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Evaluation of the Clinical Integration Model for Hospital Care Delivery

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EVALUATION OF THE CLINICAL INTEGRATION MODEL FOR HOSPITAL CARE DELIVERY

by

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Abstract

Purpose: Two studies were used to evaluate whether introduction of the Clinical Integration Model (CIM) would decrease cost, length of stay (LOS), and mortality in two populations: a psychiatric in-patient population and congestive heart failure (CHF) patients. **Objectives:** 1. Evaluate reliability and validity of a process tool, the CareGraph®, essential in the CIM. 2. Determine if there is a difference for LOS and cost between patients receiving care in the CIM and those receiving care in a traditional primary care delivery model in a psychiatric population; compare the same parameters as well as survival in the CHF population. **Methods**: Reliability of the CareGraph® tool was evaluated using Cronbach's alpha, and known-groups validity was evaluated using a t-test to compare admission and discharge scores. A retrospective pre-implementation, post-implementation design was utilized to evaluate outcomes in the psychiatric population. A retrospective comparative design was used in the CHF population. **Results:** Initial Cronbach's alpha for all CareGraph® items was .71. For the psychiatric population, LOS increased between 2010 (4 days) and 2011 (5 days) ($t\ [189] = -2.71$, $p<.01$). Although the LOS was longer after implementation of the CIM, the cost was not significantly different. Evaluation of differences between CIM hospitals and regular care hospitals using the inpatient CHF population showed a significant difference in two outcome variables; LOS, $F(3, 245) = 5.78$, $p = .001$ and cost $F(3,226) = 21.70$, $p = .000$ but no difference in survival rates.

Chapter 1. Overview of the Research

Overall Purpose of the Study

Failure to promote interdisciplinary collaboration is contributing to the fragmentation of care delivery and poor outcomes in U.S. hospitals. Higher mortality rates (Estabrooks, Midodzi, Cummings, Ricker & Giovannetti, 2005; Knaus, Draper, Wagner, & Zimmerman, 1986) and longer lengths of hospital stay (Zwarenstein, Goldman & Reeves, 2009) have been found in environments where collaboration is limited or non-existent. The purpose of this original research was to evaluate a model of care delivery which incorporates essential collaborative structures and processes called the Clinical Integration Model (CIM) (Zander, 2007).

Healthcare researchers must identify essential elements of collaboration in order to alleviate the physical and financial burden of medical errors. As many as 98,000 people die in hospitals each year as a result of medical errors due to lack of collaboration and disjointed care (Kohn, Corrigan & Donaldson, 2000). Beyond the cost of human lives, billions of dollars are spent annually for additional care resulting from medical errors. Empirical evidence in support of collaboration in the healthcare environment is available in the literature, yet there is little evidence on how to create this environment (Tschannen, 2004). These original studies begin to address the research gap in proposing successful ways to create a collaborative environment for healthcare workers.

Demonstrated positive outcomes of a collaborative model of care delivery are decreased mortality (Estabrooks, Midodzi, Cummings, Ricker & Giovannetti, 2005;

Knaus, Draper, Wagner, & Zimmerman, 1986), decreased medical errors leading to adverse patient outcomes (Boyle, 2004; Prowse and Heath, 2005), and reduced costs for the healthcare system (Zwarenstein, Goldman & Reeves, 2009). However, there is little evidence supporting the nature and cost of the essential structures and processes which produce the positive impact for the patient and healthcare system. The CIM incorporates structures and processes essential for producing a collaborative environment and validates the positive impact for the healthcare system.

The CareGraph® tool is an essential process tool used to provide a common system language for interdisciplinary patient discussions, focus care coordination, encourage professional nursing judgment, and determine care progression through quantitative classification of patient acuity. It was developed as a process tool for the collaborative CIM and has been utilized in the acute care and inpatient psychiatric units with limited psychometric testing. In order to continue further development and use of this tool, it was essential to evaluate basic psychometric properties.

Modifications Based on Pilot Study

Initial pilot work for the major study took the form of a preliminary study in a psychiatric population. The purpose was to evaluate the CareGraph® tool incorporating outcome measures, LOS, and cost to see if data extraction of these variables in a time limited pre-implementation, post-implementation design was feasible. A single-site psychiatric hospital was used for the pilot study with measurements taken pre- and post-implementation of the CIM. Once the study population, outcome measures, and time frames were determined, the study received IRB approval followed by data extraction. Initial reliability and validity for the CareGraph® tool for the psychiatric population were

favorable. The outcomes evaluation yielded a LOS which was longer after the implementation of the CIM and a cost which was not significantly different. After exploring the data with the practitioners working in this model, it was determined that there were changes in primary physician practitioner and mid-level provider during the intervention period which may have accounted for the extended length of stay finding. However, the purpose of the pilot was to test the feasibility of using this methodology for the primary study, and this goal was met.

Based on the pilot work, modifications were made to the primary study to better manage disease treatment specificity and practitioner variability for this clinical effectiveness research. Changes in the time frame of the primary Congestive Heart Failure (CHF) study were made to accommodate additional time for approvals and extraction of the types of data needed to answer the research questions based on the CareGraph® tool evaluation experiences in the pilot work. The Joint Commission (TJC) core measures for the Congestive Heart Failure (CHF) population were added as additional criteria for inclusion to manage treatment variability. All participating study hospitals met CHF core measure criteria with >92% compliance. Additionally, timeframes for evaluation were modified to increase the power of the study. Based on initial pilot work and the Theory of Diffusion of Innovation (Rogers, 2003), timeframes for the CHF study were extended to twelve months post implementation of the CIM. The stability of the practitioner group at each participating facility was evaluated prior to inclusion. Use of the pilot study is believed to have strengthened the primary study and facilitated its completion.

Introduction of Articles

Two articles are included to report the findings of this topic of research. The first article discusses the findings of a pilot study conducted at a psychiatric hospital and reports initial reliability and validity measures of a tool, the CareGraph®, for use in caring for this population. The CareGraph® is an essential process tool used to plan collaborative care in the CIM. The outcomes of length of stay and cost were evaluated pre and post-implementation of the CIM to determine the effects of this model for the hospital.

The second article reports findings of the effects of the CIM in an acute inpatient CHF population for a Midwestern Healthcare System. Four hospitals were included in this study to strengthen confidence in the results. Patient, hospital, and health system outcomes of survival, LOS and cost are evaluated. These original clinical effectiveness studies begin to address the research gap in identifying successful ways to create a collaborative environment for healthcare workers and the effects on patients, hospitals, and health systems.

Chapter 2. The CareGraph®: Initial Psychometrics and Evaluation of Length of Stay and Cost in a Psychiatric Inpatient Population

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Abstract

Problem: There are few reliable and valid patient classification tools which can be used to determine patient acuity and predict outcomes. **Objectives: 1.** Determine if the CareGraph® is a reliable tool for use in the psychiatric population. **2.** Determine if the categories for the psychiatric CareGraph® tool are consistent with the conceptualized domains. **3**. Determine if there is a difference in length of stay and cost for the psychiatric population receiving care using the CareGraph® compared to those receiving care in the same facility prior to implementation of the CareGraph®. **Methods**: Initial reliability was evaluated using Cronbach's alpha, and known-groups validity was evaluated using a t-test to compare admission and discharge CareGraph® scores. To determine if the domains of the CareGraph® are consistent with those conceptualized, a confirmatory factor analysis was performed. Lastly, a pre- and post-implementation analysis was utilized to evaluate outcomes of length of stay and cost of care between two groups. **Findings:** Initial Cronbach's alpha for all items was .71. A t- test assessing known-groups validity demonstrated a significant difference: $t(215) = 14.663$, $p=.000$. Confirmatory factor analysis revealed a six factor solution accounting for 68.9% of the variance. Length of stay increased between 2010 (4 days) and 2011 (5 days) ($t[189] = -2.71$, $p<.01$). Although the LOS was longer after implementation of the CareGraph®, the cost was not significantly different.

Key Words: CareGraph, Psychometrics, Donabedian

The CareGraph®: Initial Psychometrics and Evaluation of Length of Stay and Cost In a Psychiatric Inpatient Population

Health economists and researchers have shown a continuing interest in quantifiable outcomes associated with nurse staffing and patient care needs (Kiekkas, Sakellaropoulos, Brokalaki, Manolis, Samios, Skartsani, & Baltopoulos, 2008) however, no two patients have the same needs. Balancing individual patient care priorities with nurse staffing in an era of cost containment and a nursing shortage has made regular assessment of patient needs a relevant and pressing issue (Beck, 2009). The American Nurses Association (2008) stresses that nurse staffing should be tailored to the "specific needs of each unit" based on factors including patient needs (para 4). Multiple states have enacted legislation addressing nurse staffing and its relationship to patient care needs. Hospitals are being held accountable for the establishment of reliable and valid tools used to address nurse staffing plans which optimize patient outcomes.

Determining ideal staffing levels from reliable and valid tools which assess patient care needs is a challenging task in many health care settings. Although numerous tools exist, such as the APACHE instrument (Acute Physiology, Age, Chronic Health Evaluation)(Brennan & Daly, 2009) and the TISS-28 (Therapeutic Intervention Scoring System)(Kiekkas, et al. 2008), available instruments tend to include only physiologic components and nursing tasks. These instruments are also inflexible and lack applicability across multiple patient populations or care areas. Many of the tools developed also discourage professional judgment of the caregiver and reduce the profession of nursing to lists of tasks and procedures (Shaha & Bush, 1996).

The APACHE instrument (Brennan & Daly, 2009) is made up of three components: acute physiology score, age adjustment, and chronic health adjustment. Points are awarded in each of the three components by severity for a total of 91 points possible. Other domains important to nursing in meeting patient needs are not included in this instrument. The TISS -28 (Kiekkas, et al. 2008) is a twenty-eight item tool including seven components with score ranges from 0-78. The components include: basic activities, ventilatory, cardiovascular, renal, neurologic, metabolic and specific interventions. The TISS-28 is based on the principle that the number of therapeutic interventions is related to clinical severity; therefore, more nursing time is required for patients with higher scores . There is no consideration for psychologic factors affecting care, pain, education, or safety.

In the early evolution of acuity systems, Shaha and Bush (1996) noted that the ideal tool for assessing patient needs should:

*Focus on professional nursing, emphasizing the process of patient care.

*Be quick and easy for the nurse to use.

*Be flexible and reflect changing patient care methods.

*Be inexpensive to implement, update and maintain.

*Be of tangible value to caregivers and administrators. (p. 348)

Subsequent studies have found that in order to create an ideal tool which classifies patient needs and gives voice to professional nursing judgment, direct care staff must be involved in the development (Harper & McCully, 2007). A staff-valued tool can be created only if there is participation and buy-in at all levels of the care organization. The tool must be patient-centered and inclusive of the entire care management team (Shaha &

Bush, 1996). Since the nursing process is the gold standard (Harper & McCully, 2007) by which nurses give prudent patient care, the tool should measure the major domains associated with the nursing process: physiologic and psychologic aspects as well as others necessary to provide safe care.

In an effort to create a tool which meets the needs of the interdisciplinary care team for assessing patient needs and providing timely and efficient care, a Midwestern psychiatric center which is part of a larger regional medical system adapted a tool, the CareGraph®, (Center for Case Management, 2004) from the acute inpatient setting. The original tool for the inpatient setting includes assessment of nine physiologic components as well as psychological aspects, pain, patient education, healing relationships, and safety. The CareGraph® for the inpatient psychiatric population differs from the original in the components assessed and includes six physiologic parameters(nutrition, hematologic/metabolic, cardiopulmonary, fluid balance, immunologic/infection and wound/skin) and four psychologic parameters(thought content, suicide/homicide, mood/affect and interpersonal change quotient) along with measures of pain, patient education, medication compliance, self- care, and safety. Dialogue between and within disciplines is focused on problems identified during completion of the CareGraph® with interventions and movement toward goals discussed.

Each shift the nurse caring for the patient fills out the CareGraph® in order to determine priority patient care needs based on the quantitative values obtained when completing the CareGraph®. The information is used to focus the nursing process during each 24-hour period as well as the entire hospital stay. The staff nurse meets with the entire care team three times a week to discuss problem foci and progression of care. The

interdisciplinary care team including nurses, physicians, physical therapists, respiratory therapists and nutritional services brings their expertise to the table, competent and confident in specialty-specific skills, with the autonomy to carry out recommendations.

This study is an initial psychometric and operational evaluation of the CareGraph®, a tool used to provide a common system language for interdisciplinary patient discussions, focus care coordination, validate professional nursing judgment, and determine care progression through quantitative classification of patient acuity. Use of the instrument in the psychiatric environment has been limited.

Background

The ability to provide quality care that meets patient needs within a budgeted set of dollars requires accurate information for decision makers (Harper & McCully, 2007). It is a daily struggle for nurse managers to provide high quality care with the correct number of nursing staff and maintain budgets without the necessary tools and information. The focus on cost containment through determination of appropriate staffing levels continues to be a major issue for nursing and hospitals.

Determining staffing needs can be a challenge for nurse managers because the work of nurses in providing patient care is dependent on many factors, including patient characteristics as well as provider characteristics (Brennan & Daly, 2009; DeLisle, 2009). Acuity systems within health care facilities in the United States were developed as a way of providing the necessary information to determine appropriate staffing levels and control costs (Shaha & Bush, 1996).

Although acuity measures have been around for decades, Harper and McCully (2007) note that modest research exists on these tools. Few studies have looked at the

psychometrics of the various tools, and there is an absence of agreement on what makes a quality acuity tool. In a concept analysis, Brennan and Daly (2009) used a model based on Donabedian's (1966) Structure-Process-Outcome Model to look at categories associated with acuity. The categories in this analysis included both patient-related and provider-related structural elements (Brennan & Daly, 2009). Severity is a patient-related attribute common to many acuity tools (Brennan & Daly, 2009; Chiovitti & Gallop, 2000; DeLisle, 2009; Harper & McCully, 2007) and can include physiologic or psychosocial parameters. Additionally, nursing care needs which fall in the provider-related category can be associated with patient severity. Logically, as the severity of the patient condition goes up, so does the demand for nursing care.

An ongoing problem for hospitals relates to acuity tools which are not necessarily effective for determining staffing or controlling costs of patient care delivery. For many hospitals and health care systems, there are challenges in ensuring that the acuity tools are utilized accurately and reflect the patient population served. Rather than abandon efforts to manage patient care staffing to meet patient needs, a new imperative has emerged to engage health care professionals to develop tools which strengthen judgment and promote accountability.

Theoretical Framework

The Donabedian Model (1966) is proposed as a way of providing essential structures and process assessment for determining effectiveness of outcomes in the health care setting. Montalvo and Dunton (2007) utilized the Donabedian Model to describe a complete and balanced view of nursing care within the acute care setting. The Donabedian Structure, Process, Outcome Model provides a lens through which the

entirety of the nursing care enterprise can be assessed, evaluated, and improved for better outcomes. In this model, structure refers to the environment in which care is provided. Structure encompasses the work environment which, according to Brennan and Daly (2009), includes patient severity and nursing intensity. These structural elements tend to be relatively permanent in nature and are often thought of as key determinants to quality (Donabedian, 1988). Process elements are more flexible and readily changeable. Process encompasses the things nurses do or fail to do which shape patient outcomes (Montalvo and Dunton, 2007). Tools utilized for patient classification, as well as staffing models and budgets, are examples of processes of care which may significantly influence patient outcomes. Outcomes are the changes in patients' health attributable to their care (Montalvo and Dunton, 2007). Outcomes are influenced by the structures and processes within the health care setting and, therefore, need to be considered in evaluation. According to Donabedian (1988), changes in structures and processes of care are required to optimize patient outcomes in the health care delivery system.

Within the Structure, Process, Outcome framework, the context (structure) in which the intervention (process) occurs has an influence on the outcome (Donabedian, 1988). Patient classification systems or acuity tools are seen as processes which occur within a defined context and provide a way to assess the measured results or outcomes. The appropriate use of these tools to guide care processes requires health care providers to learn how to effectively communicate and trust each other. This methodology thrives in a multidisciplinary model of care delivery. Requisite tools need to be available to all providers, as well as methods to coordinate work flow and goals that are clearly

articulated and based on patient needs. The Donabedian Model has provided a useful structure for studying processes and outcomes of care and guided the study.

Variables

Donabedian's model reflects three main variables: structure, process, and outcomes. Operational definitions of the three variables for the study are found in Table 1.

Table 1. Conceptual and Operational Definitions of Study Variables

VARIABLE	CONCEPTUAL DEFINITION	OPERATIONAL DEFINITION
Structure	The environment in which care is provided*	Inpatient acute psychiatric care unit with specific DRG† designations
Process	The things nurses do or fail to do which shape patient outcomes**	Use of the CareGraph® tool and related care coordination processes
Outcome	The changes in patients' health attributable to their care**	Length of stay Cost per case (pre-test data – April 1 through August 31, 2010) (post-test data – April 1 through August 31, 2011)

*Donabedian, 1988
**modified from Montalvo and Dunton, 2007
† Diagnostic Related Group

The main *structural* variable in this study is the place where care is provided. An acute inpatient psychiatric unit in the Midwestern U.S. where patients receive care for the included diagnoses of mood disorder (DRG 295.90), suicide (DRG 300.9), major depression (DRG 296.33), bipolar disorder (DRG 296.8) and generalized anxiety disorder (DRG 300.02). The implementation of the CareGraph® for the specified psychiatric inpatient population and concomitant change in care coordination served as intervention. Inclusion criteria were met by being a patient during one of the two data periods. All data were collected from an extant database of records which were unidentifiable to a specific patient as received by the researcher. Use of the Caregraph® score for each patient

served to operationalize the *process*, or intervention, variable. The *outcomes* measured to evaluate change after implementation of the CareGraph® were length of stay and cost per case. Outcome data were collected from the existing database at two data points: data point #1 was prior to implementation of the CareGraph® (April 1 through August 31, 2010) and data point #2 was after 12 months (April 1 through August 31, 2011). The time sequencing was based on Rogers' Theory of Diffusion of Innovation (2003) which states that full adoption of an innovation should occur within twelve to eighteen months. For further clarification, length of stay (LOS) was determined as the day of admission through day of discharge and was calculated in days. Cost per case was calculated for each patient stay using the TSI/Eclipses System which includes variable and direct costs.

Research Design and Methods

Research Questions

1. Is the CareGraph® a reliable tool for use with the psychiatric population?
2. Are the categories of the Psychiatric CareGraph® tool consistent with the conceptualized domains?
3. Is there a difference in length of stay and cost per case for adult patients admitted to the inpatient psychiatric unit using the CareGraph® compared to the previous model of care delivery?

Design

A retrospective non-randomized comparative design using a convenience sample was used to evaluate patient length of stay and cost for two groups of patients admitted to the inpatient psychiatric unit in a mid-sized community hospital in the Midwestern U.S. The sample was limited to specific psychiatric patients on one unit. The first group was comprised of patients at the target hospital prior to implementation of the Clinical

Integration Model and use of the CareGraph®. These patients received care without specific identifiable structures and processes for communication, care planning, or classification. The patients in the second group received care after implementation of the Clinical Integration Model which used the CareGraph® instrument as a collaborative tool between disciplines and as a means to determine patient classification and quantify care needed. Resulting staffing modifications based on the care requirements indicated by the patient's score were evaluated daily by the care team. The participating hospital has an electronic medical record and central billing which allowed for capturing of needed data elements: length of stay and cost as well as Caregraph® admission and discharge scores. A pre-implementation, post-implementation design was utilized to evaluate patient and hospital level outcomes.

Psychometric testing of the CareGraph® instrument itself was done in this preliminary study. To accomplish the research goals, CareGraph® scores and other relevant data for each patient admitted to the psychiatric hospital with the target diagnoses during the designated study timeframes were gathered. The admission and discharge CareGraph® scores were utilized to evaluate initial reliability and validity of the instrument. A factor analysis was done to determine if the actual loadings were consistent with domains conceptualized by the designers of the tool. Internal consistency of the instrument was evaluated using Cronbach's alpha.

Patients admitted to the inpatient psychiatric unit are generally considered in the acute phase of illness, and CareGraph® scores should reflect the acute nature of illness. As a patient progresses toward discharge from the acute inpatient psychiatric setting to a lower level of care, the CareGraph® score should decrease. Therefore, known-groups

validity was used to assess the ability to differentiate level of care needed, or acuity. If the CareGraph® is scored appropriately, there should be a difference in admission and discharge scores.

Sample

The sample was limited to patients with the diagnoses of mood disorder, suicide, major depression, bipolar personality and generalized anxiety disorder who were admitted to a 25-bed adult inpatient psychiatric facility. Data from the specified time periods pre and post implementation of the Psychiatric CareGraph® were compared to assess outcomes of LOS and cost. In addition, the CareGraph® scores were collected at admission and discharge to determine known-groups validity.

The population was chosen because patients with these diagnoses account for greater than 90% of the patient admissions and are a fairly homogenous group relative to inpatient treatment. The patient characteristics, unit characteristics, and treatment plans were more consistent than using a total population. The specific DRG's were selected as a means to control variables. These patients were treated using standardized practice guidelines developed by psychiatric experts in an effort to improve consistency and quality of care for this population.

Instrumentation

A process tool, the CareGraph®(Center for Case Management, 2004), was developed as a means to provide a common system language for interdisciplinary patient discussions, focused care coordination, professional nursing judgment enhancement, and care progression determination through a quantitative patient classification tool. The CareGraph® also serves as a documentation instrument used on an ongoing basis for the

assessment of acuity of the patient in order to provide a context for application of an integrated clinical model in the nursing care setting. The Caregraph® for the inpatient psychiatric population includes: six physiologic categories, four psychologic categories, pain, patient education, medication compliance, self- care and safety. The CareGraph® assists the nurse in identifying specific problem foci based on a likert type (0 to 4) scale where 0 is normal and 4 is the most severe. Individual category scores are used to focus care for the interdisciplinary team, and the sum of all categories is used to produce a quantitative picture of patient needs. Dialogue between and within disciplines is focused on problems identified during completion of the CareGraph® with interventions and movement toward goals discussed.

The process for utilization of the CareGraph® starts with the nurse caring for the patient who fills out the CareGraph® each shift in order to determine priority patient care needs. The information obtained from the CareGraph® is used to focus the nursing process during each 24-hour period as well as the entire hospital stay. The staff nurse meets with the entire care team which includes the case manager, advanced practice nurse, physical and occupational therapists, and physicians three times a week to discuss problem foci and progression of care. These meetings are comprehensive and multidisciplinary with the common goals of problem management and resolution.

Results

Data Analysis

Data were extracted from patients in the included DRGs as approved by the Institutional Review Boards of the hospital system and The University of Texas at Tyler. Internal consistency reliability of the CareGraph® was evaluated with Cronbach's alpha.

Initial Cronbach's alpha for all items was .71 which is acceptable for a newly developed psychosocial instrument (Burns & Grove, 2005). Known-groups validity was assessed using a t-test to determine if there is a significant difference in admission and discharge CareGraph® scores during the post implementation period. After data cleaning, there were 108 patients and 216 pre and post evaluations for analysis. The distribution was normal for the total CareGraph® scores and parametric assumptions were met. The mean admission CareGraph® score was 18.94 compared to a discharge score of 12.18. The difference was significant, t (215) = 14.663, p=.000, representing a large effect size of .95.

To determine if the CareGraph® categories are consistent with the conceptualized domains, a confirmatory factor analysis (CFA) was completed. The sample was assessed for its suitability for factor analysis. Bartlett's test of sphericity was significant (x^2 = 602.9, p = .000) and the Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy was .711. These statistics supported the factorability of the CareGraph® (Field, 2009). CFA was conducted on 13 of the 14 CareGraph® items. Since all scores on the Gastrointestinal/Genitourinary scale were 0 for this psychiatric population, that scale was not included. The CFA revealed six eigenvalues exceeding 1. This finding indicated a six factor solution which was supported by visual inspection of the scree plot. The first factor, "psychological" consisted of six items and accounted for 23.1% of the variance. The second factor, "safety" included three items and explained 12.3% of the variance. The third factor, "pain" included two elements and explained 9.4% of the variance. The fourth factor, "nutrition," included two items and explained 8.6% of the variance. The

last two factors, "cardiopulmonary" and "hematologic" accounted for 15.5% of the variance. The total variance explained by the CareGraph® CFA was 68.9%.

Table 2. Confirmatory Factor Analysis Table of Caregraph® for Use with Psychiatric Populations

Categories	Component					
	1	2	3	4	5	6
Mood/affect	.876					
Thought content	.759					
Suicide/homicide/assault/elopement	.757					
Interpersonal/change quotient	.719					
Patient/family education	.699					
Immunologic/infection		.791				
Safety risk: falls		.757				
Mobility/self-care		.682				
Pain Management			.806			
Wound/skin			.776	.378		
Nutrition/GI				.883		
Cardiopulmonary					.915	
Medication compliance	.422				-.484	
Hematologic/metabolic						.945

Extraction method: Principal Component Analysis
Rotation Method: Promax with Kaiser Normalization
a. Rotation converged after 5 iteration

Lastly, an independent samples t-test was utilized to compare LOS and cost pre- and post-CareGraph® implementation. Pre-implementation data from April 1, 2010 to August 31, 2010 were compared to post-implementation data from April 1, 2011 to August 31, 2011. Data yielded 191 cases for evaluation, 82 from 2010 and 109 from 2011. Descriptive statistics were evaluated, and parametric assumptions met. Since Levene's test was non-significant for the LOS and cost, the t-test was interpreted assuming equal variance. The mean LOS in 2010 was 4 days and in 2011 it was 5.1 days. This increase in length of stay was significant, $t(189) = -2.71$, $p<.01$. Although the LOS was longer after implementation of the CareGraph®, the cost was not significantly different.

Discussion

This study provides a starting point for the psychometric evaluation of the CareGraph® as well as initial quantifiable outcomes. Internal consistency reliability and known-groups validity demonstrate that the CareGraph® can be used in the psychiatric population to provide a common system language for interdisciplinary patient discussions as well as quantitative classification of patient care needs. Clinically, the significant results between admit and discharge CareGraph® scores demonstrate the ability to discriminate severity of illness and provide a foundation for further study as an acuity tool.

The CFA captured the six categories conceptualized by the originators of the tool although they loaded in a different manner than anticipated. The psychologic domain included both medication compliance and patient education. The individual items of the physiologic domain overlap with other domains; consistent with the clinical picture of complex human beings. The factor loadings did make sense from a clinical and operational perspective and accounted for almost 70% of the variance in this model. Use of physiologic parameters to describe care needs of psychiatric patients may have confounded the findings due to the capricious nature of physical manifestations of psychiatric illness.

An increase in the length of stay by one day after the implementation of the CareGraph® was not anticipated and could be indicative of changes in care processes not accounted for in this study. During the study period, there was a change in the primary treating psychologist as well as changes in the Advanced Practice Clinician managing this patient population. The fact that the LOS increased could be indicative of a higher

complexity patient. Although the changes in cost were not statistically significant, they were positive from an operational perspective and may represent a positive change in efficiency.

Limitations and Future Research

Weaknesses in this design come from not knowing the exact diffusion curve of this new process. Selection bias may also play a role due to geographic limitations, homogenous groups, and inclusiveness. Generalization is also limited due to the homogenous population. This situation is no different than any study relating to human beings and systems administered by human beings; there are always extraneous variables, known and unknown, which may influence the outcomes of this study.

Future studies in varying psychiatric populations and settings would provide data for further validation of the CareGraph® tool and associated processes. Further evaluation of the ability to quantify severity of illness for acuity purposes using this tool could assist managers in provision of safe staffing. Studies assessing use of the CareGraph® instrument in different populations is needed to test its stability and utility as a means of predicting staffing needs. Future health care challenges relating to cost containment and predicting service delivery needs add to the imperative to acquire and test measurement metrics. In order for nurses to manage care and produce optimal outcomes, an instrument to quickly and efficiently assess the care delivery needs of the patient is a significant step in the right direction. Studies to test the benefits and usefulness of patient assessment instruments for acuity purposes, like the CareGraph®, can add to the ability of nurses to make meaningful contributions to health delivery solutions in the future.

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Chapter 3

Collaboration through Clinical Integration:

Evaluation of Hospitalized Patients' Survival, Length of Stay, and Cost

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Abstract

Problem: A lack of focus on interdisciplinary collaboration is contributing to the fragmentation of care delivery in U.S. hospitals. Lack of collaboration between healthcare providers contributes to the poor outcomes which plague the U.S. healthcare system. Higher mortality rates, increases in adverse patient outcomes, and longer hospital stays have been found in environments where collaboration is undervalued or non-existent. An innovative model of care delivery, the Clinical Integration Model, was developed by a Midwestern healthcare system where collaboration was purposefully woven into the structures and processes to positively impact patient and organizational outcomes. **Objective:** Determine if there is a difference in survival, length of stay, and cost for the congestive heart failure population receiving care in the Clinical Integration Model and those receiving care in a traditional primary care delivery model within one health system. **Methods**: A retrospective comparative design was utilized to evaluate clinical outcomes. The Chi Square statistic was used to analyze survival data. ANOVA was used to analyze cost and length of stay. **Findings**: There was a significant difference between groups for LOS, $F(3, 245) = 5.78$, $p = .001$ and cost $F(3,226) = 21.70$, $p = .000$. There was no significant difference in survival between the intervention hospitals and the control hospitals.

Key Words: Collaboration, Clinical Integration, Donabedian, Clinical Outcomes

Collaboration through Clinical Integration:

Evaluation of Hospitalized Patients' Survival, Length of Stay, and Costs

Interdisciplinary collaboration is an emerging mandate to decrease fragmentation of care delivery in U.S. hospitals. A variety of threats to patient safety and quality care result when a collaborative environment fails to emerge and thrive in the health delivery system. Higher mortality rates (Estabrooks, Midodzi, Cummings, Ricker & Giovannetti, 2006) and longer lengths of hospital stay (Zwarenstein, Goldman & Reeves, 2009) have been found in environments where collaboration is limited or not present. One of the factors contributing to the nation's epidemic of medical errors and subsequent mortality is the decentralized and fragmented nature of the healthcare delivery system (Kohn, Corrigan & Donaldson, 2000). As many as 98,000 people die in hospitals each year as a result of medical errors which may be traced to lack of collaboration and disjointed care. Beyond the cost of human lives, billions of dollars are spent annually for additional care resulting from medical errors (Kohn, Corrigan & Donaldson, 2000).

To provide high quality care and meet public expectations with limited resources, collaboration has become a necessity. In a landmark study, Knaus, Draper, Wagner, and Zimmerman (1986) found that hospitals where collaboration was present reported a mortality rate 41% lower than the predicted number of deaths. Hospitals where there was little to no collaboration exceeded predicted mortality by as much as 58%. Collaborative relationships have also been tied to a decrease in adverse patient outcomes (Boyle, 2004; Prowse and Heath, 2005) and reduced costs for the healthcare system (Zwarenstein, Goldman & Reeves, 2009). Although empirical evidence in support of collaboration in

the healthcare environment is available in the literature, there is little evidence on how to create this environment (Tschannen, 2004). The main structural elements necessary for collaboration in an acute care environment include a culture where relationships are valued, healthcare professionals communicate effectively, and respect is shared among all parties. A model of care delivery consistent with these cultural values and focused on patient safety is paramount. It is also necessary to provide the requisite tools for a collaborative process to occur which includes sufficient time and work flow to promote collaboration and a mechanism which holds people accountable for their contributions to a collaborative environment.

A Midwestern healthcare system designed an innovative model of care delivery where collaboration was purposefully woven into the structures and processes to effect positive change in patient and organizational outcomes. This model is called the "Clinical Integration Model" (Zander, 2007). Several of the health system hospitals adopted the Clinical Integration Model; others were introduced to this model of care delivery but chose to stay with a traditional primary care model. Comparing hospitals within the health system provides an opportunity to determine if there is a difference in survival, length of stay (LOS), and cost for patients receiving care in facilities utilizing the Clinical Integration Model (CIM) and those receiving care in facilities utilizing a primary care model.

Background and Significance

Collaboration in Healthcare

Collaboration has been defined by the American Nurses' Association (2010) as a partnership based on trust with shared power, recognition, and acceptance of separate and

combined practice spheres of activity and responsibility. Collaboration also includes mutual safeguarding of the legitimate interests of each party and a commonality of goals. The key components of shared power, recognition and acceptance, and common goals are relevant to many of the definitions found in the literature (Fewster-Thuente & Velsor-Friedrich, 2008; Petri, 2010). These components are essential for a collaborative process and can be operationalized in an acute care setting.

A number of factors have affected the ability of healthcare organizations to provide a collaborative environment including the educational system, professionalization of healthcare practitioners, as well as the nursing shortage. Studying determinants of successful collaboration, San Martin-Rodriguez, Beaulieu, D'Amour and Ferrada-Videla (2005) found that healthcare practitioners develop a strong professional identification through education. This strong professional identification often limits knowledge of other professionals within the team and is considered a main obstacle to collaboration. The dynamics of professionalization lead to further differentiation of healthcare professionals (D'Amour & Oandasan, 2005) and potential conflict hindering the development of true collaborative relationships. Within nursing, the nursing shortage has created an environment where nurses have larger patient loads and limited time to spend with each patient and the healthcare team (Fewster-Thuente & Velsor-Friedrich, 2008). Limited time may not allow for structured communication and goal setting which are key components of a collaborative process.

Collaboration in healthcare affects patient survival and decreases adverse patient outcomes. Knaus, et al. (1986) found that hospitals where collaboration was present reported a significant decrease in mortality rates (Chi square =62.9, df 12; $p<0.0001$,

r=.83). Hospitals where there was little to no perceived collaboration exceeded predicted mortality. Positive collaborative relations have also been tied to a decrease in other negative patient outcomes. Boyle (2004) evaluated unit level characteristics and the impact on patient outcomes and found a negative correlation between collaboration and failure to rescue (r=-0.53). High levels of perceived collaboration were linked to early detection of change in clinical condition and appropriate intervention leading to a decrease in failure to rescue. In a qualitative evaluation of collaboration, Prowse and Heath (2005) found when collaboration in a context-specific situation was consistently identified, there were reports of reduced individual negative patient outcomes.

Collaborative environments can positively affect health system outcomes. Ovretviet (2011) evaluated the impact of clinical coordination and collaboration and found that when collaboration and coordination were present, patients experienced a shorter LOS with lower costs to the healthcare institution. Additionally, Zwarenstein, Goldman and Reeves (2009) evaluated multiple studies to determine the impact of interprofessional collaboration and found that 80% of the studies demonstrated decreased LOS and cost savings to the healthcare institutions.

Barriers to Collaboration in Healthcare

The barriers to collaboration are rooted in the hierarchal and long-established structures of most healthcare organizations and are difficult to change. The nurse-physician relationship is one example of an established hierarchal relationship that has been a barrier to true collaboration in healthcare facilities. Hojat and colleagues (2001) conducted a cross-cultural study evaluating nurse-physician attitudes toward collaboration and found that nurses in both the United States and Mexico expressed more

positive attitudes toward collaboration than their physician counterparts ($p<0.01$). As a possible solution, the authors recommended inter-professional education to improve nurse-physician collaboration. McCaffrey et al. (2010) provided a focused intervention for nurses and residents to improve communication and overcome the power differential. The authors found that collaboration was improved which improved patient outcomes.

Another frequently appearing barrier to collaboration is the healthcare environment itself. Tschannen (2004) stated, "Although the literature has validated the relationship between collaboration and positive patient outcomes, how to create the environment supportive of collaboration has yet to be explored" (p. 313). Time is an environmental constraint relative to collaboration. The process of collaboration is facilitated when healthcare providers spend time together developing relationships and learning how to effectively communicate and trust each other. This requires healthcare leaders to recognize the importance of collaboration and allow time to create opportunities for the collaborative process to mature.

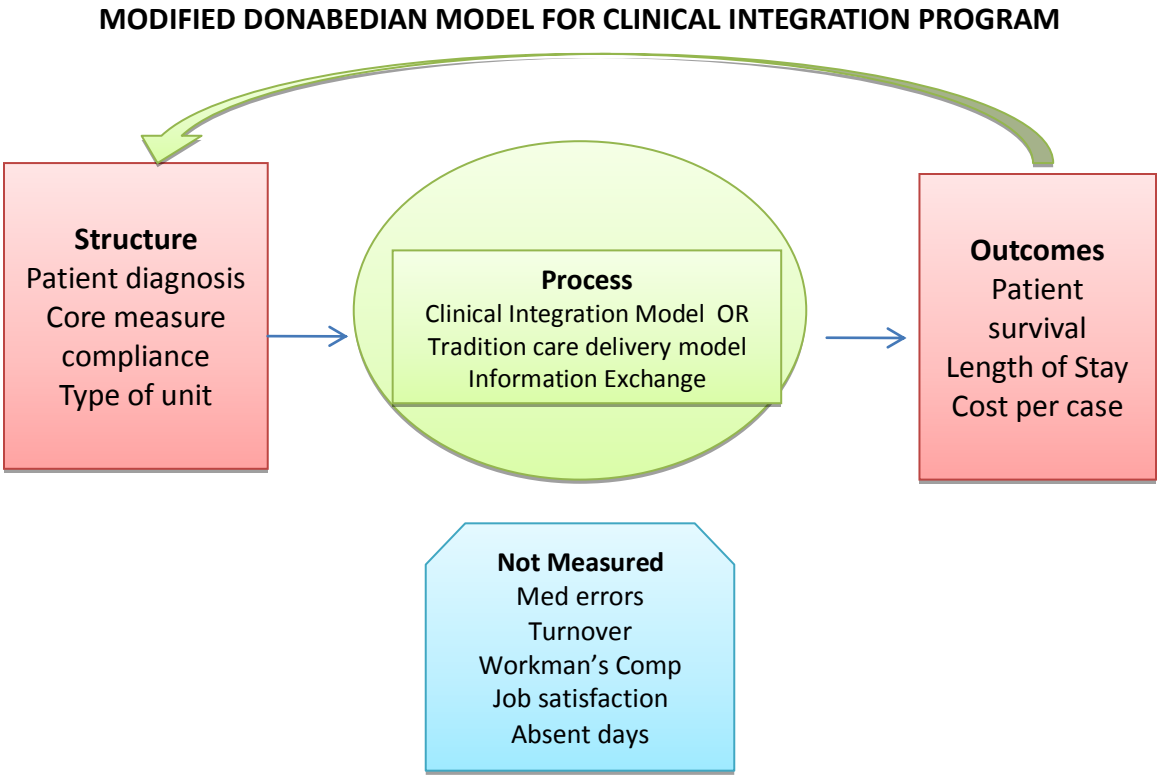
Empirically the link between collaboration and improved patient and system outcomes has been demonstrated, but there remains a gap in the literature on how to create a collaborative environment. Leaders must understand the essential elements in order to create such an environment. This study begins to fill the gap by looking at a large scale change of care delivery based on essential collaborative structures and processes and its impact at the patient, hospital and system level.

Theoretical Framework

The Donabedian Model (1966) is proposed as a way of providing essential structures and processes for collaboration in the healthcare setting. The model was used

to provide a comprehensive structure to move from inputs which form the structure of the model, through the process of care delivery, and concluding with the outcomes for this study.

Figure 1. Donabedian Structure, Process, Outcome Model, Adapted



(Donabedian, 1966)

In accordance with the Donabedian Structure, Process, Outcome Model (Figure 1), *structure* refers to the environment in which care is provided. Structure encompasses the work environment, availability of equipment and supplies, and type of unit. These structural elements tend to be relatively permanent in nature and are often thought of as key determinants to quality (Donabedian, 1988). *Process* elements are more flexible and readily changeable. Process encompasses the things healthcare workers do or fail to do which shape patient outcomes (Montalvo and Dunton, 2007). Type of care delivery

system and established communication patterns are processes of care important in developing a collaborative environment. *Outcomes* are the changes in patients' health attributable to their care (Montalvo and Dunton, 2007). According to Donabedian (1988), changes in structures and processes of care are required to optimize patient outcomes.

The Structure, Process, Outcome Model proposes that the context (structure) in which the intervention (process) occurs has an influence on the outcomes. Collaboration is seen as the process which occurs within a specific context leading to the measured results or outcomes. The process of collaboration not only requires healthcare providers to effectively communicate and trust each other, it also requires a multidisciplinary model of care delivery. Requisite tools need to be available to all providers along with coordination of work flow and goals that are clearly articulated and based on patient needs. Sommers, Marton, Barbaccia, and Randolph (2000) identified the importance of collaboration between physicians, nurses and social workers for seniors in a primary care environment in reducing utilization and improving health status. Problem-solving between nurses and physicians, when rated negatively by the nurse, was found to be an important factor when investigating the impact of an intervention (process) on outcomes of care (Pirkis, et al., 2004). The Donabedian Model has provided a useful structure for studying processes and outcomes of care and was used to guide the proposed study.

Clinical Integration Model for Interdisciplinary Collaboration

A Midwestern health system designed an innovative model of care delivery with a specific goal of interweaving collaboration into the existing structures and processes. This health system is part of a fourteen-hospital system located in multiple Midwestern

states. The drivers for change within this health system were based on an average length of stay (LOS) that was heading in an upward direction, increasing fragmentation of care delivery, increasing complexity of patient conditions, and increasing costs. The new model of care delivery, the Clinical Integration Model, was developed utilizing Donabedian's Structure, Process and Outcome Model to build collaboration into care management.

Guided by the model, changes in the structures and processes to provide a collaborative environment included: development of a process tool, the CareGraph®, (figure 2) allowing multiple disciplines to speak the same language; focus on the same patient-centered goals; and coordination of work flow around patient needs. Structural changes also included provision of unit based case managers, social workers and educators. Physicians, pharmacists, and other key healthcare providers were readily available to all nursing staff and were educated in the new model of care delivery. Other organizational changes included the clarification of roles among care givers and communication of expectations.

The CareGraph® (Center for Case Management, 2004) was developed to provide a common systems language for communication between caregivers and a graphic representation of clinical progression in incremental steps during the patient's stay. The CareGraph® identifies specific problem foci for the care team based on a likert type (0 to 4) scale where 0 is normal and 4 is the most severe. See example in Figure 2. Multiple disciplines participated in the development of the CareGraph® to ensure category validity. External content experts also reviewed the initial CareGraph® for appropriateness.

Figure 2. CareGraph example of Wound/Skin Category

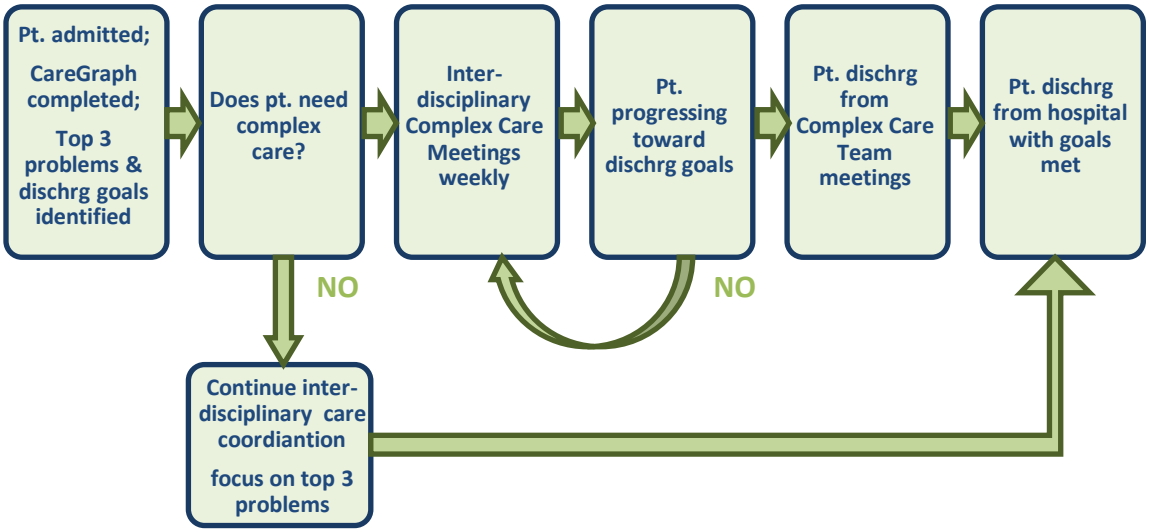
	Admit Base-line Date	Date	Date
WOUND/SKIN: **(Identify focus_____)**			
4 – Has large gaping wound that requires packing **or** complex dressing change taking >30 minutes >3 times/day	4	4	4
3 – Has draining wound with/without packing **or** complex dressing change <3 times/day **or** unable to apply wound vac	3	3	3
2 – Has draining wound with/without packing **or** constant re-enforcement **or** requires wound vac	2	2	2
1 – Has reddened area with skin intact **or** simple dressing/open to air	1	1	1
0 – Has intact skin/wound/incision	0	0	0

As a component of the Clinical Integration Model, the CareGraph® is implemented by the nurse caring for the patient with daily updates. The nurse meets with the entire care team three times a week in care coordination rounds to discuss problem foci and progression of care. Any patient stalled in progression toward optimal outcomes is referred to the Complex Care team which meets twice weekly. Complex Care meetings are comprehensive and multidisciplinary with the common goals of problem management and resolution. Once a patient is discussed at Complex Care, this same patient is discussed thereafter until discharge or until deleted from the Complex Care agenda if significant clinical progression is made.

The structure and process changes implemented with the Clinical Integration Model provide essential elements necessary for collaboration. Healthcare providers have

the ability to provide collaborative care consistent with the objectives of the American Nurses Association Social Policy Statement in order to safeguard patients' interests and develop common goals with structured communication (ANA, 2010). (figure 3).

Figure 3. Conceptual Representation of the Clinical Integration Model



The differentiation of care is the basis for the current study. Two hospitals which adopted the CIM were compared with two hospitals of similar size and service within one health system which chose to continue with a traditional care model.

Variables

Donabedian's Model reflects three main variables: structure, process, and outcomes. Operational definitions of the three variables for the proposed study are found in Table 1.

Table 1. Conceptual and Operational Definitions of Study Variables

VARIABLE	CONCEPTUAL DEFINITION	OPERATIONAL DEFINITION
Structure	The environment in which care is provided*	Inpatient acute care units where CHF patients (DRG's 291, 292 and 293) receive care.
Process	Activities which healthcare providers do or fail to do which shape patient outcomes**	Clinical Integration Model using the CareGraph® tool Or Traditional Care Delivery Model with traditional charting
Outcome	The changes in patients' health attributable to care**	Survival Length of stay in days Cost per case (direct cost)

*Donabedian, 1988; **adapted from Montalvo and Dunton, 2007

Input, or structure variables, used in this study were the number of patients admitted to each of the participating health system hospitals with the diagnosis of congestive heart failure (CHF). Type of patient population, CHF, served as the main structural variable for this study. The model of care delivery, CIM or traditional care delivery model, served as the process variable. The hospitals which implemented the CIM served as the intervention hospitals. The control hospitals were the ones which continued to deliver traditional care using conventional records, charting, and nurse care planning model. The outcomes measured to evaluate change after implementation of the CIM are survival, length of stay, and cost per case for congestive heart failure patients. For further clarification, survival referred to whether a patient was discharged alive during the acute care episode. Length of stay was determined as the day of admission to one of the participating hospitals through day of discharge and was calculated in number of 24-hour days. Cost per case was calculated using total costs.

Research Design and Methods

Research Question

Is there a difference in survival, length of stay and cost per case in the congestive heart failure population in facilities using the Clinical Integration Model compared to those using a traditional care delivery model?

Design

A retrospective non-randomized comparative design using a convenience sample over a time-limited period was used to evaluate patient survival, length of stay, and cost per case for patients with the same diagnosis in a large hospital system in the Midwestern U.S. The sample consisted of congestive heart failure patients receiving care within facilities utilizing the CIM compared to those cared for in facilities using a traditional care delivery model. All hospitals in the health system received education about the CIM, but some of the hospitals chose to stay with a traditional model of primary care. All health system hospitals have electronic medical records and central billing systems which allowed for capturing of data elements. A pre-implementation, post-implementation design was utilized to evaluate patient and hospital level outcomes.

Use of the Electronic Medical Record for research

Electronic medical records (EMRs) provide medical information that can be searched automatically to provide answers to questions that would be time consuming to answer using a paper and pen methodology (Singer, 2010). According to Murphy, Ferris, and O'Donnell (2007), EMR and electronic data collection decreases the opportunity for human error by eliminating manual data collection and offering the opportunity for analysis of large samples. Collecting data in this manner not only makes research

cheaper and easier, it reduces the amount of undue influence by researchers (Nemeth, Wessell, Jenkins, Nietert, Liszka & Ornstein, 2007), potential bias (Brown, Parker & Dixon-Woods, 2008), and potential for error. The current study is an example of research that would not be feasible without the use of the EMR for data capture.

Sample

After approval of the Internal Review Board (IRB) from the University of Texas at Tyler and the health system hospitals, a sample of congestive heart failure patients (DRG's 291, 292 and 293) admitted to the participating acute care facilities within the health system was utilized to assess patient and hospital outcomes of survival, LOS and cost per case. The CHF population was chosen because it is a relatively homogenous group. The patient characteristics, unit characteristics, and treatment plans were more consistent using a single diagnosis rather than using a total heterogenous population.

Heart failure patients were selected as a means to control variables. These patients are treated using standardized evidenced-based guidelines developed as core performance measures by the Joint Commission accrediting group in an effort to improve consistency and quality of care for this population among all hospitals in the system. Four key quality indicators for heart failure treatment were developed and are required to be applied to all CHF patients. The first standard requires all patients discharged from hospitals with the primary diagnosis of heart failure to have left ventricular (LV) function assessed before or during hospitalization (Kfourny et al., 2008). The second requires physicians to prescribe an angiotensin-converting enzyme (ACE) inhibitor or an angiotensin receptor blocker (ARB), depending on patient tolerance, for all patients with left-ventricular dysfunction. The third includes providing the patient with self-management instructions

on tracking weight, low sodium diet, reporting of symptoms, and follow-up care. Finally, smoking cessation counseling for smokers was mandated.

Major threats to internal validity for a study with a control group have been addressed in the design with use of a homogenous group, the CHF population, and pre/post evaluation. Knowing the exact dates for implementation or non-implementation of the Clinical Integration Model with use of a control group allows comparison of groups prior to the intervention to detect differences. In addition, each intervention hospital will be matched with a hospital of similar size and service availability within the health system to account for potential historical influence. Multiple outcome measures have also been added to increase validity; and demographics for the geographic area demonstrate the ability to obtain a representative sample relative to gender.

Another specific initiative, the health literacy initiative for education of all patients, was implemented within the health system at the same time period. This initiative could have an indirect effect on patient survival impacting patient outcomes due to better understanding of complications and when to call for assistance. The statistical impact should be minimal within hospital stay and would logically have a greater impact on thirty day and long term survival. Since this initiative was instituted throughout the health system affecting all of the study hospitals, it will contribute to the homogeneity of the sample and should not require further evaluation.

Inclusion Criteria

Inclusion criteria will be adult patients (> age 18) admitted during specified dates to one of the health system hospitals chosen for this study with the primary diagnosis of CHF (DRG's 291, 292, and 293). Since all hospitals provide services to patients with

multiple co-morbidities, all CHF DRG's have been included.

Recruitment/Setting

For this study, an extant database owned by the health system for patient billing, data reporting, and operations management was used to access survival, LOS, and total cost data for the participating hospitals. A convenience sample of the CHF population from Hospital A (338 beds) and Hospital B (139 beds) were used as the intervention group. These two hospitals are located in close proximity to each other with the same upper management staff, and both had implemented the Clinical Integration Model. Both hospitals offer full services with cardiology a major service line. These hospitals service over 300,000 people in the area and total over 300 CHF admissions per year. Hospital C (373 beds) was chosen from the health system as a comparison to Hospital A and Hospital D (148 beds) was compared to Hospital B. These two hospitals admit a similar number of CHF patients and are both full service facilities of like size with cardiology constituting a major portion of admissions. The number of people served by these two facilities is roughly 300,000 (U.S. Census Bureau, 2010). Essential care elements for the CHF population are rendered using core measure criteria at each hospital with compliance >92%.

Sample Size Justification

According to the health system statistics for 2010, a sample of over 600 CHF admissions per year for the participating hospitals should be available for study purposes. Power analysis using *the G-Power* program (Faul, Erdfelder, Buchner, & Lang, 2009) with moderate effect size (.50) and an alpha of .05 showed a necessary sample size of 210. Appropriateness of sample size is substantiated in the literature where Knaus, et al.

(1986) demonstrated a very large effect size (.83) comparing actual versus predicted mortality for critical care units where collaboration was present and those where collaboration was not present. Implementation of the Clinical Integration Model will serve as the proxy for collaboration in this study.

Procedures

After receiving IRB approval from both the University of Texas at Tyler and the health system, data were extracted from the health system database for survival, LOS, and cost for the CHF population from the participating hospitals. The time frame (Table 2) is based on Roger's Theory of Diffusion of Innovation (2003) which states that full diffusion of an innovation and cultural adherence would occur between twelve and eighteen months, so this timeframe is utilized for post- implementation data collection and analysis.

Table 2. Timeline for Clinical Integration Model Adoption and Outcomes

Hospital	Education on CIM*	Adopted CIM*	Dropped CIM*	Outcome measures
Hospital A	2005	Jan., 2006	N/A	Jan 1, 2007 - Jan 1, 2008
Hospital B	2006	May, 2006	N/A	May 1, 2007 – May 1, 2008
Hospital C	2006	N/A	N/A	Jan 1, 2007 - Jan 1, 2008
Hospital D	2006	May, 2006	Dec. 2006	May 1, 2007 – May 1, 2008

* CIM Clinical Integration Model

All outcome data was accessed using the TSI/Eclipses relational database. Cost accounting, payer contract management, budgeting/modeling, clinical process improvement, and patient reporting are existing modules currently utilized by the health system. It is a closed loop dataset with data extracted and used for cost accounting purposes as well as clinical performance improvement.

Results

Data Analysis

The initial data set yielded 1192 cases after data cleaning and time referencing. Descriptive statistics for each of the primary outcome variables (survival, LOS, cost) were run using the Statistical Package for Social Sciences (SPSS) version 17 and visually inspected. Outlier cases were not eliminated as they are indicative of the variability in patient or care.

Hospital A, the initial hospital adopting the CIM, accounted for 487 cases totaling 41% of the population; the smaller hospital adopting the CIM (Hospital B) accounted for only 5% of the population with 61 cases. Hospital C, the largest control hospital had 512 cases, or 45% of the population, and Hospital D had 9% of the cases. Therefore, 46% of the cases were from intervention hospitals while 54% from control.

Overall, 97% of the patients were discharged to another level of care while 3% died during their hospital stay (Table 3). All four hospitals were evaluated for patient survival using the Chi Square Statistic. Greater than 20% of the expected counts were less than 5; therefore, the intervention hospitals and control hospitals were combined for further evaluation of mortality. Crosstabs demonstrated an actual mortality equal to the expected mortality for both groups with a minimum expected count of 18.92. For the 1192 cases evaluated, there was not a significant difference in survival between the

patients admitted to the intervention hospitals and those admitted to the control hospitals; X^2 (1) = .001, p=.979.

Table 3. Mortality Between Hospitals

Hospitals	Number of Mortalities	% Mortality
Intervention (Hospitals A & B)	19	3.5%
Control (Hospitals C & D)	22	3.4%

A one-way analysis of variance (ANOVA) was conducted to evaluate the effect of the CIM on LOS and cost. Unequal group sizes and violation of homogeneity of variance required evaluation using Welch's F statistic (Field, 2009). There was a significant difference between groups for LOS, $F(3, 245) = 5.78$, p = .001 and cost $F(3,226) = 21.70$, p = .000. Post hoc evaluation of differences using the Games-Howell procedure revealed a shorter LOS for both the intervention hospitals (A and B) relative to the largest control hospital (C). This difference did not extend to the smaller control hospital (Table 4). Additionally, the larger intervention hospital (hospital A) had a significantly lower cost than the other participating hospitals in caring for the CHF population (Table 4).

Table 4. Post-hoc evaluation of Length of Stay and Cost Between Control and Intervention Hospitals using Games-Howell procedure

		Variable: Length of Stay			Variable: Cost	
Hospital	Facility for comparison	Mean difference	Significance		Mean difference	Significance
C	D	.83*	.012		$886.00	.113
Large	A	.76**	.004		$2063.00**	.000
control	B	.96*	.035		$390.00	.374
D	C	-.83*	.012		$-886.00	.113
Small	A	-.07	.994		$1177.00**	.007
control	B	.13	.986		$-496.00	.818
A	C	-.76**	.004		$-2063.00**	.000
Large	D	.07	.994		$-1177.00**	.007
intervention	B	.20	.941		$-1673.00**	.005
B	C	-.96*	.035		$-390.00	.874
Small	D	-.13	.986		$496.00	.818
intervention	A	-.20	.941		$1673.00**	.005
*p<.05; **p<.01						

Discussion

This study found positive effects for the hospitals that adopted the CIM. The greatest effect appears to be the ability to manage cost. The post hoc evaluation demonstrated a lower cost for the large intervention hospital compared to both control hospitals and the smaller intervention hospital. Operationally, the cost savings may be manifested to a greater degree as volume increases or may be due to the degree of diffusion or temporal persistence of the CIM. The degree of effect of the CIM on LOS was apparent when comparing the intervention hospitals to the large control hospital; both had statistically shorter LOS. This is consistent with current research where Ovretviet (2011) evaluated the impact of clinical coordination and collaboration and found that when collaboration and coordination were present, patients experienced a shorter LOS with lower costs to the healthcare institution.

The positive effects of the CIM on LOS and cost did not extend to patient survival. The effects of using evidence-based practice in treating the CHF population may have greater impact on patient survival than use of the CIM since none of the participating hospitals had mortality rates greater than expected. In addition, all hospitals had at least 92% compliance on all components of The Joint Commission core measure requirements (The Joint Commission, 2012).

Limitations

Weaknesses in this design come from not knowing the exact diffusion curve or temporal persistence of the Clinical Integration Model. Selection bias may also play a role due to geographic limitations, homogenous groups, and inclusiveness. Since there is no reliable method for collecting or accessing actual collaboration data, there is no way to

implicitly tie findings to length, strength, or penetration of collaboration activities established with use of the CIM.

Study Implications and Recommendations

Results of this study provide essential information about the structure, process and outcomes of an innovative model of collaborative care delivery, the Clinical Integration Model. The CIM provides the initial steps toward validation of a collaborative model for the acute care setting. This research provides administrators and practicing clinicians with a pathway for taking initial steps toward creating a more collaborative practice model to produce beneficial effects on hospital and health system outcomes.

Further testing of this collaborative model should focus on different geographical areas with varying populations, in particular, testing in large metropolitan areas with concentrated populations. It would also be beneficial to test this model with a more equivalent and larger sample. Testing the effects of a collaborative model on patient populations with different diagnoses might also provide some insights into best practices. Diagnostic-related groups whose care is contingent upon coordinated services from various providers, such as persons being treated for diabetes, cancer, neurological diseases such as Alzheimer's and Parkinson's, and end-of-life, might also provide insights into the benefits of a structured collaborative care model. Finally, studies focusing on the satisfaction levels and quality of life reported by care recipients would also provide a key piece of the puzzle regarding optimal care of chronic disease patients. With the current focus on interdisciplinary care and control of health care costs, comparative studies of care delivery models may help answer the question of how to best meet the health delivery challenges of the 21st Century.

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Chapter 4. Summary and Conclusions

The initial pilot study provides a starting point for the psychometric evaluation of the CareGraph® (Center for Case Management, 2004) as well as initial quantifiable outcomes. Internal consistency reliability and known-groups validity demonstrate that the CareGraph® can be used in the psychiatric population to provide a common system language for interdisciplinary patient discussions as well as quantitative classification of patient care needs. Additionally, the confirmatory factor analysis captured the six categories conceptualized by the originators of the tool, although they loaded in a different manner than anticipated. The factor loadings made sense from a clinical and operational perspective and accounted for almost 70% of the variance in this model. The second study found that the effects of the CIM are beneficial for both the hospital and health system. The greatest effect appears to be the ability to manage cost. The post hoc evaluation demonstrated a lower cost for the large intervention hospital compared to both control hospitals and the smaller intervention hospital. This finding is consistent with current research (Ovretviet, 2011).

The flexibility to make modifications in study design based on pilot findings was beneficial in obtaining a successful outcome during this dissertation process. The health system allowed the primary investigator to make modifications to data extraction and timeframes which is essential in obtaining well powered studies. The initial pilot study timeframes were lengthened to ensure an N value which could produce significant results based on the power analysis. Obtaining an appropriate sample size was not only essential in demonstrating acceptable reliability and validity for the CareGraph® tool in the psychiatric population, but it contributed to good discriminatory ability. The

discriminatory ability is important if the CareGraph® tool is to be used as a measure of patient acuity.

For the primary CHF study, changes in inclusion criteria and timeframes for evaluation based on Rogers' (2003) theory of Diffusion of innovation and initial pilot work were necessary to produce a scientifically rigorous study. The initial modifications in study design were met with the need to make modifications in statistical analysis. Although there were over 1100 individual cases for evaluation from four different hospitals within the health system, the group sizes were quite different. With different group sizes and violation of homogeneity of variance, modifications were made to the statistical tests to appropriately evaluate the data. Adapting statistical tests in an appropriate manner was a good learning opportunity for the primary researcher and resulted in outcomes which were consistent with research on collaboration in healthcare (Ovretveit, 2011; Zwarenstein, Goldman & Reeves, 2009).

Recommendations for future research

Results from these studies provide essential information about the structure, process and outcomes of the CIM. This research provides administrators and practicing clinicians with information on initial steps toward creating a more collaborative practice model and its beneficial effects on hospital and health system outcomes. Further research of this collaborative model should focus on different geographical areas with varying populations.

Future studies in other populations and settings would provide data for continuing validation of the CareGraph® tool and associated processes. Evaluation of the ability to quantify severity of illness for acuity purposes using this tool could assist managers in

strategic workforce planning as well as daily efforts to provide safe staffing levels. Studies assessing the use of the CareGraph® instrument in different populations are needed to test its stability and utility as a means of predicting staffing needs. Future healthcare challenges relating to cost containment and predicting service delivery needs add to the imperative to acquire and test measurement metrics. In order for nurses to manage care and produce optimal outcomes, an instrument to quickly and efficiently assess the care delivery needs of the patient is a significant step in the right direction. Studies to test the benefits and usefulness of patient assessment instruments for acuity purposes, like the CareGraph®, can add to the ability of nurses to make meaningful contributions to health delivery solutions in the future.

Future considerations not addressed in this research, but equally important, are the effect of a collaborative model on clinician satisfaction and retention. There is a need for an instrument to measure and quantify the depth, scope, and satisfaction with collaboration efforts among health professionals. This instrument should be tested for potential to predict retention of staff as well as patient outcomes. This study has demonstrated that the CareGraph® could provide insight into the evaluation and testing of such a new instrument. Collaboration is one of the key elements of the Healthy Work Environment (American Association of Critical Care Nurses, 2005) standards essential in creating an environment where healthcare workers feel safe and confident in their ability to successfully care for patients.

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Appendix A

CAREGRAPH ®

Admitting Diagnosis: _____

Goal LOS:_____ Actual LOS: _____

	Admit Baseline Date	Date	Date	Date	Date
IMMUNOLOGICAL/INFECTION:					
(Identify focus_____)	4	4	4	4	4
4 – Multi-system failure **or** septic shock	3	3	3	3	3
3 – Has sepsis with **or** without + blood culture, no signs/symptoms of shock, with **or** without neutropenia	2	2	2	2	2
2 – Is febrile **or** has signs/symptoms of infection and is immunocompromised	1	1	1	1	1
1 – Temperature resolving **or** responding to prescribed therapy **or** resolving s/s of infection	0	0	0	0	0
0 – Has absence of any signs/symptoms of infection					
FLUID BALANCE/GU:	4	4	4	4	4
(Identify focus_____)	3	3	3	3	3
4 - Has absence of urinary output **or** requires IV fluid bolus	2	2	2	2	2
3 – Has <120mL urinary output in 8 hours **or** requires total IV intake >150mL/hour	1	1	1	1	1
2 – Has <240mL urinary output in 8 hours **or** weight gain >2 lbs in 24 hours **or** requires total IV intake <150mL/hour	0	0	0	0	0
1 – Has >240ml urinary output in 8 hours **or** fluid restriction **or** weaning IV fluids					
0 - Has balanced Intake & Output					
MOBILITY/FUNCTIONAL MOVEMENT:	4	4	4	4	4
(Identify focus_____)	3	3	3	3	3
4 – Is unable/refuses to move without assistance **or** bedfast/catatonic **or** has unkept/bizarre appearance **or** refuses to bathe or dress self	2	2	2	2	2
3 – Maximum dependence on staff for ADLs **or** unable to follow verbal instructions	1	1	1	1	1
2 – Moderate assistance for ADLs **or** needs reminding to bathe or dress	0	0	0	0	0
1 – Minimum assistance for ADLs **or** needs motivation to dress/bathe					
0 – Motivated **and** moves independently					

NUTRITION/GI: **(Identify focus_____)** 4 – Is unable to take P.O. nutrition **and** not on nutritional support **or** absence of bowel sounds **or** fails to eat or maintain hydration **or** uncontrollable eating 3 – Is NPO **or** hypo/hyper bowel sounds **or** depends on others to meet body requirements 2 – Food/hydration not a priority **or** taking sips with advancement of diet **or** active bowel sounds with no flatus **or** inconsistent pattern of nutrition/hydration 1 – Is eating adequately **or** eats/hydrates adequately **or** has a fully functioning GI tract	4 3 2 1 0	4 3 2 1 0	4 3 2 1 0	4 3 2 1 0	4 3 2 1 0
WOUND/SKIN: **(Identify focus_____)** 4 – Has large gaping wound that requires packing **or** complex dressing change taking >30 minutes >3 times/day 3 – Has draining wound with/without packing **or** complex dressing change <3 times/day **or** unable to apply wound vac 2 – Has draining wound with/without packing **or** constant re-enforcement **or** requires wound vac 1 – Has reddened area with skin intact **or** simple dressing/open to air 0 – Has intact skin/wound/incision	**Admit Baseline Date** 4 3 2 1 0	**Date** 4 3 2 1 0	**Date** 4 3 2 1 0	**Date** 4 3 2 1 0	**Date** 4 3 2 1 0
CARDIOVASCULAR: **(Identify focus_____)** 4 – Life threatening cardiac status **or** life threatening pulmonary status 3 – Continuous monitoring requiring > Q2 hour assessment/intervention (i.e., Swan, art.line) **or** abnormal lung sounds **or** cough w/ cyanosis **or** edema present **or** irregular pulse 2 – Dyspneic w/ O2 >6L for oxygenation 1 – Dyspneic w/O2 <6L for oxygenation **or** risk for arrhythmia r/t telemetry/daily labs **or** risk for perfusion deficit requiring telemetry/labs 0 – Maintains patent airway/oxygenation **or** maintains perfusion **or** arrhythmia is controlled for pt status	4 3 2 1 0	4 3 2 1 0	4 3 2 1 0	4 3 2 1 0	4 3 2 1 0

HEMATOLOGICAL/METABOLIC: **(Identify focus_____)** 4 – Has critical lab values requiring immediate intervention **and** intensive monitoring 3 – Resolving critical lab values requiring every 4-8 hour assessments 2 – Has abnormal lab values requiring daily monitoring **and** intervention 1 – Has abnormal lab values requiring monitoring with **or** without intervention 0 – Has lab values within accepted range for patient	4 3 2 1 0	4 3 2 1 0	4 3 2 1 0	4 3 2 1 0	4 3 2 1 0
PAIN MANAGEMENT: **(Identify focus_____)** 4 – Reports/displays uncontrollable pain 3 – Reports upper level of pain scale consistently with use of parenteral/epidural pain medication 2 – Requires injectable pain medication 1 – Requires oral pain medication **0 –** Reports pain is at acceptable level or denies pain or has no observable indicators of pain with or without pain medication	4 3 2 1 0	4 3 2 1 0	4 3 2 1 0	4 3 2 1 0	4 3 2 1 0
EDUCATION - PATIENT/CAREGIVER: **(Identify focus_____)** 4 – No knowledge of disease process/disease management **or** unable to comprehend information **or** unable to assess education needs 3 – Limited knowledge of disease process **or** education barriers present 2 – Moderate knowledge of disease process **or** manageable education barriers 1 – Substantial knowledge of disease process **or** requires knowledge validation 0 – Extensive knowledge of disease process **or** requires no assistance	**Admit Baseline Date** 4 3 2 1 0	**Date** 4 3 2 1 0	**Date** 4 3 2 1 0	**Date** 4 3 2 1 0	**Date** 4 3 2 1 0

SAFETY: **(Identify focus_____)** 4 – Morse Fall Score high **or** requires use of sitter **or** restraint usage 3 – Risk for seizures **or** intermittent disorientation **or** has bathroom urgency **or** is receiving high risk parenteral infusions 2 – Morse Fall Score medium **or** urinary/bowel incontinence **or** receiving high risk medications 1 – Displays noncompliant behavior **or** had recent invasive procedure 0 – Morse Fall Score low	4 3 2 1 0	4 3 2 1 0	4 3 2 1 0	4 3 2 1 0	4 3 2 1 0
THOUGHT CONTENT: **(Identify focus_____)** 4 – Delusions/Halluciantions **or** requires continuous vigilance/assistance/reality testing 3 – Moderate cognition deficits **or** moderate thought disorders **or** requires reality testing **or** needs structured/timed interventions 2 – Intermittent cognition deficits/thought disorders **or** random disturbances in cognition/thought process **or** requires routine observation **or** disruption in carrying out ADLs/communication 1 – Mild disturbances in cognition **or** needs assistance with new ADLs **or** needs assistance with complex ADLs 0 – No overt disturbances in cognition **or** no reported disturbances in cognition **or** able to carry out ADLs **or** no disturbances in reality testing	4 3 2 1 0	4 3 2 1 0	4 3 2 1 0	4 3 2 1 0	4 3 2 1 0
SUICIDE/HOMICIDE/ASSAULT/ELOPEMENT: **(Identify focus_____)** 4 – Actively harming self/others **or** feels powerless against harming self/others **or** actively trying to elope **or** requires maximum protection 3 – Verbalizes potential harm to self/others **or** intent/plan to harm self/others **or** intent/plan to elope 2 – Expresses wish to harm self/others **or** expresses wish to elope **or** cooperates to keep self/others safe **or** reports thought/impulses to harm 1 – Controls thoughts of harming self/others **or** controls urge to elope **or** participates in controlling behaviors	4 3 2 1 0	4 3 2 1 0	4 3 2 1 0	4 3 2 1 0	4 3 2 1 0

0 – No discernable through to self/others **or** Denies thoughts/feelings of harm to self/others **or** no discernable plan to elope **or** denies thoughts of elopment					
MOOD/AFFECT:	**Admit Baseline Date**	**Date**	**Date**	**Date**	**Date**
(Identify focus_____)					
	4	4	4	4	4
4 – Extreme agitation/mood swings **or** absence of displayed emotions	3	3	3	3	3
3 – Unpredictable agitation/mood swings **or** periodic absence of displayed emotions	2	2	2	2	2
2 – Mood inconsistent to situation **or** affect inconsistent to situation or exhibits mood swings	1	1	1	1	1
1 –Mood mostly appropriate to situation or affect mostly appropriate to situation or significant decrease in mood swings	0	0	0	0	0
0 – Mood level appropriate to situation **or** affect is appropriate to situation					
INTERPERSONAL/CHANGE QUOTIENT:	4	4	4	4	4
(Identify focus_____)	3	3	3	3	3
	2	2	2	2	2
4 – Misinforms/avoids staff **or** blames others for current situation **or** feels others must change **or** extreme fear of change **or** denies need for WRAP	1	1	1	1	1
3 – No attempt to change life situation **or** defensive/anxious **or** acknowledges need for WRAP	0	0	0	0	0
2 – Takes steps to change situation **or** describes needed change in situation **or** steps to change fail **or** develops WRAP					
1 – Significant steps to change situation **or** verbalizes commitment to WRAP					
0 – Behaves to produce change **or** believes he/she must change self **or** consistent use of WRAP					

MEDICATION COMPLIANCE: **(Identify focus_____)** 4 – refuses all meds **or** takes meds inconsistently **or** overmedicates **or** history of overdose 3 – Inconsistent medication use **or** needs cueing for medication use 2 – Needs/uses cueing for med usage **or** accepts need for medications 1 – Takes medications **or** states/reports side effects of meds **or** participates in monitoring of meds 0 – Seeks out medication when appropriate **or** refills own medications **or** knows medications indications/side effects **or** seeks help for side effects	4 3 2 1 0	4 3 2 1 0	4 3 2 1 0	4 3 2 1 0	4 3 2 1 0
TOTAL DAILY SCORE					

SIGNATURE: _____

DATE: _____

Appendix B

IRB Approvals and Consent to Use Data

DRIVE to EXCELLENCE
TRINITY

DATE: August 28, 2011

TO: Charles Elmendorf, DO - Institutional Review Board (IRB) Chair

RE: Nursing Research Study

Dear Dr Elmendorf,

The nursing Evidence-based practice and Research Advisory Committee (ERAC) has received a request from Cheryl McKay, MSN, RN (doctoral student at The University of Texas at Tyler) to conduct her research study "The CareGraph: Initial Psychometrics and Evaluation of Length of Stay, Cost in a Psychiatric Inpatient Population" at Trinity Regional Health System. Ms. McKay's research will consist of reviewing de-identified psychiatric patient data to evaluate the impact of the CareGraph with patient financial and length of stay metrics. Cathy Kearns, BSN, RN (Trinity Informatics Nurse will be responsible for de-identifying all patient records prior to review). [please see attached UT Tyler IRB expedited approval letter and overview of proposed research]

Ms. McKay's research material was reviewed during an interactive presentation via conference call with the nursing ERAC team on August 11, 2011. After her presentation ERAC voted to endorse this nursing research study and recommends expedited review. If you concur after review of the materials, please indicate below, sign, date and scan via email to my attention. If you disagree please indicate your choice below and we will follow-up.

I thank you in advance for your time and support of nursing research at Trinity Regional Health System.

Sincerely,

Mary A. Petersen, MSN, RN
Director of Professional Nursing Practice
Director of Inpatient Behavioral Health
Magnet / Nursing Research Coordinator
Evidence-based practice and Nursing Research Committee (ERAC) Chair
PetersenMary@ihs.org
309-779-2257

********** *to be completed by the Institutional Review Board* **********

X **I approve this study for expedited review** (these documents will be included in the next Trinity IRB packet for informational purposes)

____ **This study requires Full IRB Review, please submit all materials to the next IRB meeting** - (contact the primary investigator to present this study for review by the full board)

____ **I have questions or concerns regarding this study, please contact me by phone to discuss.**

IRB Chairperson Chas Elmendorf DO
(signature)

Date: 9/22/2011

Pages to follow: 8

Appendix B (Continued)

IRB Approval – Iowa Health System

IOWA HEALTH
DES MOINES

Methodist • Lutheran • Blank

February 16, 2012

Institutional Review Board
1415 Woodland Avenue, Suite 218
Des Moines, IA 50309
515-241-5790
Fax 515-241-4185

Cheryl A. McKay, RN
The University of Texas at Tyler
College of Nursing
3900 University Blvd.
Tyler, TX 75700

Dear Ms. McKay:

I have reviewed your Application to Conduct Research on Human Subjects and protocol for the following study. Your request for a waiver for obtaining informed consent has been granted.

Hospitalized Patients – Collaboration Through Clinical Integration: Evaluation of Hospitalized Patients'' Survival, Length of Stay and Costs

This study has been approved by expedited review in accordance with federal regulation 45 CFR 46.110(b)(5) "Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis)." All expedited reviews require notification to the full Institutional Review Board at the next convened meeting. The next IRB meeting will be on March 8, 2012. ***You need not be present at this meeting***.

This protocol has been assigned the following ID Number: **IM2011-033**. Please refer to this number in all correspondence regarding this protocol. Approval of a study should not be interpreted as a granting of any hospital privileges to any of the investigators participating in the study.

Your study has been approved for a period of one year from February 16, 2012 to February 15, 2013. The continuation review for this study will be scheduled for January 10, 2013. You will receive a continuation form to complete prior to this date. **Failure to complete the continuation form will result in administrative closure, requiring full board presentation to reactivate.**

Changes in the protocol may not be implemented without prior IRB review and approval, except when necessary to eliminate immediate hazard to research subjects.

Each investigator is responsible for notifying the IRB whenever approval of the study or investigator is withdrawn by the sponsor, FDA, or HHS. Additionally, each investigator shall notify the IRB in the event that the investigator discontinues the study at any time other than the scheduled completion date, and an investigator is required to report promptly to the IRB, within one working day, any fatalities and life-threatening or serious adverse events occurring in subjects enrolled in a protocol or variance from the approved protocol. At the conclusion of the study, the IRB may require such follow-up information and documentation of a completed or discontinued study as it may determine appropriate.

This IRB operates in accordance with all applicable federal, state and local laws and regulations. Please contact me if I can be of further assistance.

Sincerely,

Timothy Drevyanko, MD, MS
Chair, Iowa Health-Des Moines IRB

Iowa Health - Des Moines is Fully Accredited by the
Association for Accreditation of Human Research Protection Programs, Inc.

Appendix B (Continued)

Data Use Agreement – Iowa Health System

LIMITED DATA SET USE AGREEMENT

This DATA USE AGREEMENT (this "Agreement") is entered into effective the 8 day of February 2012 ("Effective Date"), by and between Iowa Health System, an Iowa not for profit corporation, as a Business Associate of its affiliates that function as Covered Entities and have formed an Affiliated Covered Entity as that term is used under 45 C.F.R. 164.105(b) (together the "Affiliated Covered Entity"), and Cheryl McKay PhDc, RN, a student (the "Data User").

RECITALS

1. The Data User performs certain research and public health analyses, as well as health care operations functions of the Affiliated Covered Entity (the "Activities").

2. The Affiliated Covered Entity may disclose a Limited Data Set, as defined herein, to Data User for use by Data User in performance of the Activities.

3. The Data User agrees to limit its use of the Limited Data Set and protect the Limited Data Set according to the terms and conditions of this Agreement and the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and the corresponding Regulations, as may be amended from time to time.

NOW, THEREFORE, the parties agree as follows:

1. **Definitions**. As used herein:

a. "***Breach***" means, with respect to PHI, the impermissible acquisition, access, use or disclosure of Unsecured PHI which compromises the security or privacy of the PHI.

b. "***Designated Record Set***" shall mean a group of records as defined in 45 C.F.R. §164.501, which includes Protected Health Information ("PHI") that is maintained, collected, used or disseminated by or for the Covered Entity.

c. "***HIPAA***" means the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. §§1320d to 1320d-7.

d. "***Limited Data Set***" means PHI that excludes the identifiers as defined by 45 C.F.R. §164.514(e). The following identifiers may be part of a Limited Data Set: town and city, state and zip code; date of service, admission, discharge and death; and date of birth, age or elements of dates indicative of individual's age.

e. "***PHI***" means Protected Health Information, as defined in 45 C.F.R. §164.501, which is created, obtained or used by Data User in the performance of one or more Activities for Covered Entity.

f. "***Regulations***" means the final regulations implementing the privacy provisions of HIPAA as amended from time to time. The Regulations are codified at 45 C.F.R. Parts 160 and 164.

g. "***Secretary***" shall mean the Secretary of the Department of Health and Human Services.

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h. "***Security Incident***" means the attempted or successful unauthorized access, use, disclosure, modification or destruction of information or interference with system operations in an information system.

i. "***Unsecured PHI***" means PHI that has not been rendered unusable, unreadable, or indecipherable to unauthorized individuals by one or more of the methods outlined by the Department of Health and Human Services in 74 Fed. Reg. 70 (2009) (to be codified at 45 C.F.R. §160 and §164).

2. Purpose. As outlined in Exhibit A, referenced hereto and incorporated herein, Data User will perform the listed Activities. In order to perform such Activities, Data User will need to use the PHI listed in Exhibit A (the "Limited Data Set") of the Affiliated Covered Entity.

3. Obligations of Data User.

a. Use of Limited Data Set. The Data User may use and disclose the Limited Data Set only to perform the Activities set forth in Exhibit A or as otherwise permitted under the terms of this Agreement or as required by law. Data User shall ensure that its contractors and agents do not use or disclose the Limited Data Set in any manner that would constitute a violation of the Regulations if used by the Affiliated Covered Entity. Data User agrees not to use the Limited Data Set in such a way as to identify any individual and further agrees not to contact any individual.

b. Minimum Necessary Information. The Data User represents that, to the extent the Data User requests that the Affiliated Covered Entity disclose PHI to the Data User as described in Exhibit A, such request shall be for the minimum amount of PHI necessary for the performance of the Activities by Data User. Data User shall limit the use or receipt of the Limited Data Set to the individuals or classes of individuals listed in Exhibit A who need the Limited Data Set for the performance of the Activities.

c. Safeguards Against Misuse of Information. The Data User shall use appropriate safeguards to prevent use or disclosure of the Limited Data Set other than as permitted under this Agreement.

d. Reporting of Disclosures of Protected Health Information. The Data User shall report to Affiliated Covered Entity any unauthorized use or disclosure of PHI by Data User, its agents or subcontractors within three (3) business days of discovery by Data User, together with any remedial action taken or proposed to be taken with respect to such improper use or disclosure. Data User shall cooperate with Covered Entity in mitigating any harmful effects of such improper use or disclosure.

e. Agreements by Third Parties. The Data User shall obtain and maintain an agreement with each agent or subcontractor that has or will have access to the Limited Data Set, under which such agent or subcontractor agrees to be bound by the same restrictions, terms and conditions that apply to the Data User hereunder.

f. Access to Information. Within three (3) business days of a request by the Affiliated Covered Entity for access to PHI about an individual contained in a Designated Record Set, the Data User shall make available to the Affiliated Covered Entity such PHI

for so long as such information is maintained in the Designated Record Set. In the event any individual requests access to PHI directly from the Data User, the Data User shall within three (3) business days forward such request to the Affiliated Covered Entity. Any denials of access to the PHI requested shall be the responsibility of the Affiliated Covered Entity.

g. Availability of PHI for Amendment. Within three (3) business days of receipt of a request from the Affiliated Covered Entity for the amendment of an individual's PHI or a record regarding an individual contained in a Designated Record Set (for so long as the PHI is maintained in the Designated Record Set), the Data User shall provide such information to the Affiliated Covered Entity for amendment and incorporate any such amendments in the PHI as required by 45 C.F.R. §164.526. Data User is not authorized to independently agree to any amendment of PHI.

h. Notice of Request for Data. The Data User agrees to notify the Affiliated Covered Entity within three (3) business days of the Data User's receipt of any request or subpoena for PHI. To the extent that the Affiliated Covered Entity decides to assume responsibility for challenging the validity of such request, the Data User shall cooperate fully with the Affiliated Covered Entity in such challenge.

i. Injunction. The Data User acknowledges and agrees that the Affiliated Covered Entity will suffer irreparable damage upon the Data User's breach of this Agreement and that such damages shall be difficult to quantify. The Data User acknowledges and agrees that the Affiliated Covered Entity may file an action for an injunction to enforce the terms of this Agreement against the Data User, in addition to any other remedy the Affiliated Covered Entity may have. Data User agrees to waive any requirement for the posting of a bond.

j. Ownership of Information. The Data User acknowledges that, as between the Data User and the Affiliated Covered Entity, all PHI shall be and remain the sole property of the Affiliated Covered Entity, including any and all forms thereof developed by the Data User in the course of fulfilling its obligations under this Agreement.

k. Breach Notification. The Data User shall report to Affiliated Covered Entity's designated privacy official, within three (3) business days of discovery by Data User, any acquisition, access, use or disclosure of PHI not provided for in this Agreement or not permitted under the HIPAA Regulations, including any impermissible access, acquisition, use or disclosure that is a Breach of Unsecured PHI, together with any remedial or mitigating action taken or proposed to be taken with respect thereto. Data User shall notify Affiliated Covered Entity of any such impermissible access, acquisition, use or disclosure, including the following information in such notice:

i. A brief description of how the impermissible access, acquisition, use or disclosure occurred and how and when it was discovered.

ii. A description of whether Unsecured PHI was involved in the impermissible access, acquisition, use or disclosure.

iii. The steps Data User is taking to further investigate the impermissible access, acquisition, use or disclosure, to mitigate losses,

and to protect against further impermissible access, acquisition, use or disclosure.

Data User shall cooperate with Affiliated Covered Entity in mitigating any harmful effects of any such impermissible access, acquisition, use or disclosure, and in making any required notification to individuals in the case of a Breach as determined by Affiliated Covered Entity. Data User shall pay for the costs of such mitigation and notification if the Breach was due to a violation of this Agreement, or the negligent or intentional actions of Data User.

4. **Supervening Law**. Upon the enactment of any law or regulation affecting the use or disclosure of PHI, or the publication of any decision of a court of the United States or of this state relating to any such law, or the publication of any interpretive policy or opinion of any governmental agency charged with the enforcement of any such law or regulation, Affiliated Covered Entity may, by written notice to Data User, amend this Agreement in such manner as it determines necessary to comply with such law or regulation. If Data User disagrees with any such amendment, it shall so notify Affiliated Covered Entity in writing within thirty (30) days of Affiliated Covered Entity's notice. If the parties are unable to agree on an amendment within thirty (30) days thereafter, either of them may terminate this Agreement on not less than thirty (30) days written notice to the other.

5. **Termination**.

a. Termination upon Breach of Provisions Applicable to PHI. Any other provision of this Agreement notwithstanding, this Agreement may be terminated by the Affiliated Covered Entity upon five (5) days written notice to the Data User in the event that the Data User breaches any provision contained in this Agreement, and if such breach is capable of being cured, such breach is not cured within such five (5) day period. Data User acknowledges and agrees that in the event Data User's efforts to cure the breach are unsuccessful, the Affiliated Covered Entity has a duty to discontinue disclosure of PHI and to report the breach to the Secretary, notwithstanding any other provision of this Agreement to the contrary.

b. Return or Destruction of PHI upon Termination. Upon termination of this Agreement, the Data User shall either return or destroy all PHI received from the Affiliated Covered Entity or created or received by the Data User on behalf of the Affiliated Covered Entity and which the Data User still maintains in any form. The Data User shall not retain any copies of such PHI. Notwithstanding the foregoing, to the extent that the Affiliated Covered Entity agrees that it is not feasible to return or destroy such PHI, the terms and provisions of this Agreement shall survive termination of the Agreement and such PHI shall be used or disclosed solely for such purpose or purposes that prevented the return or destruction of such PHI.

c. The Covered Entity's Right of Cure. At the expense of the Data User, the Affiliated Covered Entity shall have the right to cure any breach of the Data User's obligations under this Agreement. The Affiliated Covered Entity shall give the Data User notice of its election to cure any such breach and the Data User shall cooperate fully in the efforts by the Affiliated Covered Entity to cure the Data User's breach. All requests

for payment for such services of the Affiliated Covered Entity shall be paid within thirty (30) days.

d. Transition Assistance. Following the termination of this Agreement for any reason, upon the request of the Affiliated Covered Entity, the Data User agrees to provide transition services for the benefit of the Affiliated Covered Entity, including the continued provision of its services required under this Agreement until notified by the Affiliated Covered Entity that the alternative provider of services is able to take over the provision of such services and the transfer of the PHI and other data held by the Data User related to its services under this Agreement.

6. Miscellaneous.

a. Covered Entity. For purposes of this Agreement, Affiliated Covered Entity shall include the named Affiliated Covered Entity and all entities covered by a joint notice of privacy practices with Affiliated Covered Entity, whether as part of an affiliated covered entity or an organized health care arrangement.

b. Survival. The respective rights and obligations of Data User and Affiliated Covered Entity hereunder shall survive termination of the Agreement according to the terms hereof and the obligations imposed on Affiliated Covered Entity under HIPAA.

c. Amendments Waiver. The provisions of this Agreement may not be modified, waived or amended, except by mutual written agreement of the parties. A waiver with respect to one event shall not be construed as continuing, or as a bar to or waiver of any right or remedy as to subsequent events.

d. No Third-Party Beneficiaries. Nothing express or implied in this Agreement is intended to confer, nor shall anything herein confer, upon any person other than the parties and their respective successors or assigns, any rights, remedies or obligations.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed as of the day and year first written above.

[COVERED ENTITY]	**[DATA USER]**
By: Kathy Cunning	By: CMcKay
Print Name: Kathy Cunningham	Print Name: Cheryl McKay
Print Title: Exec Dir, Accountable Care Strategies	Print Title: PhDE, RN
Date: 3-1-12	Date: 2/8/12

EXHIBIT A
TO
DATA USE AGREEMENT

AFFILIATED COVERED ENTITY: Iowa Health System, as a Business Associate on behalf of its affiliated Covered Entities that have formed an Affiliated Covered Entity as that term is used under 45 C.F.R. 164.105(b) for purposes of HIPAA compliance.

DATA USER: Cheryl McKay, PhDc, RN

LIST DATA USER ACTIVITIES:

a. See attached "Specifications for a Data Request in support of a dissertation entitled 'Collaboration through Clinical Integration: Evaluation of Hospitalized Patients' Survival, Length of Stay and Costs'"

b. _____

c. _____

DESCRIBE PHI DATA USER REQUIRES FOR PERFORMANCE OF ACTIVITIES:

Adult patients (> age 18) admitted during specified dates to one of the Iowa Health System hospitals chosen for this study (Trinity Rock Island, Trinity Bettendorf, Iowa Methodist and Sioux City) with the primary diagnosis of CHF (DRG's 291, 292, and 293).

LIST INDIVIDUALS OR CLASS OF INDIVIDUALS WHO NEED ACCESS TO LIMITED DATA SET:

a. Cheryl McKay

b. _____

c. _____

AFFILIATED COVERED ENTITY	**CHERYL MCKAY**
By: Kathy Cunningham	By: [signature]
Print Name: Kathy Cunningham	Print Name: Cheryl McKay
Print Title: Exec Director, accountable Care strategies	Print Title: PhDc RN
Date: 3-1-12	Date: 2/8/12

Specifications for a Data Request in support of a dissertation entitled 'Collaboration through Clinical Integration: Evaluation of Hospitalized Patients' Survival, Length of Stay and Costs'

4,085 records representing all patients discharged for heart failure during calendar years of 2005, 2006, 2007, 2008

Company/Facility identifiers: 01 IMMC, 501 SLSC, 752 TQC B, 752 TQC RI

MS_DRG codes: 291, 292 or 293

Admit Date: MM/DD/YYYY

Disch Date: MM/DD/YYYY

ACT_TOTAL_COST: 999,999.99

ACT_DIRECT_COST: : 999,999.99

ACT_VARIABLE_COST: 999,999.99

ACT_VBL_DIR_COST: 999,999.99

Appendix C

Selected Statistical Analysis Information

Patient Survival Statistics

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
PATIENT SURVIVAL * WHICH FACILITY	1192	100.0%	0	.0%	1192	100.0%

PATIENT SURVIVAL * WHICH FACILITY Crosstabulation

			WHICH FACILITY				
			A	B	C	D	Total
PATIENT SURVIVAL	LIVED	Count	499	123	469	60	1151
		Expected Count	494.4	127.5	470.2	58.9	1151.0
		Std. Residual	.2	-.4	-.1	.1	
	DIED	Count	13	9	18	1	41
		Expected Count	17.6	4.5	16.8	2.1	41.0
		Std. Residual	-1.1	2.1	.3	-.8	
Total		Count	512	132	487	61	1192
		Expected Count	512.0	132.0	487.0	61.0	1192.0

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	6.479[a]	3	.091
Likelihood Ratio	5.755	3	.124
Linear-by-Linear Association	.003	1	.954
N of Valid Cases	1192		

a. 2 cells (25.0%) have expected count less than 5. The minimum expected count is 2.10.

Descriptive Statistics for Length of Stay and Cost

Variable	Facility	N	Mean	Standard Deviation	95% Confidence Intervals
Length of Stay					
	C Large Control	512	5.24	3.50	(4.93,5.54)
	D Small Control	132	4.41	2.51	(3.98,4.84)
	A Large intervention	487	4.48	3.58	(4.16,4.80)
	B Small intervention	61	4.28	2.44	(3.65,4.90)
Total		1192	4.79	3.42	(4.60,4.98)
Variable	Facility	N	Mean	Standard Deviation	95% Confidence Intervals
Cost					
	C Large Control	512	$6534.00	$5039.00	($6097.00, $6972.00)
	D Small Control	132	$5648.00	$3733.00	($5005.00, $6291.00)
	A Large intervention	487	$4471.00	$3306.00	($4177.00, $4765.00)
	B Small intervention	61	$6144.00	$3631.00	($5214.00, $7074.00)
Total		1192	$5573.00	$4297.00	($5329.00, $5817.00)

Comparisons Between Length of Stay and Cost

Test of Homogeneity of Variances

	Levene Statistic	df1	df2	Sig.
LENGTH OF STAY	4.355	3	1188	.005
ACTUAL TOTAL COST	12.453	3	1188	.000

Welch's F Statistic

Robust Tests of Equality of Means

		Statistic[a]	df1	df2	Sig.
LENGTH OF STAY	Welch	5.780	3	245.021	.001
	Brown-Forsythe	7.172	3	677.453	.000
ACTUAL TOTAL COST	Welch	21.696	3	225.749	.000
	Brown-Forsythe	23.664	3	491.583	.000

a. Asymptotically F distributed.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED TWO PAGES.**

NAME	POSITION TITLE
Cheryl A. McKay	Chief Clinical Officer Lifecare Hospitals Dallas
eRA COMMONS USER NAME	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Mount St. Mary's College – Los Angeles, CA	BSN	1987	Nursing
Azusa Pacific University – Azusa, CA	MSN	1997	Nursing – Adult CNS
University of Texas at Tyler – Tyler, TX	PhD	2012	PhD

NOTE: The Biographical Sketch may not exceed two pages:

A. Positions:

Chief Clinical Officer — 2011 - present
Lifecare Hospitals Dallas
Dallas, TX

Director Education and Inpatient Services — 2009 - 2011
Texas Regional Medical Center
Sunnyvale, TX

Vice President of Critical Care Services/ — 2007 - 2009
Center for Nursing Education and Research
Baylor University Medical Center
Dallas, TX

Director Professional Nursing Practice/ — 2004-2007
Trinity Institute
Trinity Regional Medical Center/
Iowa Health System
Moline, IL

B. Publications/Presentations

McKay, C. (2011). Providing a Structure of Collaboration: A Leadership Challenge. *ANA NDNQI Conference.* Miami, FL.

McKay, C. and Crippen, L. (2008). Collaboration through Clinical Integration. *Nursing Administration Quarterly*, 32(2), 109-114.

McKay, C. (2007). Providing a Structure for Collaboration through Clinical Integration. *Sigma Theta Tau 18th International Research Conference,* Vienna, Austria.

McKay, C. (2006). Psychometric evaluation of the CareGraph: Where are we and where do we want to go? *Center for Case Management National Conference*, Rock Island, IL.