiveness of integrated care systems is warranted. Gaps created in the literature are also likely a result of great variability within the integrated systems. This can be explained by the fact that the subjects of examination are systems and therefore can only be explained by each system’s component interrelatedness. This can most easily be conceptualized by exploration of the General system Theory.

**Theoretical framework**

**General System Theory**

According to Senge, Kleiner, Roberts, Ross, and Smith (1994), system thinking encompasses a large and diverse body of methods, tools and principles, “all oriented to looking at the interrelatedness of forces” (p 89). Tools of the theory include causal loop diagrams, archetypes, and computer models which are based on the theoretical concept of feedback process (Senge, Kleiner, Ross, & Smith, 1994). Further examination of Systems Theory and related concepts, results in four concepts of complexity theory that assist in understanding how the General System Theory is useful in a PBHCI. These concepts are: numerosity, non-linearity, connectivity, autonomy and adaptation.
Numerosity is described as the number of elements within a system and examines the arrangement of their hierarchy. Non-linearity, also part of complex theory, suggests that when two or more elements are put together, there is a combined effect that is different than the elements in isolation. It is responsible for the fluidity of a system as it goes through phase transitions and can change to new regimens (Complexity Labs, 2017). Connectivity, the third concept, is the network of connections or how elements (subsystems) are tied together, it is what allows a system to appear as a network (Complexity Labs, 2017). In a PBHCI, connectivity can be used to illustrate the processes used by the practice to coordinate both primary and behavioral health care. Finally, Autonomy and adaptation are described as the complex system’s emergence of patterns of organization. As there is no top down mechanism of coordination, each subsystem will find its position and exerts its effect on the system as a whole (Complexity Labs, 2017). This allows for high levels of diversity to become organized around conceptual framework. (Organizational Communication Channel, 2017).

Further general constructs of this theoretical framework include holism, which is the view that a system is greater than the sum of its parts. Feedback is also integral to the theory as a dynamic process in which the subsystems are interconnected and respond to changes directly or indirectly as a response to influence from other parts of the system. In addition, subsystems are also not isolated from the community and are permeable to influence of the community in which it exists (Organizational Communication Channel, 2017). This is demonstrated in the PBHCI when health care policy is changed in response to influences such as reimbursement. When third party payers decided to reimburse only one prescriber provider within a 24-hour time frame, this caused a change in the dynamics of care in which both behavioral health and primary care were able to coordinate care for patients in real time. The effect of this change exerted on behavioral
health had a major influence on primary care to deliver the same level of coordination in care. Other concepts of General System Theory include goals within the system of subsystems that are always contingent and negotiated as well as equifinality which means that there is no one best way to achieve a goal and all ways of organizing are not equally effective (Organizational Communication Channel, 2017). These concepts allow for the systems to remain fluid and adaptable to change which is paramount in system survival.

PBHCI systems are derived from many subsystems. In addition to behavioral health and primary care as systems, subsystems exist within these larger systems such as medical and behavioral health staff, patients, supportive care (case management, education for patients) and the community in which the system exists. The interrelationship between these subsystems is what either produces an improvement of health in patients with both chronic and mental health illness or becomes ineffective in doing so.

Chronic illnesses have become prevalent in both primary care and psychiatric practices which contributes to a major source of disease burden and mortality. It is estimated that 25%-30% of patients in primary care have some sort of mental illness and that 50%-70% of psychiatric patients have significant medical illnesses which remain under-diagnosed and under-treated (Aghaegbulam, Kulkarni, Heeramun, & Bottum, 2017). Collaborative care models for chronic medical illnesses and mental illnesses have been shown to improve mental and physical outcomes in a variety of care settings, however they have not been comprehensively evaluated (Woltmann, Perron, Georges, Kilbourne & Bauer, 2012). Therefore, the intention of this study is to determine whether patients enrolled in a PBHCI have improvement in their health outcomes and by extension, reduce disease burden.

**Design and Method**
Sample and Setting

The setting of this project was conducted at a Primary and Behavioral Health Care Integration (PBCHI) practice in Syracuse, New York. The practice is listed as an Article 28 which indicates that accreditation includes more rigorous standards for practice and allows for a higher level of billing (New York State Medicaid Program, 2007). Patients included in the study will include patients enrolled in both the mental health and primary care portions of the practice. Inclusion criteria also included being an adult male or female patient between the ages of 18 and 65. Exclusion criteria included children or adolescents under the age of 18, or adults over the age of 65.

Setting of study

The practice setting is a recipient of a 1.5 million-dollar SAMHSA grant designed to allow for practice integration between primary and behavioral health care. There are currently 213 SAMHSA grants that have been awarded to integrated care systems nationally. The objectives of the grant are to support the triple aim of improving the health of those with mental illness by enhancing the client’s experience of care including quality, access and reliability and reducing and controlling the per capita cost of care by monitoring utilization, and reducing unnecessary hospital visits (Liberty Resources, 2016). Evaluation of the program grant is based on client retention (expected retention 80%-100%), and efforts to maintain engagement, practice outreach and promotion of client activation. The integrated approach incorporates Primary Care, Psychiatry, peer support services and Psychotherapy as one team (Liberty Resources, 2016). Emphasis of the program will be to assist clients who are unable to follow through with appointments and treatment recommendations by their current PCP; have severe psychotic or major mood disorders or are disorganized/impaired as a direct result of their serious mental
illness which then impairs their ability in getting to appointments, using public transportation, obtaining lab work, understanding health needs and engagement in preventative care (Liberty Resource, 2016).

**Design of study**

The chosen study design is a quantitative, quasi-experimental records review using descriptive statistics on multiple data points retrieved from chart review of data from two separate electronic health record systems as well as a retrospective review of pre-existing aggregate data contained within a computer data base owned and maintained by Liberty Resources. Patient identification was removed from the data collection sheets and replaced by a code to maintain patient anonymity. Codes used to de-identify the participants were applied prior to data collection to reduce any inadvertent disclosure of patient identification. All health outcome data measured as biologic markers were pre-existing and regularly collected as part of regular patient care therefore no further testing was requested of participants. The study compared a cohort of 180 patients who are enrolled in the Substance Abuse and Mental Health Association (SAMHSA) program, who have been enrolled for at least one year. Data was collected at six months intervals and included eleven separate biologic outcomes (see appendix A. Physical Health Indicators)

**Analysis of Data**

Repeated measures analysis of variance (RM-ANOVA) was used to determine whether there had been a change in the outcomes studied at different points in time, and to examine whether the Integrated Care system had an effect on patient outcomes. The resultant hypotheses:

- There is no difference in health outcomes of patients who have mental illness who receive bundled care in an integrated practice.
Table 1 in the appendix depicts biologic variables with connected conditions and level of at risk range.

**Legal and ethical considerations**

Integrated care systems deal with cultural and, by extension, ethical considerations at the center of their existence. The National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research produced guidelines to protect the rights of individuals in vulnerable populations, including patients with mental illness, no matter what their ethnic or racial identification (Royce, Thyer & Padgett, 2016). Due to the potential involvement of multiple health disparities, and the vulnerable nature of patients with mental illness, consultation with an Institutional Review Board was added to assure ethical standards were maintained. There was minimal risk to patients as this was a chart review of both pre-existing and regularly collected data from de-identified patient medical records with no patient contact. In accordance with upholding ethical standards in human research, a submission to the Institutional Review Board (IRB) of Liberty Resources, University at Buffalo and LeMoyne College was completed and a request for exempt status was granted due to the low risk nature of the data collection on the participants. Data collection was performed solely by the principle investigator and monitored by the practice manager. Data was maintained on a USB drive protected by password and maintained by the primary investigator. Patient identification was destroyed after codes were implemented, and the data will be stored at Liberty Resources for three years following the conclusion of the study.

**Timeline**

Data collection began after obtainment of approval from the IRB. A twelve-month retrospective review of electronic medical records was completed on 180 patients who met
include criteria. Biologic data was collected every six months for a total of three collection
dates on each participant (Appendix C).

Methods

In order to evaluate whether the integration of primary and behavioral health care has an
effect on the patients enrolled, a quasi-experimental design was used through a retrospective
chart review. The review included 180 patient charts and was conducted in two separate
electronic records. Medical Doc Assist (ADS) had been the electronic health record (EHR) used
from 2016 to January of 2018, and the EHR Medent replaced ADS in January of 2018 therefore
both records were reviewed to collect data over the one-year period of data collection.
Demographic information was also collected on each participant after which all identification of
the participants was removed and replaced with a code to maintain patient anonymity and by
extension, confidentiality. The coded data was then entered into an Excel spreadsheet. Data
points included systolic blood pressure (SBP), diastolic blood pressure (DBP), carbon monoxide
(CO) levels, total cholesterol (Tchol), low density lipoprotein levels (LDL), high density
lipoprotein levels (HDL), triglyceride levels (trig), glycosylated hemoglobin levels (HbA1c), and
plasma glucose levels (PG). Each of these data points had been obtained at six-month intervals
and recorded as baseline (1st), 6-month (2nd), and one-year (3rd) time points. Descriptive statistics
were then performed on each of the data points, and repeated measures ANOVA (RM-ANOVA)
was used to determine if there was a significant within-subjects change in data points over time.
A one-way RM-ANOVA is used when means are computed for the same people at three or more
points in time (Polit, 2010 p. 151). According to Laerd Statistics (2015), there are five
assumptions that must be met when running one-way RM-ANOVA. The first assumption is that
the dependent variable is measured continuously as an interval or ratio level. The dependent variables (biologic outcomes), in this study, are interval–level variables measured over a one-year period of time. The second assumption is that there are within-subject factors that consist of three or more categorical levels (points in time) (Laerd, 2015). In this case, within-subject factors are the same group of people who are being studied over a period of one year in three six-month intervals (levels). Both the intervention (integrated care) and time (levels) can be considered independent variables. The third assumption that must be met is that no significant outliers should be within the three levels of within-factor subjects (Laerd, 2015). Dealing with outliers in many of the variables proved to be challenging as the complexity of the patient co-morbid conditions created many outlier data points. Outliers for each variable were dealt with independently which is discussed in the results section. The fourth assumption states that distribution of the dependent variable in three levels of within-subject factors should be approximately normally distributed although, RM-ANOVA is known to be a robust test in the face of non-normality. Finally, the variances of the differences between all combinations of levels within-subject factors must be equal which is known as the assumption of sphericity (Laerd, 2015). Mauchly’s test of sphericity was computed to determine this assumption on all the dependent variables. If the assumption of sphericity is violated (assumes that the variance of population difference scores for any two time periods is not the same as the variance in any other time period) (Polit, 2010 p 153), an adjustment factor that produces a smaller degree of freedom to determine statistical significance was used. In this study, the Greenhouse-Geisser epsilon was applied in any case in which there was a violation of sphericity. Finally, to test whether there were differences of within-subject levels, the non-parametric Wilcoxin Signed Rank test which
investigated the differences between the means of the levels was conducted as this cannot be accomplished by one-way RM-ANOVA alone (Laerd, 2017).

**Demographics**

The participants in the study were men and women who were between the ages of 18 and 65 and who were enrolled in both Primary as well as behavioral health care. The majority of patients who met the inclusion criteria were white, female and between the ages of 31 and 45.

The tables below depict demographic information describing the population under study.

**Table 1**

*Race of subjects*

<table>
<thead>
<tr>
<th>Race</th>
<th>Total</th>
<th>Percentage (%)</th>
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</thead>
<tbody>
<tr>
<td>White</td>
<td>119</td>
<td>66.1</td>
</tr>
<tr>
<td>African American</td>
<td>34</td>
<td>18.9</td>
</tr>
<tr>
<td>Native American</td>
<td>1</td>
<td>.6</td>
</tr>
<tr>
<td>Asian</td>
<td>10</td>
<td>5.6</td>
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<tr>
<td>White Hispanic</td>
<td>16</td>
<td>8.9</td>
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<td>Total</td>
<td>180</td>
<td>100</td>
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</table>

**Table 2.**

*Gender of subjects*

<table>
<thead>
<tr>
<th>Gender</th>
<th>Total</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>118</td>
<td>65</td>
</tr>
<tr>
<td>Male</td>
<td>62</td>
<td>34.4</td>
</tr>
<tr>
<td>Totals</td>
<td>180</td>
<td>100</td>
</tr>
</tbody>
</table>
PATIENT OUTCOMES IN A PBHCI

Table 3.

*Age of participants grouped into four-year increments*

![Age distribution graph]

**Results**

Eleven dependent variables were computed using descriptive statistics. Data are mean ± standard deviation. The following are results from the RM-ANOVA statistical analysis which was created to test whether an integrated care system had an effect on patient outcomes as determined by changes detected of statistical significance in several biologic markers. Table 4 depicts the data collection summary; Appendix B shows a complete summary of data collection in the results.

**Variables**

A one-way RM-ANOVA was conducted on each variable to determine whether there was a statistically significant difference in between collection times over the course of one-year. Outliers were determined by box-plot and were either deleted for measurement error or included if they were determined to be a reliable outcome data point within the population. Examples included measurements recorded in waist circumference that were unusually high or low during
one time period but not the others, with no change in the BMI. These outliers were removed as measurement errors. Blood samples such as high HbA1c levels that were outliers in the data, were retained however, as they were likely a true representation of the population within the sample.

The assumptions of normal distribution and sphericity were also addressed for each variable. Systolic blood pressure (SBP), diastolic blood pressure (DBP), waist circumference (W.C), body mass index (BMI), carbon monoxide levels (C.O), plasma glucose (P.G), glycosylated hemoglobin (HbA1c), triglycerides, and total cholesterol did not meet the assumption of normality as assessed by Shapiro-Wilks test and a non-parametric Friedman test was conducted to determine significance. Low-density (LDL) and high-density lipoprotein (HDL) variables met the assumption of normal distribution. In addition to determining normality, a Mauchley test was conducted on all of the variables to determine whether they have met the second assumption of sphericity. Outcomes that violated the assumption of sphericity were dealt with by performing a Greenhouse-Geisser test in place of RM-ANOVA to adjust the degrees of freedom and determine significance. All the outcomes with the exception of P.G. and triglycerides violated this assumption. Once the assumptions were met, it was determined that the variable C.O. did show a significant difference in-between time collection levels (p = .050), Friedman (p=.008), and a post-hoc Wilcoxon Signed Rank test was used to determine between which time periods the significance was found. No statistical significance was found between the first and second time periods (p= .700) however there was statistical significance between the second and third time periods (p= .042), and the third and first (p=.000). Table 4 depicts the statistics conducted on each variable and their statistical significance.
Table 4

Statistics used in determining effect of integrated care on variables

<table>
<thead>
<tr>
<th>Variable/Sample size</th>
<th>Shapiro-Wilks distribution met Yes or No</th>
<th>Mauchly’s Sphericity violated Y/N</th>
<th>RM ANOVA/ Greenhouse-Geisser* (sig)</th>
<th>Friedman/ Bonferroni if sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBP</td>
<td>no</td>
<td>yes</td>
<td>P = .758 G.G*</td>
<td>P = .786</td>
</tr>
<tr>
<td>DBP</td>
<td>no</td>
<td>yes</td>
<td>P = .141 G.G*</td>
<td>P = .110</td>
</tr>
<tr>
<td>Waist circ</td>
<td>no</td>
<td>yes</td>
<td>P = .917 G.G*</td>
<td>P = .329</td>
</tr>
<tr>
<td>BMI</td>
<td>no</td>
<td>yes</td>
<td>P = .050 G.G*</td>
<td>P = .008, Wilcoxon Signed Rank 1-2 p=.700 2-3 p = .042 3-1 p=.000</td>
</tr>
<tr>
<td>CO</td>
<td>no</td>
<td>yes</td>
<td>P = .062</td>
<td>P = .056</td>
</tr>
<tr>
<td>PG</td>
<td>no</td>
<td>no</td>
<td>P = .137 G.G*</td>
<td>P = .137</td>
</tr>
<tr>
<td>HbA1c</td>
<td>no</td>
<td>yes</td>
<td>P = .165 G.G*</td>
<td>P = .610</td>
</tr>
<tr>
<td>LDL</td>
<td>yes</td>
<td>yes</td>
<td>P = .021 G.G*</td>
<td>P = .329</td>
</tr>
<tr>
<td>HDL</td>
<td>yes</td>
<td>yes</td>
<td>P = .314</td>
<td>P = .083</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>no</td>
<td>no</td>
<td>P = .025 G.G*</td>
<td>P = .070</td>
</tr>
<tr>
<td>Total cholesterol</td>
<td>no</td>
<td>yes</td>
<td></td>
<td></td>
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</tbody>
</table>

*Greenhouse-Geiser (G.G) used in calculation if sphericity violated

Discussion and Recommendation

This study was conducted to determine whether a PBHCl had an effect on enrolled patients as evidenced by a change in eleven separate biologic markers. Previous literature provides no consensus on whether integrated care systems support an improvement in health outcomes of their participants. Despite wide variation in previous research findings, there was great variability in the method and design of each study making conclusions unreliable to apply to the general population. Therefore, this study was developed with a similar design of the large quasi-experimental comparison study reported by Scharf and colleagues (2013), that later became the final report of the Rand Corporation, on evaluation of the SAMHSA PBHCl grant.
program. This study also used biologic markers as outcome measurements to determine effectiveness of an integrated care system although, the study was considerably larger, was conducted over a longer period of time, and used a control group as a comparison. The Rand study also measured Emergency room visits which were initially included in this study until it was determined that the data was previously aggregated and was unable to be assigned to individuals within the study. This variable was then removed as differences were examined between time periods for each individual participant.

Reduction in DBP, as well as total cholesterol was found within the Rand study, but no differences were noted in the other variables (biologic markers) therefore, an attempt was made to repeat the results of Rand study in order to assist in determining whether integrated systems were effective in changing patient health outcomes. Unfortunately, the results of this study showed no consistencies when compared with outcomes of the Rand study and, with the exception of one of the variables (CO), no statistically significant change was found in any of the other variables, thereby indicating that there was no significant effect from the integrated system. Despite findings from this study, multiple factors exist that may explain these findings.

Data collection occurred on each participant in six-month intervals however, many of the variables were not collected within the same time frame. For example, in some of the second and third measurements, several of the variables were not collected at the time of the visit (e.g: data included cholesterol levels, SBP, and DBP but waist circumference and CO levels were missing). This caused a reduction in the sample size for that variable in several cases. This means there was great variability in sample size from variable to variable which could have a potential effect on significance. For example, the sample size for SBP was n=180, but CO levels yielded an n=44. Where possible, statistical adjustment was made for variables with a sample size less than 50.
In addition to missing data, measurement errors were noted within data sets which required correction. This also affected the sample size. An example of this was findings in which the W.C. was calculated in centimeters in some participants, and in inches in others. When centimeters were re-calculated to inches, at times, the trend in data made no sense with wide variations noted in the waist circumference within the one-year time period. This led to the question of how accurately this variable was being measured by the nursing staff. Outliers within the data sets in this case had to be removed, again affecting the sample size.

As previously discussed, when using RM-ANOVA, outliers must be dealt with to avoid skewing the data. Unfortunately, due to the nature of comorbid conditions in this population, many outliers had to be dealt with and often were an accurate method of measurement (blood levels), and a typical finding in this patient population. Therefore, within this population, in the case of variables such as HbA1c and cholesterol levels, outliers are not likely measurement error but are instead a typical finding for this population which made dealing with some of those outliers problematic.

In addition to the barriers in data collection within the study design, which may have had an influence on outcomes, larger system issues may have a more significant effect on the actual outcomes of the study. The limitation of a twelve-month time period may possibly explain a lack of change within the variables over time. As many of the outcomes (biologic markers) are often the product of a complex mixture of human behavior and abilities, a one-year time frame is likely too short to elicit change on them. For example, a reduction in HbA1c, requires the patient to make changes in their diet and exercise profiles which often takes years to establish, even in a person without mental illness. Furthermore, reduction in many of the variables such as HbA1c and cholesterol levels are often accomplished by medication and affected by the patient’s disease
burden, comorbidities and mental health status. These variables each have the ability to exert great influence on the outcomes and were not controlled for within this study.

Finally, in comparing previous literature on PBHCIs, the level of integration of the practice itself was identified as an influential component in considering the effect of integrated care on patient outcomes. As described by Lyngso and colleagues (2013), levels of integration vary from practice to practice. A well-integrated practice shares common clinic space, as well as electronic medical records. These PBHCIs are much less likely to occur given the complexity of Behavioral Health and Primary Care practice regulations and reimbursement protocols. A less integrated system may not even share a common clinic and be under separate roofs but collaborate in a predictable manner. Considering there are five levels of integration defined by SAMHSA, it is easy to appreciate that it may take more time to change patient outcomes in a less integrated system. The great variability of the influence of integration levels can also be explained by the assumption of non-linearity as described by the General Systems Theory. This concept of complex theory suggests that when two or more elements are put together, there is a combined effect that is different than the elements in isolation (Complexity Labs, 2017). The availability of a nutritionist, access to consultation of specialists, smoking cessation classes, peer review classes, nurse management over medication management, and exercise classes are all examples of adjunctive care that is often found within the integrated care systems. These elements can have a profound effect on the system outcomes. As explained by non-linearity, it may be the interaction or combined effect of these additional offerings that make a difference in patient outcomes within an integrated care practice. The combined effect of the elements of the system in this case, may have more of an effect on patient outcomes and health.

**Strengths and limitations**
Strengths of the project include the use of quantitative data as biologic markers that will measure change in patient outcomes as they currently do in general practice. The variables and data collection used was a reiteration of a larger study done that was used to evaluate the SAMHSA grant programs. The biologic measures are also commonly used in practice to determine patient health, which increases the validity and reliability of the findings. In addition, a standardized approach will allow for the study to be replicated (Heale & Twycross, 2015).

Limitations include lack of randomization and a control group (as was used in the SAMHSA study); inability to control for potential influences on variables such as medications, chronic health conditions, age, race, gender, socioeconomic status and motivation to change. Amongst other factors, untested variables may account for the influence on program outcomes (Heale & Twycross, 2015), as well as the inability to determine which elements of the integrated practice may have had a positive influence on the outcomes.

Implications

After an extensive literature review that revealed large gaps in consistency within the integrated practices, and the discovery of multiple factors that influence patient outcomes, there remains the question of what characteristics of a PBHCI create an improvement in the health of patients who have co-occurring conditions and mental health disorders. As health care moves toward value-based systems, the best recipe for integrating care systems will become more important to conserve resources and reduce the cost of disease burden. Unfortunately, there are so many potential influences and variations in these systems, it is difficult to declare which elements of the system work best. It appears that if the concepts from System’s Theory are applied as framework for each integrated practice, it will allow for enough fluidity of the system to change as it meets new needs and allows for the creation of an effective change on patient
health. The following areas are a list of potential avenues for future research to begin to identify influential variables that may impact the health of this population:

- Determining whether improvement in health outcomes are a result of the practice integration or care on the part of the clinicians;
- Identification of the elements within the integration that produce better outcomes.
- Identification of psychiatric disorders that influence a participant’s adherence to the program;
- Potential influence of health disparities such as populations of race, economic status and language barriers.

The potential for future Nursing research in the area of integrated care is immense. Within each of the aforementioned suggestions, multiple opportunities for research that controls confounding variables exists. The eventual goal would create a model of care that keeps vulnerable patient populations engaged in integrated systems that create improvement in their health and longevity.

Future research could strive to determine what health disparities exist amongst minority populations that may impact the goals of integrated programs and determine if there are interventions that can be developed to reduce those disparities.
References


Complexity Labs (May 6,2017). What is a complex system? [video file], Retrieved from: https://www.youtube.com/watch?v=vp8v2Udd_PM&t=72s


New York State Medicaid Program (2007). Policy guidelines manual for article 28 certified clinics, Retrieved from:


Appendix A.

Table 1. Physical health indicator values at baseline showing participant risk and level of risk range.

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Condition</th>
<th>Range (at risk)</th>
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<tr>
<td>SBP</td>
<td>HTN</td>
<td>&gt;140</td>
</tr>
<tr>
<td>DBP</td>
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<td>&gt;90</td>
</tr>
<tr>
<td>Waist circumference</td>
<td>Metabolic syndrome</td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td></td>
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</tr>
<tr>
<td>Women</td>
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<tr>
<td>BMI</td>
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<tr>
<td>Breath C.O</td>
<td>Smoking</td>
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</tr>
<tr>
<td>Plasma glucose.</td>
<td>Diabetes</td>
<td>&gt;100</td>
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<tr>
<td>HbA1c</td>
<td>Diabetes</td>
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<td>HDL-C</td>
<td>Hypercholesterolemia</td>
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</tr>
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<td>LDL-C</td>
<td>Hypercholesterolemia</td>
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<tr>
<td>Triglycerides</td>
<td>Hyperlipidemia</td>
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### Appendix B

#### Table 2. Results table of variables

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<tr>
<th></th>
<th>N</th>
<th>Range**</th>
<th>Mean Stnd dev*</th>
<th>Distribution Y/N and number Shapiro</th>
<th>Sphericity violated (Y/N and number) Mauchley</th>
<th>RM Anova or Greenhouse-Geisser if fails sphericity</th>
<th>Friedman if sig Wilcoxon Signed Rank test if Friedman sig</th>
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<tr>
<td>SBP</td>
<td>143</td>
<td>94-186</td>
<td>124.9±15.8 125.5± 16.59 124.5± 14.35</td>
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<td>Anova F (2,282) = .285 P=.752</td>
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<td>95-190</td>
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<td>DBP</td>
<td>148</td>
<td>50-126</td>
<td>82.04± 11.151 81.51± 11.268 80.29± 8.898</td>
<td>No P=.009</td>
<td>No P=.257</td>
<td>RM Anova F (2,290) = 1.314 P=.270 Not significant</td>
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<td>56-117</td>
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<td>HbA1c</td>
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<td>4.7-13.9</td>
<td>7.143± 2.458 7.082± 2.497 6.789± 2.0732</td>
<td>No P=.000</td>
<td>Yes P=.017</td>
<td>Greenhouse-G F(1.7, 73.119)=2.098 P=.137 Not significant</td>
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<td>PG</td>
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<td>BMI</td>
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<td>18.3-66.4</td>
<td>34.591± 9.4304 34.543± 9.1823 34.615± 9.1732</td>
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<td>Yes P=.000</td>
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<td>18.2-6.0</td>
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<td>Waist</td>
<td>40</td>
<td>47.165± 12.484</td>
<td>45.487± 10.661 43.695± 10.519</td>
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<td>Yes P=.000</td>
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<td></td>
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<td>47.313± 10.484</td>
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<tr>
<td></td>
<td></td>
<td>47.53± 6.716</td>
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<tr>
<td>CO</td>
<td>88</td>
<td>0-33</td>
<td>6.89± 7.738 6.93± 8.011 5.53± 6.716</td>
<td>No P=.000</td>
<td>Yes P=.000</td>
<td>Greenhouse-G F (1.795, 152.558) =3.164 P=.050 significant</td>
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<td>HDL</td>
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<td>21-93</td>
<td>46.46± 14.851 42.39±9.937 43.29±10.062</td>
<td>Yes P=.099</td>
<td>Yes P=.045</td>
<td>Greenhouse-G F (1.840,126.94)= 4.130 P=.021 significant</td>
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<td>LDL</td>
<td>71</td>
<td>18-191</td>
<td>115.31± 40.256 110.99± 30.772 105.89± 33.243</td>
<td>Y P=.612</td>
<td>Yes P=.030</td>
<td>Greenhouse-G F(1,822, 125.728)=1.980 P=.146 Not significant</td>
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<td>Trig</td>
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<td>57-591</td>
<td>196.17± 123.647 202.34± 153.38 180.61± 119.944</td>
<td>N P=.000</td>
<td>No P=.050</td>
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* N: Number of patients, Range*: Range of values, Mean Stnd dev*: Mean and Standard deviation, Distribution Y/N and number Shapiro, Sphericity violated (Y/N and number) Mauchley, RM Anova or Greenhouse-Geisser if fails sphericity, Friedman if sig Wilcoxon Signed Rank test if Friedman sig.
*Note: Range and mean ± standard deviation measured at 3-time levels: initial, 6-months, 1-year

Appendix C

Table 3. Timeline of the study

<table>
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<tr>
<th>Task &amp; Person(s) Responsible</th>
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<th>9/18</th>
<th>10/18</th>
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<td>IRB approval requested and corrected: PI</td>
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<tr>
<td>Enrollment of participants in study: PI</td>
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<td>Retrospective chart review: PI</td>
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<tr>
<td>Collect and analyze data: PI</td>
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<td>Final Report Due: PI</td>
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<td>Report to faculty/ Defense: PI</td>
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</table>
MEMORANDUM

DATE: November 28, 2018

TO: Jody Coppola MS, FNP-BC

FROM: Dr. Paul Blackley, Co-chair
Dr. Mary Zampini, Co-chair

RE: Acceptance of University of Buffalo IRB approval

Application Number: IRB2018-47A

Proposal Title: The effects of Integrated Care on patient outcomes in a Primary and Behavioral Health Care Integration System

The Le Moyne College IRB has reviewed your study and accepted the approval granted by the University of Buffalo IRB.

- The appropriate IRB form with required attachments has been presented.
- You may now begin to carry out your retrospective chart review.
- Be advised of your responsibility to adhere to the exempt status protocol for the protection of human subjects involved in research projects. Any modifications or additions to the approved procedure must be approved and accepted by the above IRBs before they are implemented. In this case, you must submit a Request To Change An Approved Study to the Le Moyne IRB, unless the change is immediately necessary in order to eliminate a hazard to a participant. The IRB should be notified immediately in the event of a serious hazard requiring change in the previously approved procedures.

The IRB wishes you success as you undertake this research project.
University at Buffalo Institutional Review Board (UBIRB)
Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Elmwood Ave | Buffalo, NY 14222
UB Federally Assured ID: FWA00008824
APPROVAL OF SUBMISSION

October 10, 2018

Dear Joanne Coppola,

On 10/10/2018, the IRB reviewed the following submission:

<table>
<thead>
<tr>
<th>Type of Review</th>
<th>Initial Study</th>
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<tr>
<td>Title of Study</td>
<td>THE EFFECTS OF INTEGRATED CARE ON PATIENT OUTCOMES IN A PRIMARY AND BEHAVIORAL HEALTH CARE INTEGRATED SYSTEM</td>
</tr>
<tr>
<td>Investigator</td>
<td>Joanne Coppola</td>
</tr>
<tr>
<td>IRB ID</td>
<td>STUDY00002766</td>
</tr>
<tr>
<td>Funding</td>
<td>None</td>
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<td>Grant ID</td>
<td>None</td>
</tr>
<tr>
<td>IND, IDE, or HDE</td>
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</table>
| Documents Reviewed | • 612 revisions, Category: IRB Protocol;  
|                  | • data collection sheet, Category: Other;  
|                  | • IRP-503-Template Protocol revisions 3.docx, Category: IRB Protocol; |

The IRB approved the study from 10/2/2018 to 10/10/2019 inclusive. The Initial study materials for the project referenced above were reviewed and approved by the SUNY University at Buffalo IRB (UBIRB) by Non-committee Review. The IRB has determined that the study is no greater than minimal risk. Before 10/10/2019 or within 30 days of study closure, whichever is earlier, you are to submit a continuing review application with required explanations. In order to avoid a lapse in IRB approval, it is recommended that you submit your continuing review at least 30 days for an expedited study and at least 45-60 days for a full board study, prior to the approval end date of the study. You can submit a continuing review application by navigating to the active study in Click IRB and selecting ‘Create Modification / CR’. Studies cannot be conducted beyond the expiration date without re-approval by the UBIRB.

In conducting this study, you are required to follow the requirements listed in the Investigator Manual (IRP-103), which can be found by navigating to the IRB Library within the IRB system.
Full HIPAA Waiver
Based on the information you have provided in the “University at Buffalo Human Research Protections Program Request for Full Waiver of Individual Authorization for Use of Individually Identifiable Health Information” form (waiver request), the UBIRB has determined a full waiver of the individual authorization required by 45 CFR §164.508 for use or disclosure of protected health information is warranted based on the following criteria as specified in 45 CFR 164.512(i) (2). Accordingly:
A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
1) An adequate plan to protect the identifiers from improper use and disclosure;
2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
3) Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;
B) The research could not practicably be conducted without the waiver or alteration; and
C) The research could not practicably be conducted without access to and use of the protected health information.
A brief description of the Protected Health Information for which this alteration or waiver has been granted is provided on the “Request for Waiver of the Authorization for Use of Individually Identifiable Health Information” or “Request for Limited Waiver of the Authorization for Use of Individually Identifiable Health Information for Study Recruitment” which is part of this approval. If HIV information is requested, this waiver is only valid for disclosures consistent with New York Code Public Health Article 27-F. This full waiver has been reviewed and approved for the above referenced study by the UBIRB to permit you to receive personal health information as specified in section (1) of the waiver request.
UBIRB approval is given with the understanding that the most recently approved procedures will be followed and the most recently approved consent documents will be used. If modifications are needed, those changes may not be initiated until such
Modifications have been submitted to the UBIRB for review and have been granted approval.
As principal investigator for this study involving human participants, you have responsibilities to the SUNY University at Buffalo IRB (UBIRB) as follows:
1. Ensuring that no subjects are enrolled prior to the IRB approval date.
2. Ensuring that the study is not conducted beyond the expiration date without reapproval by the UBIRB.
3. Ensuring that the UBIRB is notified of:
   - All reportable information in accordance with the New Information SOP (HRP-024).
   - Project closure/completion by submitting a Continuing Review/Modification submission.
4. Ensuring that the protocol is followed as approved by UBIRB unless a protocol amendment is prospectively approved.
5. Ensuring that changes in research procedures, recruitment or consent processes are not initiated without prior UBIRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
6. Ensuring that the study is conducted in compliance with all UBIRB decisions, conditions, and requirements.
7. Bearing responsibility for all actions of the staff and sub-investigators with regard to the protocol.
8. Bearing responsibility for securing any other required approvals before research begins.
If you have any questions, please contact the UBIRB at 716-888-4888 or ubirb@buffalo.edu. Please include the project title and number in all correspondence with the UBIRB.
12/20/18

THE EFFECTS OF INTEGRATED CARE ON PATIENT OUTCOMES IN A PRIMARY AND BEHAVIORAL HEALTH CARE INTEGRATED SYSTEM

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Purpose
Investigate the relationship between a Primary and Behavioral Health Care Integration (PBHCI) system and its participants, to determine if there is an effect on the health of that population.

Background & Justification

• People with mental and substance abuse disorders often die from chronic conditions that are preventable and can be treated successfully in primary care.
• 68% of adult patients with mental illness also have chronic conditions.
• The cost to care for patients with mental illness and chronic conditions is estimated to be 75% higher than patients without mental illness.
• Patients with chronic conditions who have mental health diagnoses cost the health care system four times more than those who have a chronic condition alone.

Substance Abuse and Mental Health Administration (SAMHSA), 2017

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Background and Justification

Since inadequate access to care and increased burden of disease cost the health care system an estimated 1.24 trillion dollars, the significance of this intervention rests upon the ability of integrated care systems to streamline healthcare for vulnerable populations such as patients with mental health illness and chronic disorders to help alleviate such health inequalities and reduce premature death.

(Dankwa-Mullan et al., 2010)
PBHCI
Primary and Behavioral Health Care Integration program developed by Substance and Mental Health Services Administration (SAMHSA) in conjunction with Human Resources Services Administration (HRSA) to improve the health of patients with mental illness (SAMHSA, 2017).

Benefits include:
- Cost effectiveness through shared resources
- Client-oriented care
- Improved access to care

Literature Review
- 15 studies within the past 5 years were included
- Studies examined:
  - Practice implementation
  - Patient satisfaction
  - Reduction in glycosylated hemoglobin (HbA1c)
  - Reduction in hospitalizations and ED visits
  - Reduction in biologic markers

Capstone objective
Investigate whether the PBHCI is effective at improving health outcomes of patients who have chronic diseases and mental illness as evidenced by a change in biological markers.

<table>
<thead>
<tr>
<th>Biologic Marker</th>
<th>Condition</th>
<th>Range at Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBP</td>
<td>Hypertension</td>
<td>&gt;140</td>
</tr>
<tr>
<td>DBP</td>
<td>Hypertension</td>
<td>&gt;90</td>
</tr>
<tr>
<td>Waist circumference</td>
<td>Metabolic syndrome</td>
<td>&gt;102 cm</td>
</tr>
<tr>
<td>Max (Hip)</td>
<td>Metabolic syndrome</td>
<td>&gt;88 cm</td>
</tr>
<tr>
<td>BMI</td>
<td>Obesity</td>
<td>&gt;25</td>
</tr>
<tr>
<td>Breath carbon monoxide</td>
<td>Smoking</td>
<td>&gt;10</td>
</tr>
<tr>
<td>Plasma glucose</td>
<td>Diabetes</td>
<td>&gt;100</td>
</tr>
<tr>
<td>Glycosylated High (HBA1c)</td>
<td>Diabetes</td>
<td>&gt;5.7</td>
</tr>
<tr>
<td>HDL cholesterol</td>
<td>Hyperlipidemia</td>
<td>&gt;40</td>
</tr>
<tr>
<td>LDL cholesterol</td>
<td>Hyperlipidemia</td>
<td>&gt;130</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>Hyperlipidemia</td>
<td>&gt;150</td>
</tr>
<tr>
<td>Total cholesterol</td>
<td>Hyperlipidemia</td>
<td>&gt;200</td>
</tr>
</tbody>
</table>
Literature Review Findings

- Variable findings as well as method and design of studies
- Variability of outcomes (Oxelius, 2011)
- Lack of randomization and small sample sizes (Doherty et al., 2016)
- Potential bias in the selection of comparison groups (Scharf et al., 2013)
- Not applicable to the general population (Scharf et al., 2013)
- Variability in confounding elements (health disparities) (Rossom et al., 2017)
- Variability in levels of integration (Hwang, Chang, LaClaire, & Paz, 2013)
- Lack of integrated electronic health record (Tepper et al., 2017)

Literature Review

- Practice implementation (Busetto, GerLijkr, & Vrijhoef, 2014)
- Model of care (patient satisfaction) (Coleman et al., 2017)
- Interventions (Doherty et al., 2016)
- Organizational elements (Lyngso et al., and Oelke et al., 2015)

Literature consensus

- All studies concluded that evidence based knowledge about integrated care programs is insufficient

Gaps in practice

- Determining whether improvement in health outcomes are a result of the practice integration or care on the part of the clinicians
- Identification of elements within integration that produce better outcomes
- Identification of psychiatric disorders that may influence program adherence
- Potential influence of health disparities
CONCEPTUAL FRAMEWORK

General Systems Theory

Complexity Theory

General Systems Theory

Methods, tools, and principles all oriented to looking at the interrelatedness of forces (Kleiner, Roberts, Ross & Smith, 1994)

Complexity Theory (four concepts):
- Numerosity: examines hierarchy and arrangement of elements in a system
- Non-linearity: when 2 or more elements are put together, the combined effect that is different than elements in isolation; fluidity of a system through change
- Connectivity: network of connections/subsystems tied together
- Autonomy & Adaptation: emergence of patterns of organizations (subsystem exerts its effect on a system)

Constructs of the theory

- Holism: A system is greater than its parts
- Feedback: subsystems interconnected and response to changes directly and indirectly as a response to influence from other parts of the system
- Goals: contingent and negotiated
- Equifinity: no one best way to achieve a goal and all ways of organizing are not equally effective

(Organizational Communication Channel, 2017)

System Theory: Feedback

(inputs) → (system) → (outputs)

(input and output are organized by the environment, feedback is organized by the environment)

Directksen Limited Liability Company, 2018
Sample
180 patients enrolled in a PBHCI
- Inclusion criteria: male or female patients between the ages of 18-65 who have been enrolled for at least one year
- Exclusion criteria: children or adolescents under 18 years of age, adult patients over 65 years of age, enrollment for less than 1 year

Design
- Quasi-experimental, retrospective record review.
- Review of 2 separate EHRs
- Collection of data at 3 consecutive points in time at 6 month intervals over a 1 year period of time.
- All data collected was pre-existing and regularly collected as part of regular patient care.
- All patient identification was removed and replaced with a code to maintain anonymity.
- Data collected includes 11 biologic markers that reflect patient’s health status

Data Outcome Measures (dependent variables)

<table>
<thead>
<tr>
<th>Biologic marker</th>
<th>Initial</th>
<th>6 mos</th>
<th>1 year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic blood pressure</td>
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<td></td>
<td></td>
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<tr>
<td>Diastolic blood pressure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Waist circumference</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body mass index</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carbon monoxide</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plasma glucose</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>HbA1c</td>
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<td></td>
<td></td>
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<tr>
<td>HDL</td>
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<tr>
<td>LDL</td>
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<td></td>
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<tr>
<td>triglycerides</td>
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<td></td>
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<tr>
<td>Total cholesterol</td>
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<td></td>
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</tbody>
</table>

Demographics: Race

<table>
<thead>
<tr>
<th>Race</th>
<th>Total</th>
<th>Percentage (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>119</td>
<td>66.1</td>
</tr>
<tr>
<td>African Americans</td>
<td>24</td>
<td>13.9</td>
</tr>
<tr>
<td>Native Americans</td>
<td>1</td>
<td>.6</td>
</tr>
<tr>
<td>Asian</td>
<td>10</td>
<td>5.6</td>
</tr>
<tr>
<td>White Hispanic</td>
<td>16</td>
<td>8.9</td>
</tr>
<tr>
<td>Total</td>
<td>180</td>
<td>100</td>
</tr>
</tbody>
</table>
Demographics: Age Range

Data Analysis

- One-way repeated ANOVA was used to determine whether there was a statistically significant difference in-between measures for each variable. Outliers were either eliminated or kept (with a Friedman non-parametric test applied).
- Distribution normality was determined by the Shapiro-Wilk test although RM-ANOVA is robust to non-normality.
- Mauchly's test of sphericity was applied to determine whether variances in different access between any 2 time periods were not the same as any other 2 time periods.
- Greenhouse-Geisser adjusted the degree of freedom if sphericity was violated.

Demographics: Gender

<table>
<thead>
<tr>
<th>Gender</th>
<th>Total</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>118</td>
<td>65</td>
</tr>
<tr>
<td>Male</td>
<td>62</td>
<td>35</td>
</tr>
<tr>
<td>Totals</td>
<td>180</td>
<td>100</td>
</tr>
</tbody>
</table>

Data Analysis

- Any statistically significant findings were then subjected to a pair wise comparison post-hoc test (Wilcoxon Signed Rank Test).
- Comparison paired T test determined where difference occurred (between time points).
Results

Statistically significant differences between the second and third, and the third and first time levels were discovered for carbon monoxide levels. There were no other statistically significant differences in any of the other variables over a one-year period of time.

Discussion

- Study done to determine if there was an effect of the PBHCI on patients enrolled as evidenced by a change in biologic markers.
- Previous literature provides no consensus.
- Carbon monoxide levels were the only variable to show statistically significant differences in levels over time.
- Means of variables did show some reduction in other variables over time but not with statistical significance.

Confounding factors

- Variables collected were often not synchronized with other variables (a C.O level may not have been collected at the same time as the BP).
- Reduction in sample size due to missing data.
- Measurement errors.
- Outliers that required further consideration but were consistent with characteristics of the population.
- One year time frame too limited to show effect.
- Level of integration
- System complexity.
Strengths of Study

• Quantitative data which used biologic markers which are currently standards of measurement in practice which increases validity and reliability of measurement.

• Duplicated measured outcomes from a larger, and longer study that was used as a reference for SAMHSA evaluation, and would be uncomplicated to replicate in the future.

Limitations of Study

• No randomization or control group for comparison

• Inability to control for multiple confounding variables that influence patient health

• Inability to control for multiple confounding variables that influence the level of integration within the practice

Implications

• Integration promising as a means to reduce healthcare costs.

• Does integration improve health?

Future: control confounding variables

• Determine whether improvement in health outcomes are a result of the integration system or care on the part of the clinicians.

• Identification of the elements within the system that have an effect on health.

• Influence of health disparities.

• Identification and control of psychiatric disorders that influence adherence.

• Longitudinal studies in 3-5 year periods of investigation.
Future Investigation

• Repeat the study over a longer period of time
• Collect data on confounding variables
• Use current findings to initiate a program evaluation at Liberty Resources.

References


Liberty Resources (2016). SAMHSA Grant Information worksheet, Syracuse, NY; Author.
References


References
