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Chronic Disease Management of the Uninsured Patient at Ohio Free Clinics

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Abstract

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M.Ed., Kent State University, 1989

BS, Ohio State University, 1982

Dissertation Submitted in Partial Fulfillment

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Abstract

Management of chronic disease requires a different service delivery model from that of acute illness. The uninsured population experience poorer health status and increased incidence of chronic disease than do the insured population. The purpose of this study was to identify the supports and barriers present in providing chronic disease management to patients at Ohio free clinics. Wagner's theory of chronic disease management served as the theoretical lens. The sequential, exploratory mixed methods study collected data from 13 free clinics belonging to the Ohio Association of Free Clinics (OAFC). Quantitative questions focused on processes in clinics with high and low fidelity to the chronic care model (CCM) determined by the Assessment of Chronic Illness Care (ACIC) survey. A backwards stepwise logistic regression was used. The quantitative analysis determined the 3 highest and lowest scoring clinics on the ACIC survey who then participated in a 2 tiered multi-case study series. Qualitative questions examined supports present in high fidelity clinics and barriers present in clinics with low fidelity. Qualitative findings identified 5 support areas that centered on progressive vision and patient-centered care themes that existed in high fidelity clinics. Four barriers were identified in low fidelity clinics that focused on the theme of capacity building. These findings provide evidence to guide the OAFC's work in improving adherence to the CCM constructs, thereby elevating the quality of care to the uninsured with chronic disease to the level of those providers governed by accrediting organizations. Changes in quality of care may result in an improvement to the health status of the individual and the communities in which they live.

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Dedication

I would like to dedicate this dissertation to my wife Michele and my children Bryan, Brad, and Alex for their belief in me. The patience and support they provided and their encouragement through this journey will forever be appreciated.

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Chapter 1: Introduction to the Study

Introduction

The first decade of the 21st century reflected two historic changes in the health status of the population of the United States. First, the number of individuals lacking health insurance rose dramatically during this 10-year period from 36.5 million in 2000 to an all-time high of 49.9 million in 2010 (U.S. Census Bureau, 2012). Second, the incidence of Americans developing one or more chronic diseases increased substantially. Hoffman and Schwartz (2008) reported 31% of adults in the 18-64 age range, or 58 million individuals, had one or more chronic disease(s). Chronic disease across all age groups in the United States now consumes over 75% of all health care spending (Centers for Disease Control and Prevention, 2009).

The combination of these two phenomena has negatively affected all sectors of the U.S. health care system. According to DeNavas-Walt, Proctor, and Smith (2013), the economic burden of 15.4% of the uninsured population has shifted the cost of care on to those who do have insurance. This shift has resulted in yearly health care costs exceeding the average consumer price index inflation rate every year from 2000-2012 (YCharts, 2014). The insured population has seen their premiums, deductibles, and co-insurance rates increase steadily to levels that both employers and individuals find unaffordable. Individuals lacking health insurance have few options for receiving health services in a timely and affordable manner. Gindi, Cohen, and Kirzinger (2012) reported data from the National Health Interview Survey, January-June 2011, which reflected 62% of uninsured adults aged 18-64 made emergency room visits because they had no other place to go. Access to health care is often limited for the uninsured; however, in a study comparing treatment options, Walker (2013) found that uninsured patients accessing free clinics for primary care had a lower utilization of emergency room visits than those without access.

The increase in chronic disease in this country can be attributed to a host of factors: individual behaviors, biology and genetics, health services, policymaking, and social factors (Healthy People 2020, 2011). Vulnerable populations, described as low-income, uninsured, racial and ethnic minorities, rural and immigrant populations, and the undereducated, have been shown to have a disproportionately higher incidence of chronic diseases such as diabetes, cardiovascular disease, and obesity (Bahls, 2011; Hoffman & Paradise, 2008; Kirby & Kaneda, 2010). Chronic disease burdens individuals across economic, human, and societal spans. The economic burden of having a chronic disease is reflected in the costs of medical care, pharmaceutical drugs, and adaptive medical equipment. Additionally, the U.S. health care system has been slow to change to or adopt a model for successfully managing chronic disease.

The Chronic Care Model (CCM), developed in the late 1990s has become the benchmark model for chronic disease management (Robert Wood Johnson Foundation, 2011). However, health systems and providers have been slow to adopt the six principle elements of the model due to reimbursement limitations, implementation costs, technology requirements, and time constraints (Bodenheimer et al., 2004; Bodenheimer, Ghorob, Willard-Grace, & Grumbach, 2014; Nutting et al., 2011; Oswald, 2001;

Stellefson, Dipnarine, & Stopka, 2013; Wagner, Davis, Schaefer, Von Korff, & Austin, 1999). For those individuals who do not have health insurance, access to health care is a huge issue in America.

Community safety nets are one option the uninsured population has to access health services. Federally Qualified Health Centers originated in 1991. Their mission is to enhance primary care services to underserved, underinsured, and uninsured Americans, as well as migrant workers, and non-U.S. citizens (Centers for Medicare and Medicaid Services, 2011).

Free Clinics are another community safety net option to the uninsured. Free clinics began in the late 1960s and early 1970s as community safety nets for substance abusers and ethnic minorities (Weiss, 2006). Over time, free clinics evolved to provide primary medical care. Their popularity grew as the number of individuals without health insurance grew. Free clinics quickly became a viable option for access and affordability to health care services for the uninsured. The National Association of Free Clinics formed in 2001 to create an umbrella association and a voice that would represent individual clinics in their ability to provide services to an underrepresented population (National Association of Free and Charitable Clinics, 2014a, 2014b). Individual states created state associations. Free clinics in the State of Ohio formed the Ohio Association of Free Clinics (OAFC) in 2000, which now represents 51 clinics throughout the state (OAFC, 2014).

Free clinics are a loosely associated group of clinics in that they are free to provide services they feel are important to their community. Free clinics, unlike most regulated health care facilities, are held to lower levels of accountability and are not beholden to the rigorous and onerous standards such as those of the Joint Commission on Accreditation of Health Care Organizations, Centers for Medicare and Medicaid Services, or commercial insurance companies due to their 501(c)(3) status and the fact that most free clinics do not bill insurance companies.

Health care research literature to date involving free clinics has been scarce due to: (a) the historical lack of identification of free clinics as legitimate providers of health care services; (b) the lack of uniformity of services provided among free clinics; and (c) the less rigorous reporting and accountability standards to which free clinics are held accountable (Brennan, 2013). These factors have led to gaps in the research literature identifying how chronic disease management is conducted in the free clinic settings. This study aimed to identify the fidelity with which Ohio free clinics have adhered to the six key constructs of the CCM. Additionally, the clinics most compliant with the CCM were compared to the clinics that had the least amount of fidelity. Supports and barriers were identified that may provide free clinics with information, resources, and strategies to better enable them to meet the health care needs of their constituents.

This chapter is organized into 12 sections. The first section discusses the background to the study. The second section states the problem. The third section addresses the purpose of the study. The fourth section addresses the research questions while the fifth section provides the theoretical framework to the study. The sixth section discusses the nature of the study. The seventh section provides definitions of terms used in the study. The eighth, ninth, and tenth sections address the assumptions, scope, delimitations and limitations. Finally, the eleventh section addresses the significance of the study followed by the twelfth section, the summary.

Background

The consequences of a lack of health insurance have been shown to affect many aspects of life including quality of life, increased financial burden, health morbidity, and ultimately mortality (Bailey, 2012). The uninsured often lack a usual and consistent source of care, creating issues of continuity. When compared to the insured population, the uninsured are more likely to skip or postpone needed care due to cost, miss preventative care, and be diagnosed with cancer at later stages resulting in earlier death (Institute of Medicine, 2012; Kaiser Family Foundation, 2011). Dorn (2008) estimated that 137,000 adults between the ages of 25 and 64 died due to the lack of health insurance from 2000-2006. This estimation is consistent with the research of Bailey (2012), who reported 134,120 premature deaths between the years 2005-2010 of people between the ages of 25 and 64 due to lack of health insurance.

Advances in medical care, health education, and health literacy have reduced the mortality for those with health insurance as evidenced by the increasing life span for both males and females, while the uninsured have a 25% higher chance of dying prematurely when compared to adults with insurance (Institute of Medicine, 2009). Bovbjerg and

Hadley (2007) reported that health outcome measures indicate that having medical insurance results in better health and less morbidity and mortality related to illness when compared to the uninsured. The disparity in health status of the insured and the uninsured occurs partly due to the complex system of private health insurance and government provided health insurance that exists.

Healthy People 2020 (2010) provides a broad and encompassing definition of the term *health disparity*:

> A particular type of health difference that is closely linked with social, economic, and or environmental disadvantage. Health disparities adversely affect groups of people who have systematically experienced greater obstacles to health based on their racial or ethnic group; religion; socioeconomic status; gender; age; mental health; cognitive, sensory, or physical disability; sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion. (para. 5)

Health disparities exist in our country partly due to the structure of our health care system. Government supported health care for the young, 0-19 years old, is provided through the State Children's Health Insurance Program, and for the aged, 65 and older, Medicare exists through the Centers for Medicare and Medicaid Services. For the age group 19-64, a mix of limited government coverage exists for the disabled and disadvantaged. Medicare covers those under the age of 65 if they are disabled and have been receiving Social Security Disability Insurance for more than two years. Individuals with End-Stage Renal Disease or Amyotrophic Lateral Sclerosis also receive Medicare benefits (Medicare Rights Center, 2011). The Medicaid program, funded jointly by the federal government and the states, provides health care coverage to pregnant women, parents with children under the age of 19, and individuals with disabilities. States must provide the federal minimum coverage but have options to expand coverage based on federal poverty levels. Individuals between the ages of 19 and 64 who do not meet any of the above criteria must rely on commercial insurance. Annually, data collected by the Agency for Health Care Research and Quality addresses the scope of health care disparities in two reports: National Health Care Quality Report and the National Health Care Disparities Report. Outcomes regarding access to health care show a disproportionate representation of vulnerable populations (Agency for Health Care Research and Quality, 2011a, 2011b).

Disparities are often described in the context of access, quality, and cost. The lack of health insurance excludes the majority of the uninsured from access to most traditional aspects of the health care system: a usual source of care, timely care, preventative screenings, vaccinations, checkups, dental and vision care, pharmaceutical services, and health education specific to their problem. The uninsured are often left to rely on community safety net services as their primary source of health care. While meeting certain health care needs, community safety net services often lack comprehensive services, continuity, and timeliness that impede quality. The lower an individual’s economic status, the higher the probability that individual will be uninsured. The cost of medical care is a large impediment to health insurance. Medical cost is one of the leading contributors to personal bankruptcy filings in the country today (Berkowitz & Miller, 2011). The consequence of this scenario manifests itself in additional costs and poorer health status. The uninsured cross all racial, ethnic, and socioeconomic classifications; however, the disparity of access to medical care, preventative services, and affordable and timely treatment does not affect all populations equally (Bahls, 2011). Chronic disease is just one manifestation of the ill effects of being uninsured (Stremikis, Berenson, Shih, & Riley, 2011).

Chronic disease as defined by the U.S. National Center for Health Statistics classifies a chronic disease as one lasting three months or longer. Chronic diseases generally are not preventable by vaccine or curable by medication. Chronic diseases historically have long courses of illness with increasing medical complications and decreasing quality of life. Chronic diseases account for the most common and costly health problems in America, but most chronic diseases are also preventable (Centers for Disease Control and Prevention, 2012). Chronic disease often starts asymptomatically and can progress undiagnosed without warning signs or symptoms for many years without regular medical checkups and preventative screenings.

The Institute of Medicine (2012) refers to chronic disease as a condition that is slowly progressive, has a lengthy duration, and does not resolve itself. Common chronic diseases most prevalent among Americans are: cancer, stroke, obesity, arthritis, chronic respiratory disease, diabetes, hypertension, cardiovascular disease, and chronic kidney disease. This list is by no means definitive and many other chronic diseases exist, affecting millions of people. Manifestation of chronic disease presents in loss of physical function, quality of life, and productivity. Chronic disease affects an estimated 145 million Americans (Centers for Disease Control and Prevention, 2012). Without significant changes in our health care delivery system and lifestyles, the number of Americans with chronic disease is projected to grow to 171 million Americans by 2030 (Improving Chronic Illness Care, 2012; Robert Wood Johnson Foundation, 2011).

Historically, chronic disease is a relatively recent phenomenon. Emerging in the 1940s and 1950s, chronic disease followed centuries of infectious disease. The advent of cleaner water supplies, sanitary sewers, and advances in medications allowed the reduction or elimination of most infectious diseases (Floyd, 2012). Chronic disease, also known as noninfectious disease, began emerging as lifestyles, health determinants, and population migration changed (Andersen, 2007). As the average lifespan of the population expanded, the elderly became more susceptible to chronic disease as they aged. The majority of Americans experiencing a chronic disease are past the age of 65 years. However, the research of Hoffman and Schwartz (2008) for the 10-year period of 1997-2006 showed a steady increase in chronic disease among the 18 to 64-year-old population. More alarming was the research of Van Cleave, Gortmaker, and Perrin (2010) whose longitudinal research on children from 1988-2006 showed almost a 14% increase in chronic disease for the population less than 19 years old.

The State of Ohio has not fared much better than the nation in chronic disease prevalence. In 2011, Ohio ranked 36th overall in health rankings, a decrease of three spots from the previous year (United Health Foundation, 2011). Ohio is ranked 47th in the country in public health funding and is ranked above the 50-state average ranking for smoking, obesity, diabetes, high blood pressure, and high cholesterol (Centers for Disease Control and Prevention, 2009; Ohio Department of Health, 2011a).

The increased prevalence of chronic disease over the years has steadily strained the American health care system, both public and commercial. Traditional health care delivery models for primary care medicine have not met the medical, social, or psychological needs of chronically ill patients. In their pioneer work on chronic disease management, Wagner, Austin, and Von Korff, (1996) found that doctors trained to heal and cure acute illnesses were treating more patients with chronic disease, which required additional time and resources that they were not trained to provide. Meanwhile, insurance companies balked at the growing and ongoing expenses required to support chronically ill patients.

The pioneering work of the Robert Wood Johnson Foundation to fund research on chronic disease management began in the late 1970s and continues today. Early research, while productive, did not produce outcomes that resulted in systemic change in the care delivery system for chronic disease (Robert Wood Johnson Foundation, 2011).

In the 1990s, the Robert Wood Johnson Foundation funded a national research initiative called Chronic Care Initiatives in Health Maintenance Organizations (HMO).

Dr. Edward Wagner led one research team located in Seattle, Washington. Their research began by compiling what they knew was not working in the care of the chronically ill; They identified the current medical model, the use of medical personnel, and the lack of reliance on self-management and community resources. They subsequently identified office staff coordination and organization of patient information as contributing to suboptimal care of those with chronic disease (Wagner et al., 1996). Knowing what did not work combined with the evidence of what did work from research collected for the previous twenty years allowed the research team to develop the initial framework of the CCM.

The CCM identified six key constructs that were essential in the delivery of care to those with chronic disease.

- The Health System advocates that the health care organization create and promote a culture of quality care and commitment to chronic disease management (CDM).
- Delivery System Design advocates transforming the delivery team to personnel who possess the expertise needed in chronic disease management (CDM) and that visits are planned, purposeful, and productive.
- Decision Support supports the use of evidenced-based guidelines, patient preferences, and improved health literacy.

- Clinical Information Systems support the use of information systems at the patient and population levels to identify and organize care delivery and allow information sharing and outcome monitoring.
- Self-Management Support advocates the empowerment of the patient in his/her care through the provision of resources and responsibility.
- The Community acknowledges the need to expand resources beyond the organization to community collaborates (Wagner et al., 1996).

The model stressed the interdependency of the elements as important to the effectiveness of chronic disease management. In 1998, the Robert Wood Johnson Foundation funded the Improving Chronic Illness Care program with the purpose of implementing the CCM on a national level. The Improving Chronic Illness Care program identified collaborative partners throughout the country to assist in implementation training and research outcomes of the model. The Improving Chronic Illness Care program evolved to reflect the changes and challenges of chronic disease (Robert Wood Johnson Foundation, 2011).

Research on clinical care using the CCM supports its effectiveness. Hung et al. (2008) and Rittenhouse et al. (2010) reported reductions in disabilities, improved quality of life, and enhanced clinical outcomes. The research on the CCM has almost exclusively been conducted on individuals with health insurance. To date, only one research study on the effectiveness of the CCM has been conducted in a free clinic setting with a population of uninsured individuals (Stroebel et al., 2005).

Free clinics are a unique provider in the American health care delivery system. Their uniqueness comes from their relative obscurity in the provider network. Free clinics were long ignored as a viable source of medical care by the traditional health care community (Weiss, 2006). The ever-growing population of uninsured has fueled the viability and visibility of free clinics. Until two recent national surveys, Darnell (2010) and Gertz, Frank, and Blixen (2011), were conducted, little was known about free clinics and their outreach into the health care delivery system.

Free clinics over the past fifteen years have grown in number and in acceptance by the mainstream health community as evidenced by: (a) the number of medical professionals volunteering their time, (b) the U.S. government extending medical malpractice protection to those medical professionals, and (c) charitable foundations and organizations donating to their cause.

There are an estimated 1,200 free clinics nationwide, 51 in the state of Ohio (National Association of Free and Charitable Clinics, 2014a; OAFC, 2014). The majority of these clinics have originated in the past 20 years. Darnell's (2010) national survey found that these clinics serve over 1.8 million patients per year and account for over 3 million visits annually. Additionally, most clinics rely on volunteer medical personnel for direct patient care. Over 50% of clinics have some paid staff who are usually performing administrative tasks. Free clinics vary in size and scope. According to Darnell's study, clinics open less than five hours per week represented 28% of the total while clinics open 40 plus hours per week represented 25% of the surveyed clinics. Most clinics utilized both scheduled appointments and walk-in appointments. Further, the majority of clinics generated their revenue from private charitable donations, civic groups, churches, and foundations. Over half the clinics surveyed indicated that they provided services at no cost to the patient, while some clinics charged a nominal fee with the average being less than ten dollars.

Gertz et al. (2011) found the range of services offered at free clinics nationally varied based on: (a) the number of professional volunteers and their expertise, (b) the needs of the community, (c) the number of community collaborations established, and (d) the funding available for services. The majority of clinics offered primary care medical examinations, pharmacy medications, patient education, and case management services. Additional services offered may have included: urgent care, women's health, laboratory services, and vision and dental services. In the survey, Darnell (2010) reported 73% of clinics responding indicated they provided chronic disease management services. The survey did not investigate the scope, depth, or nature of the chronic disease management services provided. The survey did not address the CCM or the six key elements of the model.

Little has been published in the literature regarding the free clinics in the state of Ohio. The OAFC promotes the association clinics and operates a website that provides information and education regarding access and eligibility. Little is known about the scope, depth, or nature of the chronic disease management services at these clinics.

Research literature involving free clinics has mostly involved single site case studies that have limited value due to the lack of consistency between clinics. To date only one research study has been conducted regarding the CCM and a free clinic. Stroebel et al. (2005) conducted a pilot project at an established free clinic. Patients diagnosed with diabetes and/or hypertension were enrolled in the 22-month study using the CCM as a template for care delivery. The focus of this study was aimed at measuring improvements in clinical outcomes achieved by using the CCM model rather than changes in the organization with the implementation of the model into everyday practice.

The number of Americans living without health insurance increased steadily to approximately 49.9 million in 2010 with minorities and individuals on the lower end of the socioeconomic scale composing the majority of the uninsured (DeNavas-Walt et al., 2013). Subsequently, many of these same minorities and economically depressed individuals have a higher incidence of chronic disease (Grimmer-Somers, Guerin, Luker, Jones, & Zucco, 2009). The uninsured are more likely to rely on community safety net services for access to health care services, and as a result, free clinics have developed in many communities as a viable safety net health care source (Geller, Taylor, & Scott, 2004). While free clinics report that they provide chronic disease management services (Darnell, 2010), the extent and nature of those services both nationally and in the state of Ohio has not been studied and is not known.

The Patient Protection and Affordable Care Act enacted in 2010 provided access to health insurance for many of the estimated 49.9 million uninsured Americans (U.S.

Department of Health and Human Services, 2014). The Affordable Care Act, however, was not designed to be a universal health care system, and according to a report by the Congressional Budget Office, an estimated 31 million Americans will still be without health insurance after its implementation (Congressional Budget Office, 2013). For these uninsured Americans and undocumented immigrants, access to affordable quality health care still falls to community safety nets for which free clinics will still be a viable option.

Problem Statement

Ideally, the management of chronic disease in primary care medicine should incorporate a model that includes a team-based approach using evidence-based medicine, patient self-management, and current technology to achieve optimal clinical outcomes. However, uninsured individuals often are forced to rely on community safety net services for their health care. Free health clinics are considered within the circle of the community safety net. The level of reporting and accountability required of free clinics is often less than that of traditional health care providers due to their: (a) non-reliance on insurance for reimbursement; (b) providing charitable care; and (c) utilizing volunteer professional medical staff. Subsequently, free clinics have existed in relative obscurity in the health care provider market. Little is known regarding chronic disease management in free clinics despite the fact that they provide care to the population most affected by chronic disease. This study proposed to address the gap in knowledge by assessing the status of chronic disease management provided at free clinics and identifying the supports and barriers associated with fidelity to the CCM.

In their research on vulnerable populations, Stremikis et al. (2011) reported that this population is at higher risk for not having health insurance. The absence of health insurance has been shown to result in a poorer health status and increased risk for chronic disease; and those lacking health insurance are forced to rely on community safety net services such as free clinics for access to services (Stremikis et al., 2011).

Although free clinics serve a vital role in the community safety net for uninsured and underinsured individuals, little is known about the service delivery models being used for chronic disease management in these clinics. Most free clinics are held to a lower level of accountability for oversight, regulatory compliance, and accreditation (Health Resources and Services Administration, 2014; Weiss, 2006). This phenomenon is due in part to the fact that most free clinics do not bill insurance for care provided, and under the Federal Tort Claims Act, the federal government provides medical malpractice coverage to free clinics that meet the requirements (Health Resources and Services Administration, 2014; National Association of Free and Charitable Clinics, 2014a). The decreased level of accountability to outside agencies may potentially be influencing the decisions regarding the delivery care models being used at free clinics.

Many free clinics may still use a traditional primary care medical model by which the physician and patient have an isolated relationship. Under this type of model, the impetus for care is placed upon the physician and patients assume a passive role in their care. However, changes in the delivery of health care have shifted a larger burden of responsibility to patients to be an active participant in their medical care. Newer delivery service models like the CCM have evolved in health care, especially relating to chronic disease management. The CCM involves ancillary health care providers such as nurses, pharmacists, therapists, dieticians, and social workers as part of the patient’s care team. Other components incorporate community resources, personal accountability, information technology, and best practices or evidence-based medicine (Martin, 2007).

There are many possible factors contributing to why free clinics may not have adopted a more efficient and effective model in their management of patients with chronic disease. Darnell (2010) identified some possible factors including limited financial resources available to implement components of newer models. Free clinics rely heavily on charitable donations and volunteer staff to carry out operations. Shortages of volunteers or staff expertise may limit a clinic's availability to offer a wider range of services.

This study contributed to the body of knowledge needed to address this problem by examining: (a) the patient populations served by the clinics, (b) the size and scope of the clinics, (c) the personnel providing services, and (d) clinic resources. Identification of the supports present within free clinics with high fidelity to the CCM and barriers present in clinics with low fidelity to the CCM allows increased knowledge of service delivery models and operational change.

Purpose of the Study

The purpose of this sequential explanatory mixed methods study was to: (a) determine the level of fidelity by Ohio free clinics to the six key constructs of the CCM,

(b) define the correlational relationship between demographic variables (independent) and the Assessment of Chronic Illness Care (ACIC) survey scores (dependent), and (c) conduct a two-tiered design multiple case study series explaining the supports present in high ranking clinics and the barriers low ranking clinics experience.

The first phase addressed the quantitative aspect of the study. The goal of this phase was to identify the fidelity Ohio free clinics have to the six key constructs of the CCM in their provision of chronic disease management. This fidelity was determined by each clinic completing the ACIC survey (Appendix A). The survey consisted of six construct sections and one integration section for a total of seven sections. Each section varied from three to six components to be scored. Each component was scored on a Likert scale of 0-11. The higher the score for each component, the more compliant that component was to the CCM. An average for each section was calculated as well as an average of all seven sections to provide an overall average score per clinic, thus allowing a rank order to be established for each participating clinic. Additional demographic information was also collected (Appendices B and C). Key demographic variables common among all free clinics were used as independent variables to be correlated to the ACIC score (dependent variable) through multiple stepwise logistic regressions to predict which independent variables have the strongest likelihood to influence ACIC scores.

The second phase of the study took the three highest scoring clinics per total mean score and the three lowest scoring clinics per total mean score and conducted a two-tiered design multiple case study series. The purpose of this phase of the study was to identify the supports allowing clinics to adopt the key constructs of the CCM and identify barriers in clinics scoring low in fidelity to the key constructs.

Research Questions and Hypotheses

The quantitative research questions of this study were:

RQ1: Does the weekly average in hours of operation at Ohio free clinics significantly contribute to increased compliance with the CCM?

$H_0$1: The average in weekly hours of operation does not significantly predict compliance with the CCM at Ohio free clinics.

H_a1: The average in weekly hours of operation does significantly predict compliance with the CCM at Ohio free clinics.

RQ2: Does the size of the annual operating budgets of Ohio free clinics significantly contribute to increased compliance with the CCM?

$H_0$2: The size of the operating budget does not significantly predict compliance with the CCM at Ohio free clinics.

$H_\mathrm{a}2_\mathrm{A}$: The size of the operating budget does significantly predict compliance with the CCM at Ohio free clinics.

RQ3: Does the amount of electronic health record integration significantly contribute to increased compliance with the CCM at Ohio free clinics?

$H_0$3: Electronic health record integration does not significantly predict compliance with the CCM at Ohio free clinics.

H_a3: Electronic health record integration does significantly predict compliance with the CCM at Ohio free clinics.

The qualitative research questions for this study were:

RQ4: What supports are present at Ohio free clinics with high ACIC scores that allow them to have a greater fidelity to the CCM?

RQ5: What barriers exist that prevent Ohio free clinics with low ACIC scores from achieving higher ACIC scores?

Theoretical Foundation

The failure of traditional health care delivery systems to address the challenge of a rapidly growing chronic disease epidemic called for an alternative approach to chronic disease management. The concept of chronic disease management incorporates various models that either singularly or in concert with others aim to improve the health status of the chronically ill. Key elements of chronic disease management revolve around: (a) coordinated care among all care providers, (b) the use of evidence-based medicine, (c) patient role in self-management activities, and (d) outcome assessments (Cartwright-Smith, 2011).

According to Sackett, Rosenberg, Gray, Haynes, and Richardson (1995), evidence-based medicine has become the new normal in the delivery of health care services and interventions. Health care professionals and now policymakers are expected to adhere to proven methods and techniques. Evidence-based medicine is founded on providing care based on proven research outcomes. Evidence-based medicine helps minimize underuse, overuse, and misuse of interventions (Walshe & Rundall, 2001).

Within successful chronic disease management lies the key element of effective self-management. The relationship between a person's level of self-efficacy and his/her ability to perform self-management activities of the chronic disease are directly related. The need to fully assess the different dimensions of self-efficacy and tailor educational programs of self-management activities is recommended to achieve better outcomes of disease management (Marks & Allegrante, 2005).

Health provider team effectiveness, another key element of chronic disease management, is vital in making the transition from the traditional model of primary care medicine. The physician, while still the figurehead and ultimate decision maker in newer chronic disease management models, relinquishes many responsibilities to the health care team. Shortell et al. (2004) in their study on team effectiveness found three factors associated with positive outcomes: (a) focus on patient satisfaction, (b) presence of a team champion, and (c) physician involvement. Team effectiveness was also positively associated with the number and depth of changes made in efforts to improve chronic illness care.

Nature of the Study

According to Darnell (2010), there has been a lack of research and data on the operations of free clinics. Little empirical knowledge exists regarding their operations or outcomes. Darnell’s survey revealed 73 % of free clinics offer chronic disease management for their clients, but the nature and the extent of the services are not known.

The present mixed methods sequential explanatory study provided more in-depth information regarding the level of chronic disease management provided at Ohio free clinics. Further, the demographics and characteristics of free clinics that positively influence compliance or provide barriers to the CCM were studied. For the proposed study, clinics completed the ACIC survey. The scores derived from the survey served as the dependent variable. Results from the survey provided scores from the six construct sections and one integration section for a total of seven sections. An average sum for each of the seven sections was calculated. An average sum of all seven sections was calculated to provide an overall average sum per clinic, thus allowing a ranking to be established from the highest scoring clinic to the lowest scoring clinic. Demographic characteristics—hours of operation, annual operating budget, and electronic health record integration—served as independent variables. The independent variables were analyzed using descriptive statistics. A backwards-stepwise logistic regression was completed in an attempt to establish a prediction model for CCM compliance. The three highest scoring clinics from the ACIC mean scores and the three lowest scoring clinics were involved in a two-tiered design multiple case series. Qualitative analysis including triangulation and rich thick descriptions of the case studies aimed to explain the findings of the quantitative result through integrative analysis.

Creswell and Plano-Clark (2011) expressed support for the use of mixed methods sequential explanatory design in social and health related research. The mixed methods model provided not only quantification of chronic disease management service delivery but also rationale for implementation or lack thereof for the services.

The research methodology and instruments used to conduct the research are discussed in detail in Chapter 3.

Definitions

Chronic care model: A model of care designed to effectively manage chronic disease (Improving Chronic Illness Care, 2012).

Chronic disease: A condition that is slowly progressive, has a lengthy duration, and does not resolve itself (Institute of Medicine, 2012).

Community safety net: Providers who organize and deliver a significant level of health care and other related services to uninsured, Medicaid, and other vulnerable patients (Lewin & Altman, 2000).

Comorbidity: Two or more coexisting medical conditions or disease processes that are additional to an initial diagnosis (The Free Dictionary, 2012a).

Fidelity: The degree to which a particular program follows a well-defined set of interventions and procedures to help individuals achieve some desired goal (Bond, Evans, Saylers, Williams, & Kim, 2000).

HbA1c screening: A common blood test used to gauge how well an individual is managing his/her diabetes (Mayo Clinic, 2011).

Primary care medicine: The first contact in a given episode of illness that leads to a decision regarding a course of action to resolve the health problem. A physician often provides primary care medicine, but nurses also provide primary care functions (The Free Dictionary, 2012b).

Vulnerable populations: Low-income, uninsured, racial and ethnic minorities, rural and immigrant populations, and the under educated (Commonwealth Fund, 2012).

Uninsured: A person not covered by health insurance.

Operational Definitions of Research Variables

Annual operating budget: The dollar amount each Ohio Free Clinic has budgeted for the period of January 1st through December 31st that reflects all costs associated with operating the clinic.

Assessment of Chronic Illness Care: The Assessment of Chronic Illness Care, developed by the staff at Improving Chronic Illness Care (2012), is a 34-item Likert scale survey. The 34-item survey consisted of four parts representing seven categories. Free clinics were asked to self-assess the fidelity of their clinic to the standards of the CCM by scoring each item on a scale of 0-11. A score of zero represents no fidelity exists and a score of 11 means complete fidelity exists. Responses for each of the seven categories were totaled and divided by the number of items in that category to acquire a mean score. The mean scores of the seven categories were then totaled and divided by seven to achieve a total mean score.

Average hours of operation: The hours a clinic is open to direct patient care will be reported as a weekly average.

Electronic health record integration: Ohio free clinics scored themselves for computer based health care information technology they have integrated into the normal operations of the clinic. The variable was scored (0) for no computer based health care information technology being used. Seven additional questions addressed common information technology use common to health care operations. Clinics answered these questions Yes/No based on the use in their clinic. A summed total was obtained from how many questions were answered affirmatively (Appendix C).

Assumptions

The Assessment of Chronic Illness Care survey is designed to be completed either individually or with multiple person input. The following assumptions were proposed for this study.

1. It is assumed that the individual(s) who completed the survey and participated in the case series had sufficient knowledge of the governance and operations of the clinic.
2. It is assumed that the individual(s) who completed the survey scored the survey in a manner that truthfully reflected the governance and operations of the clinic.
3. It is assumed the individuals completing the survey had English reading and comprehension skills at a level sufficient to provide valid responses.

Scope and Delimitations

The purpose of this sequential explanatory mixed methods study was to: (a) determine the level of fidelity by Ohio free clinics to the six key constructs of the CCM; (b) define the correlational relationship between demographic variables and the ACIC scores; and (c) conduct a two-tiered design multiple case study series explaining the supports present in high ranking clinics and the barriers low ranking clinics experience. It was essential to have a high rate of participation among the Ohio free clinics.

The scope of generalization was limited due to the wide variation of services provided among free clinics statewide. The lack of standardization between clinics is due in part to the limited accreditation standards to which they are held. In addition, clinics tend to customize the services they offer to the needs of the community they serve. Standards for membership in the OAFC are broadly defined and do not specifically address delivery model clinical services. Differences in clients, mission, and purpose limited the generalization of outcomes beyond Ohio free clinics. However, these differences present opportunities for additional research in the future.

Limitations

One limitation to this study was the exclusion of free clinics in the state of Ohio that provide primarily mental health services or acute medical services. These clinics were not considered despite meeting the free clinic criteria set forth by the OAFC. Free clinics located in states other than Ohio were not considered due to differing criteria in determining free clinic status. There are 51 identified clinics in Ohio that met the inclusion criteria. All 51 were extended an invitation to participate in the study. This convenience sampling has inherent limitations in generalization and inference making to the entire population, and researcher bias tends to be a greater risk in convenience sampling and with small sample sizes (Fowler, 2009). Chapter 3 discusses these limitations in detail.

Significance

To date, there has been little research on free clinics serving the underinsured and uninsured in America. Only recently has there been research detailing the organizational characteristics, patients served, scope of services provided, staffing and volunteers, and revenue and expenses of operations (Darnell, 2010; Gertz et al., 2011). Research on clinical outcomes at free clinics is even more limited. While free clinics have grown in importance as community safety net providers due to the expanding numbers of uninsured, little is known as to the scope and quality of the services they provide to mainly at-risk populations. Darnell (2010) reported that of the responding free clinics in the nationwide survey, over 73% stated they provided chronic disease management to clients. The purpose of this study was to establish the degree of fidelity free clinics in Ohio have to the CCM. By determining the top and bottom ranked clinics, this study sought to identify the supports or barriers that exist to allow/prevent free clinics from achieving a high ranking. This research could contribute to the existing, albeit limited, body of research on free clinics and the role they serve in the health care delivery system.

The outcome information gained from this study could also serve as a springboard for future research.

Vulnerable populations comprise the majority of Americans who live without health insurance. This statistic has been steadily increasing for the past decade. The consequences of living without health insurance have been shown to be detrimental not only to the individual but also to the communities in which they live (Bahls, 2011). Health disparities persisting over time affect not only quality of life but also morbidity and ultimately mortality (Commonwealth Fund, 2012). Improving the scope and quality of services provided at free clinics to those experiencing chronic disease will move health care in the direction of reducing health disparities in at-risk populations.

The current study focused on the vulnerable populations that were uninsured. Vulnerable populations are more likely to experience one or more chronic disease(s) in their lifetime (Frohlich & Potvin, 2008). The lack of consistent and coordinated health services allows a more rapid progression of the disease process to occur. The uninsured face barriers to accessible, affordable, and quality health services and often rely on community safety net services, when available, for their health care. Free clinics, a community safety net resource, are one option that gives vulnerable populations access to health services.

The CCM has been shown to improve clinical outcomes of individuals experiencing chronic illness (Wagner et al., 2001). The six constructs of the model have interdependency within the model, and in the current study, fidelity to the constructs was measured using the ACIC survey. The main purpose of the survey was to provide organizations a feedback tool regarding compliance with the model. Adoption of the model provided free clinics in Ohio a framework by which to improve health services for the uninsured. The implications for social change from this research may improve the service delivery model for the uninsured receiving their health care at free clinics, resulting in an improvement not only to the health status of the individual but also the communities in which they live through reductions in disease, disability, and premature deaths.

Summary

Chapter 1 introduced the problem of chronic disease management at Ohio free clinics. The number of uninsured individuals relying on community safety nets for basic health care needs has grown. Free clinics are one provider in the safety net umbrella. At-risk populations are frequent users of free clinics and more likely to have a chronic disease. The scope and depth of chronic disease management services varied among free clinics. The intent of this study was to add to the limited empirical knowledge that existed regarding free clinics in Ohio. The knowledge gained from this study could prove useful in changing the service delivery model regarding chronic disease and ultimately improve the health care status of not only the individual but also the communities in which they live through reductions in disease, disability, and premature deaths.

Chapter 2 reviews the literature that was relevant to this research study. This review presents literature that provided background and understanding of the uninsured, vulnerable populations, chronic disease, the CCM, community safety nets, and free clinics.

Chapter 3 describes the methods and instruments used for examining chronic disease management at Ohio free clinics. The chapter also discusses data analysis approaches.

Chapter 4 shows the results of data gathered from the study and results of the analytic tests used on the data.

Chapter 5 provides a summary interpretation of all the data. The findings are discussed as they relate to potential social implications and change. Lastly, chapter 5 presents opportunities for future research.

Chapter 2: Literature Review

Introduction

Ideally, the management of chronic disease in primary care medicine should incorporate a model that includes a team-based approach using evidence-based medicine, patient self-management, and current technology to achieve optimal clinical outcomes. However, uninsured individuals often are forced to rely on community safety net services for their health care. Free health clinics are considered within the circle of the community safety net. The level of reporting and accountability required of free clinics is often less than that of traditional health care providers due to free clinics not billing insurance for reimbursement, providing charitable care, and utilizing volunteer professional medical staff. Subsequently, free clinics have existed in relative obscurity in the health care provider market. Little is known regarding chronic disease management in free clinics despite providing care to the population most affected by chronic disease. This study proposed to address the gap in knowledge by assessing the status of chronic disease management provided at free clinics and identifying the supports and barriers associated with fidelity to the CCM.

The purpose of this sequential explanatory mixed methods study was to: (a) determine the level of fidelity by Ohio free clinics to the six key constructs of the CCM, (b) define the correlational relationship between demographic variables (independent) and the Assessment of Chronic Illness Care (ACIC) survey scores (dependent), and (c) conduct a two-tiered design multiple case study explaining the supports present in high ranking clinics and the barriers low ranking clinics experience.

This problem affects the uninsured and socioeconomically disadvantaged populations who are more likely to utilize a free clinic. The uninsured and vulnerable populations have demonstrated a higher incidence of chronic diseases such as diabetes, cardiovascular disease, and obesity (Bahls, 2011; Hoffman & Paradise, 2008; Kirby & Kaneda, 2010). Some possible factors limiting implementation of more progressive chronic care management at free clinics may include limited financial resources, lack of appropriate personnel, limited technology to create disease registries and track clinical outcomes, and few community collaborators.

The review of the literature began with a comprehensive view of chronic disease. I provide a working definition of the broad concept of chronic disease as well as a description of the prevalence of chronic disease in the United States and the state of Ohio. In addition, I present the impact of chronic disease on the U.S. health system. I explore risk factors and causes of chronic disease and the cost of treating chronic disease. Next, I present the evolution of chronic disease management and describe the six principles of the CCM. I examine the relationship of chronic disease to health insurance with an analysis of the uninsured in the United States and Ohio. Finally, I discuss accesses to health services for individuals with chronic disease with a focus on free clinics.

This chapter is organized into five sections. The first section provides an introduction to the chapter. I restate the problem and the purpose and present a synopsis of current literature connected to the problem. The second section identifies the databases, search engines, and search terms I used. I also address the scope and type of literature searched and used. In the third section, I address the theoretical foundations of the study. Included are the major propositions and the rationale for their use. The fourth section reviews the literature related to the key variables and concepts of the study. The final section provides a summary and conclusion to the chapter.

Literature Search Strategy

I used a wide range of strategies to review the literature. Search strategies included EBSCO, PubMed, ProQuest, and Sage databases. A search of governmental agencies included the Department of Health and Human Services, U.S. Census Bureau, Centers for Disease Control and Prevention, and Ohio Department of Health. The majority of articles, information, and data were retrieved from the Walden University Library, Youngstown State University Library, and Internet search engines including Google Scholar. The scope of the literature search focused on the past six years (2009-2015) with an additional focus on seminal literature on the evolution of chronic disease management and the development of the CCM.

Key search terms included *chronic disease*, *chronic disease management, chronic care model, community safety net, evidence-based medicine, free clinics, health disparities, patient self-management, uninsured,* and *vulnerable populations*.

A review of the literature revealed a scarcity of peer-reviewed information regarding free clinics. Only one published article exists that addresses chronic disease management and free clinics. I therefore relied on information about chronic disease management that existed in traditional health care settings. There is no peer-reviewed information addressing the implementation of the CCM in the free clinic setting. The lack of knowledge about free clinics further substantiated the need for additional research in this area.

Theoretical Foundation

Dentzer, Editor-In-Chief of the highly respected *Health Affairs Journal*, wrote in an introductory op-ed to the January/February 2009 journal dedicated to chronic disease that "at the heart of the problem is lack of care coordination" (Dentzer, 2009). The inability to coordinate care manifests itself frequently in the American health care delivery system. The theory of chronic disease management is a prime example of the failure to coordinate efforts effectively as a proven, evidence-based model exists and yet the American health care system has spent the last fifteen years struggling with its adoption. At the policy level, two of the main perils of the system are access and costs. The 2010 U.S. Census data reflects that over 49.9 million Americans are without health insurance (DeNavas-Walt et al., 2013). Without the prerequisite of health insurance, either government funded or commercially provided, the provision of health care is fragmented and often unaffordable to the uninsured.

At the organization and provider level, the American health care system has been slow and resistant to adapt to the unique medical and social needs of those with chronic disease. The origin of the chronic disease management theory began with the Robert

Wood Johnson Foundation. The long-time pioneer in funding research to improve chronic illness care began funding projects as early as 1979 (Robert Wood Johnson Foundation (2011). The Chronic Disease Care Program, a funded initiative in 1979, was one of the first aimed at decreasing hospitalizations and inpatient care for chronically ill patients by improving the effectiveness of systems and processes used by hospitals and physicians (Robert Wood Johnson Foundation (2011). Between the years 1979-1999, the Robert Wood Johnson Foundation funded, collaborated, and assisted in numerous programs and projects targeting improvements in care for the chronically ill. Retrospectively, these programs used a shotgun approach to identify the needs of the chronically ill and the effectiveness of interventions (Robert Wood Johnson Foundation (2011). While these programs were producing useful information, little transformation in the national delivery system occurred (Improving Chronic Illness Care, 2012).

The sum of the years of research identified two main needs: the need for better system integration and the need for increased coordination of care. In 1992, the Robert Wood Johnson Foundation funded two national programs that effectively began to change the landscape in chronic illness care. The Chronic Care Initiatives in HMOs and Building Health Systems for People with Chronic Illness addressed the two needs through a series of projects that began producing results and outcomes that garnered national attention (Robert Woods Johnson Foundation, 2011).

The Chronic Care Initiatives in HMO’s project involved the Group Health Cooperative of Puget Sound, Washington. This Seattle-based nonprofit health care system was charged with creating a new model for the delivery of chronic care. Under the direction of Ed Wagner, M.D., the research team began detailing what they knew did not work. The Puget Sound Collaborative research presented constructive criticism of the current medical model, the use of health care personnel, and the lack of reliance on self-management and community resources.

The role of primary medicine had historically been to diagnose and treat acute or urgent problems. Diagnosis occurred through a systematic approach to differentiating illnesses and the use of diagnostic tests. Treatment consisted of either relieving symptoms or providing an intervention that cured the illness, disease, or problem. This process was provided in the typical patient-doctor visit relationship and was not intended to be ongoing and long term (Wagner et al., 1996). Reimbursement for this type of care was payment by fee for service.

The ongoing needs and long-term care of patients with chronic disease were not well met by primary care medicine at the time. Doctors educated and trained to heal and cure the sick struggled to find satisfaction in treating the chronically ill. Insurance companies balked at the ongoing expenses incurred by the chronically ill. The systems and processes in place were not meeting the medical, social, and psychological needs of the chronically ill patient (Wagner et al., 1996). Other shortcomings identified included failure of the office staff to coordinate the ongoing needs of the chronically ill and failure to organize patient information. Follow-up care, referrals, and test results were a few of the many needs that chronically ill patients had unlike the acutely ill patient. The volume of medical records of the chronically ill patient made for poor record keeping, organization, and transfer of information as well as frequent errors in care continuity and treatment (Wagner et al., 1996).

Wagner and his research team also focused on the growing body of research being developed on chronic disease. The identification of integration and coordination of care as significant issues for individuals with chronic disease was not a new phenomenon. Isolated and fragmented theoretical concepts of chronic disease management as we know it today began appearing in the research literature in the late 1980s and early 1990s. Concepts like self-management (Clark et al., 1991), patient education and psychosocial support (Sobel, 1995), and doctor compliance with recommended guidelines (Stockwell, Madhavan, Cohen, Gibson, & Alderman, 1994) were identified as problematic to the overall improvement of individuals with chronic disease.

This growing assortment of research projects resulted in a larger collection of evidence-based medicine. New knowledge of specific interventions that resulted in patient improvement and positive outcomes were seen as a beginning to the standardized care of chronic conditions. New approaches to address the shortcomings of the primary medicine model focused on the use of ancillary health care providers such as nurses, dieticians, pharmacists, and therapists to provide education, support, and care within the scope of their expertise, which was missing in the traditional medical model (Wagner et al., 1996).

The major propositions of the theory that evolved from Wagner and the Group Health Cooperative for practice redesign consisted of five main elements:

1. The use of explicit plans and protocols.
2. The reorganization of practice to meet the needs of patients who require additional time, resources, and follow-up.
3. Systematic attention to the informational, educational, and behavioral needs of the patient.
4. Ready access to necessary expertise.
5. Supportive information systems.

Wagner and the Group Health Cooperative had designed the blueprint for future chronic illness care, a model they named the Chronic care model (CCM). They identified the pertinent subcomponents of chronic disease care through analysis of past research studies to determine effectiveness. More importantly, they acknowledged the role of the interdependency of these components in the overall management of the disease process; in other words, the whole was greater than the sum of its parts. The task then became how to disseminate and implement the plan (Wagner et al., 1996).

Supported by RWJF, a new national program referred to as Improving Chronic Illness Care began in 1998 with the purpose of implementing the CCM. The Improving Chronic Illness Care program still exists today; however, the core objectives have evolved over time to reflect present health care challenges to chronic illness. Wagner served as the program director and was supported by a national advisory committee comprised of sixteen leaders in the health care industry. An early initiative of the Improving Chronic Illness Care was to collaborate with the Institute for Health Care Improvement. The Institute for Health Care Improvement (IHCI) was a Massachusetts-based nonprofit whose mission focused on health quality improvement. The IHCI implemented a series of national and subsequent regional training programs to instruct, educate, and advise health organizations in altering their processes and outcomes in the care provided to the chronically ill. During this same time, collaborates provided training to implement the CCM into mainstream medicine; the Robert Wood Johnson Foundation funded nineteen major research projects exploring the knowledge gaps and barriers to implementation of the CCM model (Robert Wood Johnson Foundation, 2011).

The CCM was comprised of six constructs that identified key activities and strategies that, when used in conjunction with each other could produce the optimal quality in care for chronic disease management. The model has not been a static concept over time but rather a dynamic and fluid evolution reflecting improvements validated by research and adaptations to the health care environment. The six principle constructs of the CCM are:

- The Health System
- Delivery System Design
- Decision Support
- Clinical Information Systems
- Self-Management Support

- The Community

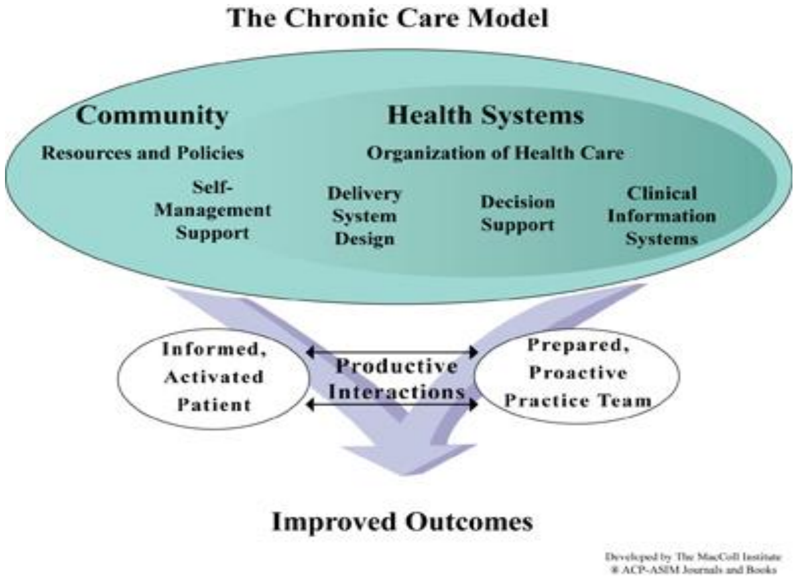

Figure 1. The chronic care model. Wagner E. H., 1998, Chronic Disease Management: What Will It Take to Improve Care for Chronic Illness? *Effective Clinical Practice*, *1,* p. 3.
"Developed by The MacColl Institute, © ACP-ASIM Journals and Books, reprinted with permission from ACP-ASIM Journals and Books" (Appendix H).

Implementation of the CCM has had mixed results over time. The complexity of the model is often seen as overwhelming to health care organizations to adopt as a whole, resulting in competing priorities, lack of organizational readiness for change, and commitment (motivation) to change (Hroscikoski et al., 2006; Lemmens, Strating, Huijsman & Nieboer, 2009). Insufficient resources are often cited as barriers to the implementation of the CCM. These barriers may be financial, human, or structural in nature. Other barriers to implementation cited in the literature involve political decisions and organizational attributes regarding culture, management, motivation, and climate (Lauvergeon, Burnand, & Peytremann-Bridevaux, 2012; Pearson et al., 2005).

Successful implementation of the CCM is often attributed to patients' being actively involved in their own care, staff understanding and use of clinical guidelines, and adequate resources for staffing and technology. The flexibility for changes in staff roles and clinical management were identified as key components to successful implementation (Lemay, Beagan, Ferguson, & Hargraves, 2010; Leykum et al., 2011; Nutting et al., 2011). Health care organizations that were required to report quality measures to external compliance organizations were more likely to use care management processes than those not obligated to report (Rittenhouse et al., 2010).

Outcomes of the CCM across time have positively reflected the impact the model has had on improving the health status of those with chronic disease. Stellefson, Dipnarine, and Stopka (2013) conducted a systematic review of 16 studies between the years 1999-2011. Nine of the studies were randomized controlled trials that included primary care practices and private practices. The evidence supported the CCM as effective in managing chronic disease. These results are consistent with previous studies evaluating the effectiveness of the CCM. Outcome improvements included increased patient knowledge, medication compliance, decreased hospitalizations, increased self-management, increased clinical outcomes, and improved quality of life (Coleman, Austin, Brach, & Wagner, 2009; Hung et al., 2008). One element for which the CCM has not shown evidence of positively effecting change is the ability to decrease health care expenditures. Results of studies evaluating cost effectiveness of the model have been mixed, citing health care inflation and reimbursement as factors influencing outcomes (de Bruin, Heijink, Lemmens, Struijs, and Baan, 2011).

Imbedded within the six constructs are theories that build and support the effectiveness of the CCM. The construct of decision support is based on the theory of evidence-based medicine. The landmark report *Crossing the Quality Chasm* by the Institute of Medicine (2001) brought to light the gap in quality between the care patients received and the care they should have received. The report specifically addressed the growing amount of evidence in the medical sciences and the difficulty translating that evidence into medical practice. The gap in translation has led to wide variations in how care is provided. The net result is disparities in both the quality of care and the cost of health care services. The Institute of Medicine report further stated that the delay between research discoveries and their incorporation into everyday practice ranged from 15 to 20 years. However, the rapid adoption of computer technology and the internet is quickly closing this time gap.

The concept of evidence-based medicine (EBM), while not new, has gained a stronger foothold in American medical practice. The use of sound clinical research that produces valid and reliable results is the basis for evidence-based medicine. The definition put forth by Sackett et al. (1996) and colleagues is one of the most accepted in the medical world today:

> Evidence based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients.

> The practice of evidence based medicine means integrating individual clinical expertise with the best available clinical evidence from systematic research. (pp. 71-72)

The task of determining when scientific evidence is acceptable to become clinical guidelines and protocols or be adopted into policy lies with many groups in the United States and throughout the world. The principle U.S. organization responsible for evidence-based medicine is the Agency for Health Care Research and Quality (AHRQ), a division of the U.S. Department of Health and Human Services. The agency currently funds fourteen evidence-based practice centers, as well as two specialized evidence-based research programs: an outcomes and effectiveness program and the U.S. Preventive Services Task Force (Agency for Health Care Research and Quality, 2012). While the AHRQ strongly encourages the use of EBM through the adoption and use of evidence-based disease process guidelines, the medical community at large is not obligated to adopt or use any or all of the guidelines.

Determining whether specific medical science research is worthy of becoming evidence-based medicine is a process whereby experts in medicine and research analyze existing research studies. Statistical analysis using meta-analysis and systematic reviews are two common practices to determine if the research is worthy of evidence-based medicine.

The dissemination and adoption of evidence-based guidelines in clinical practice has flourished tremendously with the growth of the internet. The proliferation of medical journals converting to electronic subscriptions, web-based search engines of scholarly work and social media outlets have all contributed to the evidence-based medicine movement (Spigel, 2008).

The Cochrane Library is a collection of systematic reviews of medical studies. This private international organization has over 12,000 members and has produced over 1,000 clinical practice guidelines in addition to its health economic evaluations database (Spigel, 2008). This electronic library is accessible by subscription only (Spigel, 2008).

The trends in the use of medical care for the treatment of chronic care have changed significantly over the past two decades. The research of Decker, Schappert, and Sisk (2009) compared ambulatory care visits from 1995-1996 to 2005-2006, and hospital discharges from the years 1996 and 2006 for eight major chronic conditions. The results showed a substantial increase of 21% in the ambulatory visits while hospital discharges fell over 9%. The authors speculated that this shifting trend in care was due to numerous factors, including evidence-based medicine, which over time has shown that care provided in an outpatient setting was more effective and efficient in a lower cost environment.

The surge in volume of chronic care cases was not sustainable for an inpatient model mainly due to the high cost of institutional care. However, the rapid influx to the outpatient model equally stressed a medical system that was short of primary care physicians and had limited technology capacity and a less than current understanding of evidence-based medicine regarding chronic disease (Margolius & Bodenheimer, 2010).

Five changes are needed in primary care to better manage the influx of patients requiring chronic care management: (1) a shift from the traditional patient-physician episodic care model to a population health management model, (2) diversification and expansion of the physician’s team members to more efficiently and effectively manage the various needs of chronic illness, (3) appropriate stratification of patients into preventative, acute, and chronic service models with appropriate team members delivering services based on need, (4) the role of the primary care physician evolving from sole care provider to delegator of care, thereby freeing time for patients who need a physician’s expert care, and finally (5) changing the reimbursement model currently being used in the provision of outpatient services (fee for service) that is incongruous with the innovations in EBM care needed for chronic disease management. The fee for service model, which rewards quantity over quality, does not adequately address services provided by non-physicians, group encounters, and daily/weekly encounters via telephone, e-mail, or social media venues (Margolius & Bodenheimer, 2010).

These challenges will only be accentuated with the growing shortage of primary care practitioners. While most medical school students are seeking higher status and income in specialization fields, the number of prospective graduates entering primary care is shrinking at an alarming rate. Hauer et al. (2008) conducted a survey of fourth-year medical students at eleven medical schools in the United States that revealed that only 7% of those students chose primary care as their career choice. As outlined above, without process redesign and incorporation of evidence-based medicine changes into practice, the growing number of individuals with chronic disease will soon face issues with accessibility regardless of insurance status.

Despite the overwhelming growth in evidence-based medicine over the past decade and access more readily available via the internet, electronic journals, and web pages, some physicians are slow to embrace evidenced-based medicine in their practice. One must ask why evidence-based medicine is not more universally accepted. A number of elements have influenced physicians over the years to raise a skeptical eye towards evidence-based medicine. Spigel (2008) noted that not all medicine is grounded in scientific research. Many cultures practice some form of holistic health that encompasses many beliefs and interventions that lack scientific evidence. Many older, trained physicians tend to practice in primary care and have little training and understanding of formal research and statistics. Further, he noted medical school education during this era was based on case reports and anecdotal information and not double blinded, randomized control studies that are the gold standard today. Lack of awareness was a main impediment to the adoption of evidence-based medicine prior to the internet era of the last decade. Hard copy journals and infrequent continuing education were the prime distribution routes of evidence-based medicine. Skeptical physicians have long distrusted research due to the agendas of the funding agencies conducting the research. The pharmaceutical industry has a long history of manipulating research outcomes for their products in order to gain Federal Drug Administration approval and ultimately millions or billions of dollars in profit on a particular drug (Spigel, 2008). Finally, health care reimbursement has not reflected the many changes proposed by evidence-based medicine and physicians are reluctant to provide services that are not reimbursable (Spigel, 2008).

The construct of self-management support is rooted in the theory of self-management. A significant paradigm shift has occurred in patient education with the growth of chronic disease management (Sobel, 1995). Traditional patient education models put the physician or health care provider as the expert possessing the knowledge. In this relationship, the health care provider decides what and how much information is provided to the patient with the expectation that the patient will follow all directions and instructions. The patient in this relationship is neither empowered nor engaged to take an active role in determining their health status. The patient is the passive recipient of the provider’s decision-making, goals, and behavior modification solutions. The paradigm shift centered around two key components in the patient-provider relationship. Collaborative care consists of the patient and the provider working together as one in making health care decisions; self-management education engages the patient in education about managing the disease and empowers the patient to develop problem solving skills about their own health status (Bodenheimer, Lorig, Holman, & Grumbach, 2002).

The shift in focus and responsibility evolved through the need for patients with chronic illness to become more engaged in their own health status and less reliant on the health care system to solve their problems. A person with chronic illness has many needs that extend beyond the medical realm. Tasks such as medication management or monitoring body functions of blood pressure, blood glucose levels, and dietary intake remain vital to good health. However, persons with chronic illness require self-management skills in adapting to new limitations and roles in life as a result of their disease process. Psychosocial issues of depression, anxiety, and fear are common to both the newly diagnosed patient as well as long-term survivors (Bodenheimer et al., 2002).

The seminal work of Gruman and VonKorff (1999) with the CCM set forth four major propositions for successful patient self-management.

1. Collaborative problem solving for patient-defined problems and medical problems.
2. Identification of attainable goals, planning, training, and action plans to achieve the goals as defined by the patient's context.
3. The provision of ongoing training and support services that address the spectrum of patient needs.
4. Provision of follow-up care that monitors health needs, identifies potential risks, and reinforces adherence and compliance.

Primary care medical practices that lack the adoption of CCM principles have struggled to provide the needed elements of effective self-management that is patient-centered.

In 2006, the American Diabetes Association and the American Association of Diabetes Educators formed a joint taskforce to update national standards for diabetes education. The original standards, established in 2000, were primarily prescriptive and instructive in nature. The new standards were based on a set of guiding principles that encompassed elements of self-management set forth in the CCM. Patient empowering, comprehensive in scope, incorporating behavior modification and psychosocial issues, and contextual to culture and age were principles built into the national standards. The standards were built around three frameworks: structure, process, and outcomes. Each standard was supported by evidence from past research that was deemed credible (Funnell et al., 2009). This process for developing standards in self-management for one of the largest chronic illnesses worldwide raised the expectation of care to a new level.

The evolution of self-management over the past decade has revolved around particular themes. Raising health literacy either individually or within the population is necessary in order for patients to be active participants in their care. The ability to seek, understand, and apply health information is essential to engage patients. The need to continue building an evidence base in self-management literature is another theme. Determining effectiveness of interventions, delivery modes, and outcomes is essential to successful management. The complexity of conducting research on self-management is often complicated by the many variables patients bring to research. Education levels, language deficits, socioeconomic status, and comorbidities are a few examples of variables that complicate the research of effectiveness (Glasgow, Jeon, Kraus, & Pearce-Brown, 2008; Jordan, Briggs, Brand, & Osborne, 2008).

Funnell (2010), in an ongoing study of diabetes self-management, acknowledged the need for basic education to initiate behavioral changes. Funnell believes that additional education and supports are required in order to sustain and progress behavioral change. Funnell researched effective behavioral interventions through analysis of multiple research studies and meta-analysis of diabetic literature. Behavioral strategies such as goal setting, problem solving, social support, communication skills, and exploration of emotions have proven to be effective in diabetic self-management. The use of peer groups or peer-based programs is another behavioral strategy that has grown in popularity due to limited education resources, excess patients requiring self-management education and skills, and a growing body of literature supporting its efficacy. In their research of self-management interventions, Glasgow, Orleans, Wagner, Curry, and Solberg (2001) found that when applied to lifestyle modifications, the principles were successful in increasing changes in prevention measures.

The rapid development of self-management educational programs over the past decade resulted in a wide range of variability among programs. From a research perspective, these variations created difficulty in establishing generalizations across populations. Another approach was to create generic self-management programs, but again, researchers found this approach proved less effective with select age, gender, and cultural groups. Jordon and Osbourne (2006) found that support and promotion by primary care providers was crucial to patient success in developing self-management skills. Lack of endorsement is often attributed to limited evidence of effectiveness for a particular population. Self-management programs are often limited to people of lower socioeconomic status and education as well as men due to access constraints.

While access is one impediment to self-management programs, attrition is another problem self-management programs regularly encounter. Gucciardi, DeMelo, Offenheim, and Stewart (2008) conducted 267 telephone interviews of individuals who had attended a diabetes education program. The attrition rate of those interviewed was 44%. The primary reasons given for the high attrition rate were conflicts with their work schedule and the program’s schedule, the age of the clients, patients’ sense that their knowledge and skills were sufficient, and travel distance. The authors concluded that to decrease attrition, programs would need to implement a range of strategies focusing on accessibility, communication, and improved relationships with primary care providers.

Two popular adaptations to the accessibility and attrition limitations of self-management have been the use of group medical visits and the use of the internet for education and training of individuals with chronic illness. Greer and Hill (2009) studied the use of group visits with metabolic syndrome patients. Their testing consisted of pre- and post-knowledge-based tests as well as tracking physical performance measures through the duration of the program. Results of their research showed this model of intervention created strong peer support. The group model provided encouragement amongst the participants, accountability expectations, and continuity. Outcomes related to behavioral health changes were found to be statistically significant at ($p = .0466$).

Lorig, Ritter, Laurent, and Plant (2008) studied a cohort of arthritic patients using the Arthritis Self-Management Program via an internet based delivery mode. This randomized trial separated 855 participants into two groups: an intervention group and a usual care group. Measures included six health status variables, four health behaviors, and five utilization variables. Patient follow-ups were conducted at six months and at one year from completing the program. Results indicated that the intervention group at one year had improved in four of the six-health status variables. Measures of health behaviors and utilization variables showed no significant differences. The internet proved an effective tool for providing an intervention with carry over.

Literature Review Related to Key Variables and Concepts

In this next section, key variables and concepts are divided into five sections for the literature review: section one reviews the constructs of the CCM; section two reviews chronic disease; section three reviews literature on the uninsured; section four reviews free clinics; and section five reviews research design, methods, and data analysis related to this study.

The delivery system design construct was meant to define roles and tasks of team members, provide case management services, incorporate technology to assist in identifying disease registries, plan and schedule regular follow-ups, and organize patient medical records (Improving Chronic Illness Care, 2012). The initial excitement the CCM generated and the influx of grant money to validate the benefits of the CCM provided a wealth of research studies. Early results from organizations initiating the CCM showed mixed results. Common themes evolved among health organizations attempting to implement the CCM. Significantly noted were: changing culture, limited resources to fund required technology changes, additional personnel required for team processes, limited resources for patient education and self-management, and reimbursement not reflective of services provided (Bodenheimer et al., 2004; Oswald, 2001; Wagner et al., 1999).

The structure of the health organization greatly influenced their success in modeling the CCM. Large physician organizations, especially those operating within a HMO, were more likely to have success implementing the various subcomponents. These organizations had more financial resources, were already computer equipped and integrated, and typically had a wider representation of the workforce necessary for case management teams (Wagner et al., 1999). Independent practice associations, which represent solo or small physician practice groups, experienced greater difficulty implementing the CCM. They argued that the CCM benefitted hospitals and insurance companies more than physician providers due to the significant cost savings for reduced hospitalizations. The insurance companies' reluctance to change reimbursement to more adequately reflect the resources being extended in the CCM by physician groups led to active resistance by some providers (Oswald, 2001).

While not overwhelmingly positive, these early outcomes reflecting health status, cost, and patient satisfaction were productive enough for the CCM to gain integration in the national health care delivery picture. Clinical outcomes supported by systematic reviews (Renders et al., 2001) reinforced the movement towards multifaceted interventions with enhanced patient education.

An early dichotomy in the provision of chronic illness care had been identified (Wagner et al., 1999). At the patient care level, outcome indicators reflected that the CCM was effective in improving clinical benchmarks. At the provider and organizational level, policy and processes were not properly aligned to allow maximal benefit from chronic disease management. It did not take long for the payers of health care, i.e. the insurance companies, to create their own product to address chronic disease management. The number of disease management companies grew exponentially beginning in 1997. Revenues reported in 1997 were $85 million and grew to over $600 million by 2002 (Foote, 2003). Unlike the CCM, disease management companies provided many similar services the CCM did without the direct involvement of the physician. Contracted by insurers, these disease management companies excelled where medical groups struggled. They employed innovative technology systems that allowed patient modeling for chronic disease, efficient patient processes for scheduling, patient outcome results, and better organization. Lastly, they were able to employ specially trained health professionals to provide education and assistance to patients. Their business model was to provide services via telephone and the internet. While this model grew in popularity, it was not without weaknesses also. The impersonal lack of face-to-face interaction and relationships led to decreased compliance and adherence to treatment protocols and interventions (Casalino, 2005).

Of the six constructs of the CCM, changing the health system in regards to its culture, organization, mission, and values is often the most challenging. Cultural change by nature does not happen easily even when faced with poor outcomes. The American health care delivery system is a prime example of this phenomenon. Patients with chronic disease comprise approximately half of the population and consume a disproportionate share of resources and health care spending. In their study of chronically ill patients in the United States and seven other countries, Schoen, Osborn, How, Doty, and Peugh (2008) found that the United States had the highest percentage of patients reporting trouble accessing care due to cost, problems with coordination, and experiences with medical errors when compared to patients from seven other countries. These results were consistent with their 2010 results of the U.S. health care system's performance compared to the same seven international countries.

In the five dimensions of health care studied—quality, access, efficiency, equity, and long healthy productive lives—the United States ranked last or next to last in every one. Overall, the United States ranked last in the five dimensions, as it has since 2004 (Davis, Schoen, & Stremikis, 2010). The United States earned these results while spending over $7,200 per capita, more than double that of any other country in the study. This spending represents over 16% of the U.S. gross domestic product, a number most economists believe is unsustainable (Davis, Schoen, & Stremikis, 2010).

These quality and coordination problems have been consistent in the American health system for an extended period. The issue at hand is why the system has not changed. Rattigan (2012) attributes the poor outcomes achieved by the U.S. health system to a misalignment of interests. The coexistence of government and commercially funded health coverage creates an imbalance of nonprofit and for-profit interests. Physicians resent insurance company attempts to control the prescription of medicine and a fee for service reimbursement system that rewards provider inefficiency. The CCM, on the other hand, aspires to have a health system whereby the mission and philosophy are present and visible throughout the organization from top executives to frontline workers. The organization must embrace efficiency while achieving comprehensiveness of care in an environment that strives for quality. The ability to collaborate and coordinate care with other organizations and providers is essential in achieving better outcomes (Improving Chronic Illness Care, 2012).

The main construct of the clinical information systems principle at the time the CCM was being developed was to use computer technology to organize patient information, thereby allowing more coordinated care. Patient registries or databases were one such tool recommended to collect and organize data on specific patient populations. Research has shown that the use of patient registries has improved outcomes with various chronic diseases (Glasgow et al., 2001; Schmittdiel, Shortell, Rundall, Bodenheimer, & Selby, 2006).

Patient registries organized data to assist organizations in redesigning how care was to be delivered in the CCM. Patient registries were able to track key indicators of care such as HbA1c results for diabetics or provide reminders of scheduled preventative tests and screenings. Registries also had valuable scheduling components such as tracking missed appointments. The ability of patient registries to transform health care to a proactive model in a way that influenced outcomes that are more positive was the intent of the clinical information systems principle (Ortiz, 2006).

A key component of chronic disease management is compliance with evidence-based guidelines. Registries provided clinicians with an organized and visual report of compliance, benchmarks, and outcomes on an individual patient basis or for a disease population as a whole. The ability to assess care delivery and care coordination was enhanced when the registry was rooted in the daily operations of the organization. The decision of what information to collect, how and who would collect the information, how to create user friendly process designs, and what outcomes were to be tracked were vital to successful use of the tool (McEvoy & Laxade, 2008; Nutting et al., 2007).

The concept of evidence-based medicine has been slow to be embraced and embedded into clinical practice due to a variety of issues. Likewise, not all health care providers have adopted the use of patient registries into clinical practice. Community safety net organizations, the providers of care to the majority of uninsured and underinsured in our country, have been one sector of the health care provider network that has been slow to adopt the use of registries. The national and state networks of free clinics fall under the umbrella of community safety net organizations. The uninsured and underinsured are comprised of a disproportionate share of both racial and ethnic minorities. These minorities over time have experienced increased disparities in health outcomes. The work of Glasgow et al. (2001) and Schmittdiel et al. (2006) has shown improved outcomes with the use of patient registries, which raises the question of why the providers of the most vulnerable populations have not embraced the tool that will support improved care delivery and enhanced care coordination and ultimately decrease health disparities. Hanratty et al. (2008) identified barriers potentially prohibiting community safety net organizations from developing registries: (a) poor financial resources, (b) poor information technology resources, (c) inconsistent client base due to high turnover of patients, and (d) decreased financial incentives for increased health outcomes.

Increased electronic and digital technology advances since the inception of the CCM have allowed for greater integration of technology into clinical information systems. Using data from a national survey of all medical groups and independent practice associations with 20 or more physicians in the United States during 2006-2007, Robinson et al. (2009) found higher uses of clinical information technology in organizations that had regular external auditing for reimbursement and those required to provide public reporting. Organizations conducting quality assurance initiatives also had higher integration into clinical information technology. The authors identified 19 individual information technology capabilities and medical record functions. Larger medical groups consistently had higher compliance than smaller independent practice associations in most individual categories. When viewing the 19 functions as a whole, the larger medical groups offered a greater percentage of the 19 functions to their physicians than the independent practice associations did for their physicians. These findings were consistent with the findings of DesRoches et al. (2009), who surveyed individual physicians regarding their use of clinical information technology. Once again, physicians in large practices were more likely to have access to basic electronic functions when compared to physicians in solo practices.

The evidence is clear that small and solo physician practices so far have been slow to embrace clinical information technology due to resource constraints, a lack of incentives, and unclear benefits to their practice. Coleman, Austin, Brach, and Wagner (2009) advocate providing financial incentives and support services for quality improvements to small practices to offset the initial cost of implementing technology changes. Robinson et al. (2009) concluded that economic incentives drive the acceptance and use of information technology. The benefits are not the reduction of paper but the reorganization of practice, incorporation of evidence-based medicine, expanded capabilities to interact with patients, and potential reimbursement incentives.

The expansion of digital information technology is not just limited to physician practices. The constant and continual expansion of web-based interactive technology is growing at such a rapid rate that knowledge and understanding of all the new applications and programs is not feasible. Clinical information technology began as a means to organize data, track disease populations, and coordinate care. Over time, technology expanded access to evidence-based medicine and increased communication methods with patients.

Technology is now advancing to a stage of dynamic interaction between two parties. Real-time interaction and exchange of information and data between two parties is the next frontier in the use of clinical information technology. Real-time support systems, data submission portals, web-based educational programs, and decision management programs are all emerging to support both providers and patients with current, accurate, and timely information (Siminerio, 2010).

An innovative program being adopted by the Veterans Health Administration is the use of remote patient management (RPM). The program was developed to reduce cost, decrease emergency room visits and hospital admissions, and support the patient in self-management of their disease process. Early attempts to develop this technology were slow due to limited availability of the technology, loss of locus of control on the provider end, and lack of trust in patient compliance. However, results have shown that patients using RPM have less re-hospitalization, fewer emergency room visits, increased prescription adherence, and better communication with health providers (Coye, Haselkorn, & DeMello, 2009).

The last construct of the CCM is The Community. This construct is the least developed and researched because it falls outside of the patient-health system relationship. The initial intent of the principle was to augment self-management activities through community programs (Wagner et al., 1999). As the number of uninsured individuals has steadily risen over the past twenty years, the role of community health agencies has taken on a larger scope to meet the unmet needs of its residents. The long term effects of being uninsured eventually become health problems for a community. Large groups of chronically uninsured raise the demand for basic health care services from community providers. Public health agencies, non-profit organizations, and faith-based groups are a few of the many community organizations that have expanded services to meet the demands of the uninsured and underinsured. The recent passage of the Affordable Care Act designated the U.S. Department of Health and Human Services to provide states and communities with over 121 million dollars in grants to combat chronic disease. The grants will primarily fund prevention programs shown to have positive evidence of improving health. The grants will address two activities: (a) implementing proven interventions and (b) building capacity for sustained provision of services.

The U.S. National Center for Health Statistics classifies a chronic disease as one lasting three months or longer. Chronic diseases generally are not preventable by vaccine or curable by medication. Chronic diseases historically have long courses of illness with increasing medical complications and decreasing quality of life. Chronic diseases account for the most common and costly health problems in America, but most chronic diseases are also preventable. Eliminating controllable risk factors and modifying health behaviors are the two most influential actions to preventing or controlling chronic disease.

The study of chronic disease epidemiology in the United States began in earnest in the mid-20th century. The rise in chronic disease followed closely behind the reduction and elimination of centuries-old infectious diseases. The role of public health agencies to provide clean water and sanitary sewer systems helped stem the tide of epidemic diseases. The development of vaccines for infectious diseases like typhoid fever, tetanus, and diphtheria assisted in decreasing mortality rates. Lastly, the advent of new medications such as sulpha drugs and penicillin became readily available to the population (Anderson, 2007).

The medical community quickly began to see a rise in a new class of disease. Non-infectious diseases represented by cancer, coronary artery disease, respiratory diseases, diabetes, and stroke became the new threats to the health of the population. The challenge of epidemiologists studying infectious disease was to identify the single agent causing the disease, while the challenge of researchers studying chronic disease was to establish casual inferences of the identified risk factors (Andersen, 2007). The steadfast increase in chronic disease among Americans has stressed the American health system in terms of access, quality, cost, and outcomes. Seven of the ten leading causes of death, accounting for over 70% of all deaths, were directly attributable to chronic disease at the turn of the 21st century as compared to only four of the top ten causes of death in 1900. Those four causes accounted for only 21% of the deaths (Andersen, 2007).

In 2010 almost one out of every two Americans, 145 million, had at least one chronic disease, and half of those had two or more chronic diseases. That number is projected to grow to 171 million by 2030 without changes in our health care system (*Improving Chronic Illness Care*, 2012; Robert Wood Johnson Foundation, 2011). The steady increase in chronic disease over the past half century has been attributed to an increased longevity or life span of Americans and the advances of the pharmaceutical industry. The physiological process of aging tends to make older individuals more susceptible to developing chronic diseases. The ability of the pharmaceutical industry to develop drugs to combat the disease process of chronic illnesses has allowed individuals to live longer with one or even multiple chronic illnesses (DeVol & Bedroussian, 2007).

National Health Information Survey data on non-elderly adults age 18-64 for the time span 1997-2006 showed a 3% increase in chronic disease. In 2006, 31% of adults in the 18-64 age range, or 58 million individuals, had one or more chronic disease(s) (Hoffman & Schwartz, 2008). However, as alarming as an increase in the prevalence among non-elderly (18-64) individuals is, a more astounding increase is being seen in children under the age of 18. Van Cleave et al. (2010) conducted a prospective study of chronic disease in children using data from the National Longitudinal Survey of Youth-Child Cohort for the years 1988-2006. The researchers saw an increase in chronic disease prevalence from 12.8% in 1994 to 26.6% in 2006, citing asthma and obesity as the two diseases most accountable for the increase. The research indicated that having a chronic disease as a child is a risk factor for having the chronic disease as an adult. However, not all chronic conditions in children are permanent and many resolve over time with medical intervention and normal childhood development.

The state of Ohio is not faring any better than the population of the United States in controlling risk factors or determinants of general health or in achieving better health outcomes. The 2015 health rankings of individual states by the United Health Foundation (2016) found Ohio ranked 39th overall among all the states. This statistic represents a decrease of three positions from the 2010 rankings. Ohio had an average ranking above the national average of adults who smoke. In 2015, 21.0% of the Ohio population smoked, which represents an increase from 20.3% in 2010. Obesity also ranked above average with 32.6% of Ohio adults classified as obese, an increase from 21.5% over the past ten years. Ohio is currently ranked 47th out of the 50 states in public health funding. The total dollar amount of state and federal funding dedicated to public health was the common determinant of public health funding. Ohio's uninsured rate was 9.7% for the year 2015 as compared to the overall United States rate of 8.3% in 2015. According to the Centers for Disease Control and Prevention (2012), Ohio had higher percentages of the population experiencing high blood pressure and high blood cholesterol when compared to the U.S. average. The high percentages of chronic illness reflect the poor rankings of health determinants in Ohio.

Diabetes was present in 10.1% of the Ohio population as compared to 8.3% nationally (Ohio Department of Health, 2011a). Ohio also had higher percentages of the population experiencing morbidity and mortality because of heart disease, cancer, stroke, and chronic respiratory disease when compared to the U.S. population (Centers for Disease Control and Prevention, 2009).

Estimates that over 75% of all health care costs are directly related to chronic disease and by 2011over 800,000 Americans are projected to die from heart disease and over 600,000 to die from cancer (Centers for Disease Control and Prevention, 2009). The United Health Foundation (2011) projected that the cost to the American health system was over $536 billion in 2011 for these two chronic diseases alone. In the state of Ohio, the total economic cost of chronic disease is estimated to be over $56 billion per year (DeVol & Bedroussian, 2007). The cost of treatment expenditures and lost productivity have negative implications for Ohioans' health and the economy and projections, if left unchecked, could quadruple health care costs for Ohioans by 2018 (United Health Foundation, 2011).

To help understand why some people are healthy and some unhealthy, why some individuals develop chronic disease and others do not, epidemiologists study determinants of health. In the ongoing federal program Healthy People 2020, health determinants are (a) personal, (b) social, (c) economic, and (d) environmental. These factors can fall into one or more of the broad categories within society: (a) policymaking, (b) social factors, (c) health services, (d) individual behaviors, and (e) biology and genetics.

Smoking is one example of the interaction between health determinants and social categories. Smoking is an individual behavior, but the social community and environment where an individual resides greatly influences the likelihood of whether one becomes a smoker. Public policy can influence restrictions on smoking in public places, the marketing of tobacco products, and the cost of tobacco products through taxation. Health insurance may determine if a person will have coverage to treat tobacco related illnesses or cessation interventions (Healthy People 2020, 2011).

Health insurance and public health services are not the sole basis for determining whether individuals will develop a chronic disease in their lifetime. Factors such as transportation, access to grocery stores and healthy food products, clean water supply, clean air, avoidance of environmental toxins, physical activity, and education all contribute to the health of the population. Continuing with the example of smoking and tobacco use, a broad approach to diminishing usage has been in effect for the past 20 years. Policy changes driving up the cost of tobacco products through taxation and restrictions for use in public places, funding for education, and increased coverage for cessation through private health insurance as well as public health programs have greatly reduced the number of individuals who use tobacco products. Smoking rates in 2011, as measured by the United Health Foundation, were at their lowest over the previous 22 years. In 2011, 17.3% of the adult population smoked as compared to 29.5% in 1990, a 41% decline (United Health Foundation, 2011).

The assault on the obesity epidemic has proven to be more challenging than reducing the number of individuals who smoke. Early attempts to reduce obesity were aimed at changing behavior through personal responsibility much the same as with tobacco use (United Health Foundation, 2011). Unlike tobacco use, however, obesity affects the whole range of the population from early childhood to late adulthood. One component of obesity is nutritional intake. However, public policy cannot simply ban food products deemed unhealthy, unlike tobacco, and putting restrictions in place for public consumption is, in most cases, not feasible.

Two studies of childhood obesity exhibited the complexity of changing negative health determinants. In two separate randomized control studies, Caballero et al. (2003)

studied preschool children who participated for 12 months and Reilly et al. (2006) studied elementary level children who participated for three years. The preschool children participated in an enhanced physical activity program and home-based education program, while the intervention program the elementary school children participated in consisted of four components: (a) a change in dietary intake, (b) an increase in physical activity, (c) classroom education, and (d) a family involvement program. Results from both studies post-intervention showed no significant changes in body fat/body mass index in either group. Positive results were evident in the intervention groups for knowledge, attitudes and behaviors, and motor skills (Caballero et al., 2003; Reilly et al., 2006). These results, although discouraging, display the complexity upon which chronic diseases manifest themselves. Similar studies in adult populations have shown similar results (Sampsel & May, 2007). Research has shown that the concept of personal responsibility alone changing health behavior and ultimately health outcomes has limited success in the obese population.

The influence and interaction of health determinants on our personal behaviors, the environment in which we live, and our genetic makeup expose our susceptibility to chronic disease. As epidemiologists learned through the period when infectious disease ruled, fighting infectious agents early and determining the source from which they spread was most advantageous. As the epidemiology of chronic disease progresses, researchers, health care professionals, and public health agents are slowly beginning to understand the role of the relationship between personal behavior and public health or what is now referred to as collective responsibility.

The Ohio program, Creating Healthy Communities, demonstrates how public health strategies and personal behavior choices can work together to improve individual and community health. The program targets health care providers, vulnerable communities, worksites, and schools. Providing accessible and affordable food choices in schools and promoting community gardens and farmers' markets were some of the components addressing nutrition and obesity. Twenty-seven new walking trails were built in various communities to promote physical activity. Lastly, physicians were equipped with toolkits aimed at early detection of obesity and other chronic diseases (Ohio Department of Health, 2011b). Program initiatives like these combined with federal, state, and local policy proposals enhance healthy lifestyles. Policy proposals include protecting children from deceptive marketing strategies and requiring schools to provide healthier menu choices. The consumer's right to truthful information resulted in the Nutrition Labeling and Education Act of 1990. Other policy initiatives include restrictions of food marketing, regulation of food ingredients, and possible taxes on identified food products deemed unhealthy (Brownell et al., 2010). These non-personal behavioral changes are often addressed as structural interventions. Policy changes, taxes, and zoning regulations all fall under structural interventions. Removing unhealthy food choices from vending machines in schools is considered a structural change. Katz (2009) likened today’s structural interventions against chronic disease to sewage treatment for clean safe water or seatbelts for improved automobile safety.

Insured individuals with chronic disease struggle to obtain appropriate care from qualified providers in a delivery mode that optimizes evidence-based medicine. Such care is comprehensive in scope and empowers the individual, but it is difficult to find. The struggle of individuals without insurance is often monumental. The lack of insurance or the burdensome out-of-pocket cost directly affects the quality and quantity of care provided to chronically diseased individuals. According to the Kaiser Family Foundation (2011), individuals between the ages of 19 and 64 have the highest risk of being uninsured because government-provided insurance tends to go to the age groups younger than 19 and older than 64. Individuals who fall below the poverty level compose the largest group of uninsured at 40%. The uninsured face challenges in gaining access to the health care system due to their inability to pay for care. Individuals with chronic disease and lacking insurance face even more serious barriers due to the constant monitoring of the disease process involved in chronic disease (Kaiser Family Foundation, 2011).

The RAND Health Insurance Experiment conducted in the 1970s attempted to control health care expenditures during a time when health care costs were spiraling upward on a consistent yearly basis. The group believed that if insurance companies increased cost sharing with patients, health care expenditures would decrease. While the RAND experiment proved this belief to be true, it failed to examine the long-term effects on health status, especially individuals with chronic disease (Chernew & Newhouse, 2008). The researchers found that increased cost sharing had many startling effects on health status. First, increased cost sharing disproportionately affects three groups of individuals: those with chronic disease, those uninsured, and those with low-income. If a person happens to fall into all three categories, the person's health status will be affected to a greater extent over a shorter period of time. Additionally, Hoffman and Schwartz (2008) found that increased cost sharing decreased medication compliance and the use of appropriate services. In their ten-year study on of out-of-pocket spending for chronic conditions, Paez, Zhao, and Wang (2009) concluded the costs for copayments, coinsurance, durable medical equipment, and deductibles were highest for the poor and those with multiple chronic diseases, both of whom were the least able to afford needed care. Chernew and Newhouse (2008) concluded that when there is an overconsumption of health services, cost sharing is an effective tool to limit usage; however, when the care provided is appropriate, cost sharing leads to decreased health status.

Both Hoffman and Schwartz (2008) and Wilper et al. (2008) noted that insured individuals with a chronic condition are four times more likely to have a usual source of care compared to uninsured individuals. They also reported at least 25% of uninsured individuals with chronic disease had gone at least one year without visiting a health professional (Hoffman & Schwartz, 2008; Wilper et al., 2008). For people who are uninsured and have chronic conditions requiring medical prescriptions, over 32% reported forgoing filling prescriptions, taking half doses, or skipping doses altogether.

According to Hoffman and Scwartz (2008), out-of-pocket costs of the uninsured with a chronic condition were 75% higher than insured patients.

Hadley (2007) and Hall, Rodriguez, Boyko, Chertow, and O'Hare (2009) studied uninsured individuals with chronic disease examined over time compared to similar patients with medical insurance as to the health status of their conditions. They compared uninsured patients with chronic kidney disease to patients with similar kidney disease who were insured. Results showed that the uninsured were at a higher risk for disease progression, were less likely to afford and receive the recommendations and interventions that would slow disease progression, and had increased risk to develop end-stage renal disease (Hall et al., 2009). Hadley (2007) studied the medical care outcomes of uninsured and insured individuals who had been diagnosed with the onset of a chronic condition. Hadley gathered the longitudinal data from the Medical Expenditure Panel Surveys conducted during the period 1997-2004. Results were consistent with other findings, whereby, individuals with chronic disease and who were uninsured received less medical care and experienced poorer outcomes in health status, both short term and long term.

According to the Health Policy Institute of Ohio (2010), there are over 1.3 million uninsured adults and children in the state of Ohio. The two groups that comprise the largest number of uninsured are low-income adults and young adults. The provision in the Affordable Care Act that took effect in 2010 allowing young adults between the ages of 19 and 26 to go back on their parents' insurance will reduce that number significantly in future statistics. In examining health disparities that exist in Ohio, the Health Policy

Institute of Ohio (2010) found men had a higher rate of being uninsured than women, but women were more likely to be living below the 200% poverty level. Men had a higher incidence of cardio-vascular disease while women were more likely to be diagnosed with cancer. The Institute found other health disparities; Hispanics were twice as likely to be uninsured as whites while African-Americans had more than an 80% chance of being uninsured compared to white adults in Ohio. This discrepancy in health insurance is evident in the stronger likelihood among African-Americans to be obese, have increased blood pressure, have diabetes, and incur a stroke compared to that of white adults. In the state of Ohio, medicaid is the largest payer of health services with an enrollment of over 2.3 million individuals, representing 17% of the total population in Ohio. Analysis of this data combined with the Ohio Department of Health data paints a dismal picture of Ohioans' health status.

The Ohio Department of Health (2010) participated in the Behavioral Risk Factor Surveillance System that conducts ongoing health surveys among a representative sample of Ohioans. The Ohio Behavioral Risk Factor Surveillance System is part of a nationwide health assessment system conducted by the Centers for Disease Control and Prevention. Results show that individuals with low-income, low educational achievement, and insufficient health insurance were at greater risk for poor health outcomes and unhealthy behaviors.

The health insurance landscape both nationally and in Ohio points to a bleak future if significant changes are not enacted. The passage of the Affordable Care Act provides relief for some of the more troubling trends that are driving up the number of uninsured individuals. One trend adding to the state's growing population of uninsured is the rising costs of premiums and deductibles for those who have insurance. Schoen, Fryer, Collins, and Radley (2011) conducted research on the rising cost of insurance premiums and deductibles for health insurance coverage between the years 2003 and 2010. Total premiums rose 50% during that time, with the employee's contribution to premiums increasing by 63% over the seven-year period. The cost of health premiums for family coverage projects to reach $24,000 by the year 2020 (Schoen et al. 2011). The average annual employee premium share for a family plan in 2010 was $3,721 compared to a cost of $2,283 in 2003. Meanwhile, the average family deductible in 2010 was $1,975, an increase from $1,079 in 2003. This increase for deductible represents an 83% increase over the seven years. These increases in premiums and deductibles exceeded increases in national income data for the same period of time (Schoen et al. 2011).

The rapid rate of increase in health insurance premiums and deductibles are just two of many factors that have driven the number of individuals without health insurance to record highs. Access to health services has become a major obstacle to the health status of millions of individuals. Free health clinics during this period of time have seen an overwhelming increase in referrals and demand for services that parallels the increase in the number of uninsured patients.

The Free clinic movement was an offspring of the rebellious social and cultural movements of the 1960s and early 1970s. Early clinics served patients whose needs were a reflection of the times. In his profile of America’s free health clinics, Weiss (2006) describes the early clinics serving three distinct populations: drug clinics serving the hard-core drug addicts, the minority clinics serving racial or ethnic groups, and youth clinics serving the teenager and college-age students of the day. The early free clinics often changed focus and clientele based on societal needs and cultural demands of the times. Free clinics lacked organization on any state or national level, and there was little cohesion among clinics due to different focuses and clientele.

The growth of the uninsured population was one of the unifying forces behind free clinics. The increased demand for medical services among the uninsured brought about a unification of free clinics and standardization of clinic services. The societal and cultural movement of the 1990s and 2000s dealt with a fast-growing population that lacked health insurance, resulting in decreased health status for individuals and ultimately threatening the health of the population overall. The increase in free clinics throughout the country over the past 15 years has resulted from an ever faster increase in the number of uninsured. Most free clinics that exist today resemble mainstream medical clinics in operations and services provided (Weiss, 2006).

The expansion of free clinics across the country has brought about new levels of organization. The National Association of Free Clinics exists as the focal organization for state organizations and free clinics across the country. The National Association of Free and Charitable Clinics (2014b) defines a free clinic:

> Free and charitable clinics are safety-net health care organizations that utilize a volunteer/staff model to provide a range of medical, dental, pharmacy, vision and/or behavioral health services to economically disadvantaged individuals. Such clinics are 501(c)(3) tax-exempt organizations, or operate as a program component or affiliate of a 501(c)(3) organization.

Free clinics reflect the needs of the communities they serve, resulting in a variety of service models and structures. However, Darnell (2010) conducted a national survey of free clinics that provided data that substantiated the contributions of free clinics to the American health care system. Significant findings in Darnell's study showed that free clinics serve up to nearly 2 million individuals on a yearly basis. That survey revealed other data that corroborated earlier findings by Isaacs and Jellinek (2007), Cervantes-Rodriguez (2009), and Reynolds (2009). These findings included: (a) care was provided at no cost or minimal cost to patients; (b) the majority of patients served were uninsured; (c) most clinics operated on a volunteer basis with minimal paid staff; and (d) most clinics had small budgets with little to no consistent means of revenue. Isaacs and Jellinek (2007) report a common trait of free clinics was their bond with the community. Weiss (2006) attributes the good will generated by free clinics in the community to the perception that individuals without health insurance lack access to health services. Free clinics provide a solution to a societal problem, free clinics provide a service to a population other health professionals do not serve, and free clinics are a positive economic alternative to the health care access problem.

Community good will, successful volunteer programs, and efficiently run organizations characterize most free clinics; however, Isaacs and Jellinek (2007) objectively point out that free clinics are not without their challenges. Foremost, most clinics experience a demand that far exceeds their capacity to serve everyone. Based on the 2010 survey, Darnell (2010) cites the average budget for a free clinic as $287,810, too insignificant to support a clinic's ability to grow and expand in its scope of services. Other challenges experienced by free clinics include a changing patient mix, namely sicker and older patients. The increase of chronic disease in the population results in patients who are more dependent on the health system. Free clinics already stressed by the excess demand for services struggle to provide proper care for the chronically ill patient.

Gertz et al. (2011) also conducted a national survey of free clinic providers as well as patients who receive their care at free clinics. Their survey identified 1,114 free clinics in the United States. A mean of 4,310 visits per clinic was reported. Patients reported primary care and pharmacy services as the two most needed services. When posed with the prospect of eliminating free clinics, 24% reported they would not seek alternative care due to costs. Patients responding to the survey reported 97% satisfaction with the services received. These results were not unlike those found by Keis, DeGeus, Cashman, and Savageau (2004), who reported the characteristics of patients at three free clinics. Their results indicated that patients lacked alternative options for health care if the free clinic was not available. Most patients used the clinic for medical and pharmacy needs. An important conclusion, the authors noted that free clinics experienced the greatest strain on resources in serving patients with comprehensive and continuous care needs.

Patients with comprehensive and continuous care needs make up a growing sector of free clinic constituents. Scariati and Williams (2007) conducted health risk assessments on individuals who utilized a free clinic. Patients completed the 43-question Health Risk Appraisal assessment to identify risk factors, chronic illnesses, preventative test usage, and overall health indicators. The results provided patients with risk years to be gained by adopting health behavior modifications to identified risk factors. The tool also served as a useful guide to the free clinic in managing limited resources for patients with chronic illness.

To date, only one formal research study has addressed the use of the CCM in a free clinic setting. Strobel et al. (2005) studied 149 patients with single or multiple chronic diseases for a period of 18 months. The free clinic adopted the CCM model and the six principles of care. One hundred nine patients successfully completed the program, with 40 lost to dropout. Seventy-nine patients were successful in demonstrating significant improvement with at least one chronic illness. The vast majority of literature regarding free clinics revolves around descriptive demographic information of populations served and services offered. The health insurance status, racial and ethnic backgrounds, and socioeconomic and educational status of patients are well documented. In addition, much has been written concerning operational issues of free clinics and the volunteer movement that keeps these clinics staffed. However, there is little research and documentation of how free clinics are managing the burden of providing care for the population that has chronic disease and what disease management processes free clinics use with this population.

The OAFC was established in 2000. To date, 51 free clinics are members of the association. In 2008, over 54,000 individuals were served by over 6,000 volunteers and paid staff at Ohio free clinics. Each clinic in Ohio is a 501(c)(3) non-profit organization (OAFC, 2014).

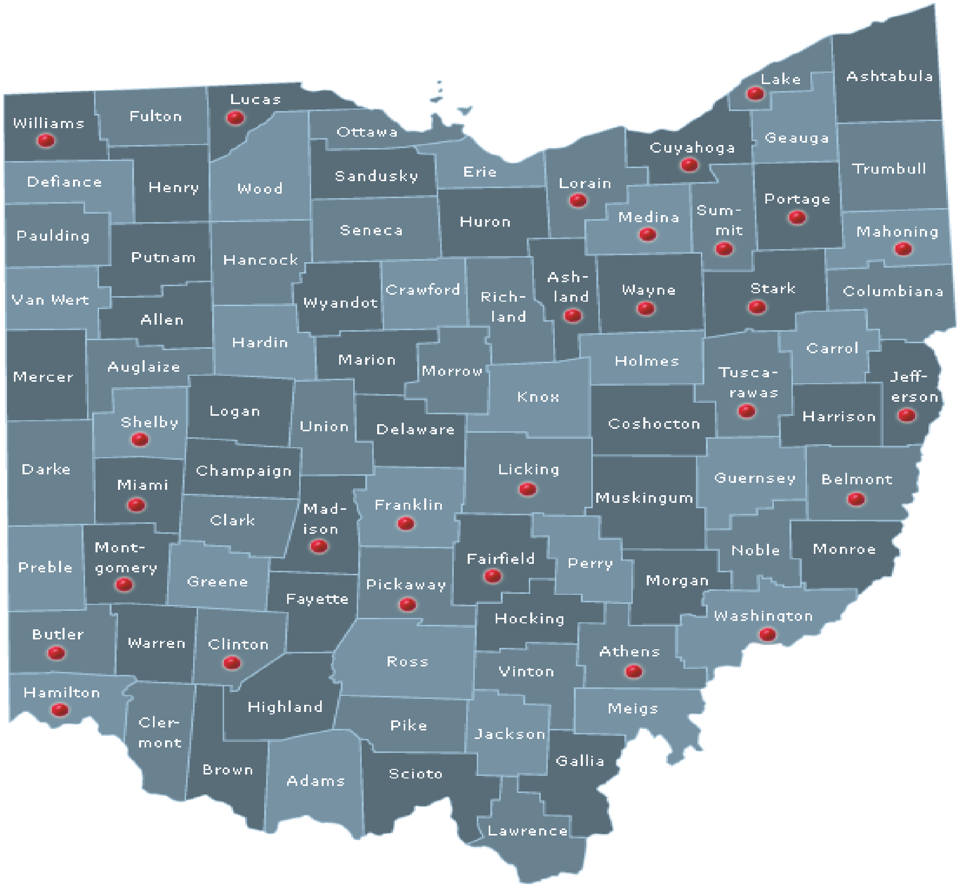

Figure 2. Ohio Free Clinics. From the Ohio Association of Free Clinics (2013)

The review of the literature on chronic disease revealed a variety of methodological forms. Chronic disease management literature reflected the same research methods found in health care research including quantitative, qualitative, or mixed method models. The methodology, tools, and analytical calculations all varied to the research purpose and research questions.

Often complex questions cannot adequately be answered by either a quantitative or qualitative design approach alone. In their review on mixed methods research in health sciences, Creswell, Klassen, Plano-Clark, and Smith (2011) reported that the research design must be driven by the fit to the research question or problem being studied. The use of multiple methods of data collection using different strategies results in complementary strengths reflective of a mixed methods approach (Greene, 2007). Often considered as the third major approach in the research paradigm, mixed methods began as an alternative to quantitative and qualitative designs. Johnson, Onwuegbuzie, and Turner (2007) provided this definition of mixed methods:

> Mixed methods research is the type of research in which a researcher or team of researchers combines elements of qualitative and quantitative research approaches (e.g., use of qualitative and quantitative viewpoints, data collection, analysis, inference techniques) for the broad purposes of breadth and depth of understanding and corroboration. (p. 123)

The origin of mixed methods is often credited to the work of Campbell and Fiske in the 1950s. Their research using multi-trait, multi-method design was the precedent for today’s mixed method models (Tashakkori, 2009). Creswell (2003) reported six separate mixed methods designs that varied by data collection occurring sequentially or concurrently, the order of the sequence, the priority given to quantitative or qualitative data, when and if the data were mixed, and whether a theoretical perspective guided the research. The six designs are: (a) sequential explanatory design, (b) sequential exploratory design, (c) sequential transformative design, (d) concurrent triangulation design, (e) concurrent nested design, and (f) concurrent transformative design.

The use of mixed methods research in social work and health care related research has grown over the past decade. While there is a strong emphasis on empirical evidence-based research in clinical applications, there also is an equal need for research that addresses the social and ethical questions of health care (Schifferdecker & Reed, 2009). Researchers have reported that one strength of using mixed methods when investigating health services is that it more fully allows researchers to explore a person’s health and health care in the context of that person’s environment (O’Cathain, 2009).

In a need to improve the quality of health care research, the use of multi-level approaches for complex health issues has grown. The complexity of the health issue may result due to the context of the setting or investigation of the processes used that influence outcomes. The mixed methods model is not without its critics, though. Limitations often cited include excessive time to collect data due to having two separate collections, additional cost to conduct a study, grant funders not familiar with the model, and journal editors resistant to publishing research utilizing this model (Teddlie & Tashakkori, 2009).

The human element of health care research is often difficult to define in a quantitative methodology alone. The qualitative approach is often more appropriate in satisfying the need to discover the how and why of the problem. Creswell and Plano-Clark (2011) stated that one methodology often insufficiently addresses the research problems and presents an incomplete understanding of the research question or problem being studied. Quantitative results often lack explanation of the relationships that can exist between and among variables. The use of qualitative methods can provide that additional understanding. A mixed methods model is an appropriate model to use to connect data sets that took place over a broader period of time.

The literature review revealed a range of research methodologies used to study the CCM as a whole and as separate parts. In studies designed to determine health status improvements, the choice of design methodology was mainly quantitative design (Darnell, 2010; Decker, Schappert, & Sisk, 2009). In studies that incorporated quality of life or patient perception, studies tended to be either mixed methods or qualitative studies (Dennis et al., 2008).

The design of mixed methods research is unlike designs of quantitative studies in that the list of design typologies is not a finite list of designs (Teddlie & Tashakori, 2009). The criteria used to decide on research design vary among experts in the field. Teddlie and Tashakori (2009) advocate the use of four criteria while Creswell and Plano-

Clark (2011) recommend using upwards of seven criteria. Health care research techniques reviewed in this literature search employing quantitative methodology commonly used surveys as the primary means of generating their data. Qualitative methodology employed in the literature reviewed involved interviewing and case studies. Many studies employed the use of representative data from government websites and national surveys conducted over time (Centers for Disease Control and Prevention, 2009).

Similar to the research design, analysis methods employed by the researchers covered a broad scope of procedures. Darnell (2010) used a combination of descriptive statistics as well as univariate and multivariate logistic regression analyses. Dennis et al. (2009) used a systematic review with qualitative data synthesis. Gertz et al. (2010) used JMP version 7.0 to analyze data and also employed Pearson chi-squared tests and two-tailed Fisher-exact t-tests in the data analysis.

In the present research, I used a mixed methods sequential explanatory design. This methodology allowed for a multi-faceted data collection as well as analysis approach to answer my research questions.

The quantitative data portion of the research consisted of: (a) the ACIC survey (Appendix A), (b) the collection of clinic demographic data (Appendix D), and (c) each clinic’s annual survey submitted to the Ohio Free Clinic Association (Appendix B). I used descriptive statistics to report frequency distributions and measures of central tendency for the demographic and annual association survey data as well as each of the individual (7) constructs of the ACIC survey. To determine the effect size (R^2) each independent variable had on the dependent variable, I conducted a backwards stepwise logistic regression. Through the process of a backwards stepwise logistic regression, independent variables were tested and removed if determined to be a weak predictor as determined by their correlation coefficient. This process determines which coefficients of the independent variables are strongest at predicting the dependent variable (Berkman & Reise, 2012; Munro, 2005; Norusis, n.d.). This process is also helpful when the sample size is small.

Multiple forms of regression analysis were available to me. Hierarchical and stepwise are two of the more common methods. Hierarchical regression is often the preferred regression choice because the researcher has more control of the order in which the variables are entered into the regression. This order is often determined based on past research or theory. Hierarchical regression is the desired method when theory testing is being conducted.

Stepwise regression is commonly used when the research analysis is more exploratory rather than theory testing. Prediction was the outcome goal of the current research method. Stepwise regression can be either forward or backward. In a forward stepwise regression, variables are entered one at a time. If the variable meets the set statistical criteria, it stays in the model. Hence, backward regression begins with all predictors in the model and deletes predictors based on failure to meet statistical criteria. This process continues until only statistically significant predictors exist. In my research, I chose backward stepwise regression due to the maximum sample size of 51. I identified three independent variables in my research design. Backward regression provided a better analysis methodology for my small sample size. The sample size of a study is determined based on statistical power analysis. However, my study had a finite sample size. Power is defined as the probability that a statistical test will correctly lead to the rejection of the null hypothesis (Portney & Watkins, 2009). The power of a study is determined by the standardized effect size, alpha level, and sample size.

For the quantitative portion of the data analysis, I used descriptive statistics such as frequency distribution and measures of central tendency. I employed backward stepwise regression analysis to determine the relationship between the independent variables and the dependent variable. In the qualitative portion of the research, I used case studies of selected clinics to build explanations and match patterns in an attempt to further explain the barriers and supports used by free clinics in their delivery of chronic disease management.

Summary and Conclusions

The use of the CCM emphasized an interactive approach to chronic disease management focusing on six principle elements in the provision of care (Bodenheimer et al., 2004; Improving Chronic Illness Care, 2012; Robert Wood Johnson Foundation, 2011; Wagner et al., 1996; Wagner et al. 1999).

The use of the CCM of disease management has shown evidence of effectiveness across a variety of clinical settings and among different patient populations (Renders et al., 2001; Robert Wood Johnson Foundation, 2011; Wagner et al., 1999). Not all studies supported the CCM in its early stages. The process of changing care delivery and philosophical beliefs of health care roles were not always readily accepted (Hanratty et al., 2008; Oswald, 2001; Spigel, 2008).

The use of evidence-based medicine in the delivery of care has grown in acceptance and usage in the health care system. Access to research information and its dissemination via the internet has broadened the knowledge base (Agency for Health Care Research and Quality, 2012; Spigel, 2008; Sackett et al., 1996).

The rapidly increasing statistics of individuals with chronic disease in America is at epidemic proportions. As a result, the needs of the chronically ill have stretched the U. S. health care system to near collapse. More Americans lack health insurance now than at any other time in our history. The consequences of having one or more chronic diseases and being uninsured are a poorer health status and access barriers to the health system (Hadley, 2007; Hall et al., 2009; Hoffman & Schwartz, 2008; Kaiser Family Foundation, 2011; Wilper et al., 2008).

Free clinics play an important role in providing services to the uninsured. As part of community safety net services, free clinics provide a needed service not otherwise met in many communities (Cervantes-Rodriguez, 2009; Darnell, 2010; Isaacs & Jellinek, 2007; Reynolds, 2009).

The gap in knowledge is the unanswered question to what extent do free clinics embrace and utilize the CCM in providing services to a population shown to be the most vulnerable to health disparities. The uninsured with chronic disease are frequent users of free clinics in Ohio and nationwide. Only one study identified in the literature has researched the use of the CCM in a free clinic (Strobel et al., 2004). This study examined the extent to which the 51 free clinics in Ohio have adopted the six principle elements of the CCM.

Chapter 3: Research Method

Introduction

Ideally, the management of chronic disease in primary care medicine should incorporate a model that includes a team-based approach using evidence-based medicine, patient self-management, and current technology to achieve optimal clinical outcomes. However, uninsured individuals often are forced to rely on community safety net services for their health care. Free health clinics are considered within the circle of the community safety net. The level of reporting and accountability required of free clinics is often less than that of traditional health care providers because free clinics do not bill insurance for reimbursement and they provide charitable care and utilize volunteer professional medical staff. Subsequently, free clinics have existed in relative obscurity in the health care provider market. Little is known regarding chronic disease management in free clinics despite the fact that they provide care to the population most affected by chronic disease. This study proposed to address the gap in knowledge by assessing the current status of chronic disease management being provided at free clinics and to identify the supports and barriers associated with fidelity to the CCM.

The purpose of this sequential explanatory mixed methods study was to: (a) determine the level of fidelity by Ohio free clinics to the six key constructs of the CCM, (b) define the correlational relationship between demographic variables (independent) and the Assessment of Chronic Illness Care (ACIC) survey scores (dependent), and (c) conduct a two-tiered design multiple case study explaining the supports present in high ranking clinics and the barriers low ranking clinics experience.

This chapter is organized into six sections. The first section discusses the setting. The second section includes the research design and its rationale. In the third section, I discuss my role as the researcher in this study, and in the fourth section, I address the proposed methodology. The fifth section discusses threats to validity. Finally, the sixth section addresses issues of trustworthiness.

Research Setting

The study took place geographically in the state of Ohio. The state is representative of the larger demographics of the United States. Ohio is ranked 7th in population among the states (U.S. Census Bureau, 2013). That population is divided between large urban cities (Cincinnati, Columbus, and Cleveland) as well as rural farming. The percentage of individuals without health insurance in Ohio is 13.6% compared to the national rate of 15.4% (DeNavas-Walt et al., 2013). Ohio is estimated to rank 29th nationally in comparing populations with chronic disease (Milken Institute, 2016). Ohio has 51 free health clinics per the OAFC, (2014). The National Association of Free and Charitable Clinics (2014) estimates over 1,200 free clinics exist in the United States.

Research Design and Rationale

The quantitative research questions of this study were:

RQ1: Do the weekly average hours of operation at Ohio free clinics significantly contribute to increased compliance with the CCM?

$H_0$1: The average number of weekly hours of operation does not significantly predict compliance with the CCM at Ohio free clinics.

H_a1: The average number of weekly hours of operation does significantly predict compliance with the CCM at Ohio free clinics.

RQ2: Does the size of the annual operating budgets of Ohio free clinics significantly increase compliance with the CCM?

$H_0$2: The size of the operating budget does not significantly predict compliance with the CCM at Ohio free clinics.

H_a2: The size of the operating budget does significantly predict compliance with the CCM at Ohio free clinics.

RQ3: Does the amount of electronic health record integration significantly contribute to increased compliance with the CCM at Ohio free clinics?

$H_0$3: Electronic health record integration does not significantly predict compliance with the CCM at Ohio free clinics.

H_a3: Electronic health record integration does significantly predict compliance with the CCM at Ohio free clinics.

The qualitative research questions for this study were:

RQ4: What supports are present at Ohio free clinics with high ACIC scores that allow them to have a greater fidelity to the CCM?

RQ5: What barriers exist that prevent Ohio free clinics with low ACIC scores from achieving higher ACIC scores.

In order to achieve this, I used a mixed methods model using sequential explanatory design. This design was characterized by the collection and analysis of quantitative data. Scores from the ACIC survey dictated which clinics were chosen for qualitative data collection via a multiple case study and analysis. *Integration* refers to the stage whereby data analysis of the quantitative and qualitative methods was combined. In this study, the integration occurred at the final analysis stage. Integration can occur at multiple stages in the sequential explanatory design model. Common mixing stages come prior to the study when determining purpose and questions, in between the quantitative and qualitative stages, and at the interpretation of the outcomes phase of the study (Hanson, Creswell, Plano-Clark, Petska, & Creswell, 2005; Teddlie & Tashakkori, 2003).

The sequential explanatory design in the present study was a multi-phase design with the quantitative phase occurring first. One portion of the data analysis ranked the clinics in a numerical ranking order based on their mean ACIC score. The three highest scoring and the three lowest scoring clinics were invited to participate in the qualitative phase of the design. If either a high or a low scoring clinic declined to participate in this phase of the research, the next highest or lowest ranking clinic as indicated on the list was chosen. A multiple case study composed the qualitative portion of the study. The purpose of the qualitative portion of the study was to provide a more comprehensive explanation of the quantitative results. Creswell and Plano-Clark (2011) offered that this design provides the researcher with a distinct delineation between the two phases. Other benefits included allowing a single researcher to conduct the research and that the final conclusions from the study were based on data from both phases of the study (Teddlie & Tashakkori, 2009). While there are many potential benefits from the sequential explanatory design, time constraints for conducting the research is often seen as a limitation.

The quantitative portion of the study employed the use of a survey. Surveys are widely used in research pertaining to the social sciences. Survey research offers the researcher many advantages including minimal costs, convenient and efficient data gathering, and minimal subjectivity. However, a host of limitations exists with survey research, including poor return rates, limited scope, and poor design. Surveys have been useful in assessing attitudes and actions (Fowler, 2009).

The qualitative portion of the study employed a multi-case study format. Yin (2009) explained that case studies focus on the *how* and *why* research questions. Data collection in a case study takes place in the environment being studied and has a real-life context. The use of multi-case studies differs from a single case study. The advantage of a multi-case series is that data compiled from multiple cases makes for more compelling evidence. Multiple source data can provide evidence that more fully supports the propositions made about the study. Multiple cases also allow the development of rich theoretical frameworks. Stake (2006) describes this phenomenon as the *quintain*. Yin (2009) states that frameworks are necessary to describe the circumstances in which a phenomenon may be found. Frameworks thereby allow more generalization of the results. This study employed a “two-tailed” multicase study design. Three clinics with the highest and three clinics with the lowest ACIC scores from the quantitative portion of the study were purposively chosen as cases. The number of cases allowed for theoretical replication both across and within each subgroup.

Role of the Researcher

The role of the researcher is to plan the research study, identify and recruit the participants, organize the data collection, analyze the data collected, and interpret the data in relation to the research questions. The researcher must carry out these activities while maintaining an ethical and unbiased position throughout the process (Welch, 2004).

In the present study, my role was to plan the research design, recruit participants, and distribute and collect surveys for the quantitative data portion of the study. The qualitative portion of the study was a case study series in which my role was to collect data from an identified subset of the sample. This data collection required my active interaction with clinics through interviews with designated personnel, viewing of clinic operations, and reviewing documents.

I had informal relationships with many of the free clinics in Ohio through membership in the OAFC. I was not involved in any leadership or authoritative relationships with intended participants. I approached the proposed study without bias either positive or negative towards the participants or outcomes. As an incentive to participate, individual clinics will be provided with the statistical results of their clinic and the relationship of that clinic to the group as an aggregate. No other enticements or incentives were provided.

In order to meet all ethical standards for this study, the researcher designated that the Executive Director of each clinic act as the clinic’s representative. The Executive Director should have the most comprehensive understanding of the clinic’s operations. The Executive Director completed part one of the informed consent prior to commencing participation in the study. The informed consent served to educate the participants about their rights regarding participation and their right to refuse or withdraw at any time. The informed consent also stated the purpose of the study and provided the researcher’s contact information should the need arise to answer any questions or concerns during the study.

Methodology

Sampling Strategy

For the quantitative portion of the study, the sample consisted of the population of Ohio free clinics that met the inclusion criteria. The main attraction to this population was the accessibility to participants. However, limitations exist with the use of convenience sampling in research literature. Generalizability to the larger U.S. population of free clinics is a concern when using convenience sampling.

For the qualitative portion of the study, I used a purposive sampling strategy. Within the case study series, I used a two-tiered design. A criterion sampling strategy was used with clinics participating in the quantitative portion. The three clinics with the highest ACIC mean score and the three clinics with the lowest ACIC mean score were selected to participate in the case study portion of this research. This dichotomy represents the extremes of fidelity to the CCM.

Criteria for Participating in Study

Inclusion criteria for the identified population for this study were free clinics located in the state of Ohio that are members of the OAFC. The criterion of membership ensured that all clinics participating in the study met a minimum set of operating standards (Appendix C). The OAFC membership standards include: (a) 501 (c)(3) non-profit status; (b) an identified medical director; (c) limitations on billable income; and (d) documented participation levels of uninsured clients thereby allowing free clinics to operate and serve vulnerable populations (OAFC, 2014). The association held its members to these standards. The potential sample size was drawn from the association membership. Members were identified from the public listing of Ohio free clinics on the OAFC website (Appendix E). I personally contacted the Executive Director of each clinic via letter of invitation to establish the Executive Director as the designated contact person, verify clinic contact information, and to solicit tentative participation in the study. The preferred method of communication for this study was via e-mail; however, if clinics had an alternative preference, it was honored.

Exclusion criteria for this study consisted of association member clinics whose primary mission and the population they served did not include individuals with chronic disease. For example, if a clinic functioned as an urgent care provider, this type of clinic was excluded for the purposes of this study. In addition, free clinics providing primarily mental health services were not considered. While mental health is considered a chronic disease, the needs and services required to treat individuals with mental health issues differ from those of traditional physical chronic diseases.

Any free clinic with which I had a formal association was excluded from the study.

Sample Size

The quantitative portion of the study used members of the association who met the inclusion criteria. The sample size of a study was determined based on statistical power analysis. Power is defined as the probability that a statistical test will correctly lead to the rejection of the null hypothesis (Portney & Watkins, 2009). The power of a study is determined by the standardized effect size, alpha level, and sample size. By convention, the accepted value for power is typically .80 or 80%. The researcher decides what the alpha level will be for a study. Typical values for alpha are $\alpha = .05$ or $\alpha = .01$. Studies that use larger values of alpha have stronger power. The accepted alpha level is .05 for most social science research studies. The effect size of this study determined the strength of the relationship between the independent and dependent variables through the use of correlation coefficients (r^2) or R^2.

Based on prior conventions of social science research and reviewed literature, I chose the following statistical parameters in which to conduct this research: alpha .05, power .80, and medium effect size, with three predictor variables using backward stepwise logistic regression analysis.

The present study intended to conduct six case studies from the potential sample of free clinics in Ohio. Within each case study, the potential of at least four interviews existed for a total of 24 total interviews. Bowen (2008) explained the right sample size for qualitative research is when the subjects' best fit the research topic. Bowen also felt that a saturation of data and information can be obtained with these sample sizes. Bowen (2008) further defined saturation as when no new data is being discovered. In a study of Ph.D. dissertations using qualitative research, Mason (2010) found that of the 560 qualitative research dissertations meeting the study's inclusion criteria, the mean sample size was 31 with a standard deviation of 18.7. Researchers like Bowen (2008) hold to the belief that the focus of qualitative research should be on sample adequacy and not sample size. Bowen defined adequacy as when saturation is met.

Quantitative Instrumentation

I used self-administered surveys to collect demographic information from the participating clinics and to measure clinic fidelity to the CCM. The surveys were available via electronic copy or hard copy.

The demographic information collected from each clinic consisted of a copy of their 2013 annual report required by the OAFC (Appendix B). These annual reports detail a variety of clinic demographics involving size and scope of services and clientele served. In addition, demographic survey information not collected by the OAFC, such as geographical location, years of operation, and integration of health care information technology, were collected (Appendix D).

Table 1

Research Variables

IV	DV
Average weekly hours of operation	Assessment of Chronic Illness Care
Size of the operating budget	
Electronic health record integration	

The final survey, the ACIC, is an assessment tool developed in 2000 by staffers at the Improving Chronic Illness Care organization based in Seattle, Washington. The tool has two main intentions: (a) to assist in identifying areas of chronic illness care that need to be improved prior to starting a care improvement project and (b) to assess the change in care after a care improvement project is completed (Pearson et al., 2005). The tool developed in 2000 has been used extensively worldwide. The ACIC is a comprehensive tool that evaluates the organization of care rather than clinical outcomes with chronic disease management.

The ACIC assessment is aligned with the six key constructs of the CCM: community linkages, self-management support, information systems, organization of care, decision support, and delivery system design. Version 3.5 of the ACIC scores 28 items corresponding to the six constructs of the CCM as well as six additional items measuring integration of the constructs of the CCM. Each item to be scored has four levels (A-D) reflecting differing levels of chronic illness care, and within each level, the rater can choose from three additional delineations of care. In all, each item is scored on a

0-11 scale. The ACIC requires 15-30 minutes to complete and may be completed either individually or as a team. Permission to use the tool has been granted by the Improving Chronic Illness Care program (Appendix J).

Reliability and validity values for pretest-posttest scoring have been established (Bonomi, Wagner, Glasgow, & VonKorff, 2002). The tool has been translated into seven additional languages using the World Health Organization's "Process of translation and adaptation of instruments" (Improving Chronic Illness Care, 2012). Cramm, Strating, Tsiachristas, and Nieboer (2011) confirmed the validity, reliability, and sensitivity to change of the ACIC in their development of an ACIC short version. Bonomi et al. (2002) demonstrated that the tool was responsive to changes organizations made regarding the six elements of the ACIC. In their research on patients with diabetes or congestive heart failure, significant improvement ($p < .05$) and moderate to high correlations ($r > .30$) were achieved in the elements of the ACIC. However, in the current study, the instrument was administered one time to establish a benchmark score. The ACIC is responsive to changes clinics make in their delivery systems and correlates well with other measures of productivity and system change. The ACIC tool has been used on a wide range of chronic disabilities and CCM improvement projects with positive results (Patel & Parchman, 2011; Stange et al., 2010; Yu & Beresford, 2010).

Qualitative Instrumentation

Yin (2009) identified six sources of evidence in case study research: (a) documentation, (b) archival records, (c) interviews, (d) direct observations, (e) participant observation, and (f) physical artifacts. I collected Qualitative data for this study through the use of interviews, documentation, and direct observations. The tools used to collect the qualitative data were all self-developed to meet the unique characteristics for the wide range of clinics being studied.

In order to establish validity for the qualitative questions, I conducted a consensual validation activity by engaging two experienced people who worked directly with free clinics. Maureen Cronin, Esq., Executive Director of the Midlothian Free Health Clinic, and Deborah Miller, Executive Director of the OAFC and past Executive Director of the Good Neighbor House free clinic in Dayton, Ohio, participated in the consensual validation process. Both experts had a working understanding of the proposed research. I presented the clinic experts with the proposed list of qualitative questions and asked them to review the questions for readability, understandability, clarity, appropriateness to free clinics, and content validity.

Each of the clinic experts provided feedback. Ms. Cronin constructively suggested splitting three different questions into two parts in order to further clarify the intent of the questions. Ms. Miller suggested changing multiple words to limit the scope of the questions. Each expert thought that the panel of questions presented addressed the operational issues of a free clinic.

After revisions to the questions were made, each expert agreed to the changes and consensus was achieved (Appendix F).

I conducted structured interviews utilizing open-ended questions with key personnel from each clinic. The interviews took place at each clinic or at a location of convenience. Individual interviews were the preference, but group interviews were conducted if necessary. The interviews did not exceed 30 minutes in length and were audio recorded. Individuals choosing not to be audio recorded were given a copy of the questions and were afforded the opportunity to provide written answers.

The executive director, medical director, board chair or other board member, and clinical operations director were identified as key personnel to interview. I chose these personnel because of their unique role in both the operations and administration of free clinics. The positions they held allowed them to analyze the present needs of the clients and to participate in future strategic planning, making them uniquely qualified to assess the clinic's fidelity to the CCM. A predetermined list of interview questions (Appendix F) and a sequential format was employed to ensure consistency across all cases and to develop data that allowed cross comparison among clinics (Seidman, 2006; Yin, 2011). The questions developed for this study addressed each of the six constructs of the CCM. The interviews were audiotaped and transcribed. In addition to the interviews, other qualitative evidence collected included direct observation and document review (Appendices K & G). The use of documents and observation allowed me to corroborate the evidence collected with information from the interviews. These forms of evidence may also lead to new discoveries that require investigation for use in the research study (Yin, 2009).

The use of direct observation as part of the evidence collection during the multi-case study provided contextual meaning to corroborate other evidence. For example, watching the process a nurse uses for conducting phone follow-up consultations and the processes used in education with diabetic clients corroborates the system redesign construct of the CCM.

Validity for my case study research was achieved through a variety of processes. For example, the documentation process established a case study protocol defining specific procedures and the order in which they were carried out. Creating a case study database of data collected from each case allowed for more accurate analysis and comparison (Yin, 2009). The accuracy of my transcribed audiotapes, cross-checking of coding, and member checking of information all helped establish the credibility and validity of my data (Creswell, 2009; Stake, 2006; Yin, 2011). I used triangulation to verify data from multiple sources to build a more comprehensive understanding of the phenomenon (Stake, 2006).

Procedure for Recruitment, Participation, and Data Collection

A list of potential participants for the study was obtained from the member list on the publicly available OAFC website.

After IRB approval, I initially contacted executive directors from the identified clinics by letter of invitation via email. Non-responders were sent a second email after 10 days as a reminder. When potential participants were still non-responders after 20 days, I placed a phone call to the clinic contact person. Those agreeing to participate were sent part one of the informed consent containing information to allow participants to make an informed decision. The risks and benefits of the study were disclosed as well as contact information and time frames. The informed consent included assurances that participation is voluntary and identities would be kept confidential.

Once clinics responded affirmatively to part one of the informed consent, they were (e-)mailed a packet containing the ACIC survey and the additional demographic survey. Participants were given three weeks to complete the survey and return all information. Clinics received an email reminder of the deadline at the two-week interval. Clinics not returning their survey within the three-week window received an additional email reminder. I then then entered survey and demographic data into a Microsoft Excel spreadsheet and exported to a Statistical Package for the Social Sciences (SPSS). Clinics not falling into the top three or bottom three in the ACIC survey were excluded from further analyses.

For those clinics falling into the top and bottom three on the ACIC survey, I sent an additional email to the executive director notifying them of their status. The top and bottom three clinics were determined by the results of the survey. The survey consisted of six construct sections and one integration section for a total of seven sections. Each section varied from three to six components to be scored. Each component was scored on a Likert scale of 0-11. The higher the score for each component, the more compliant that component is to the CCM. An average for each section was calculated as well as an average of all seven sections to provide an overall average score per clinic, thus allowing a numerical rank to be established for each participating clinic. The qualitative data was collected at the site of the six free clinics involved in this portion of the study. I gave additional options for scheduling an onsite visit aimed at meeting their convenience. The intent of the onsite visit was to collect all the data outlined for the qualitative portion in one visit lasting one day for each site. Prior to the visit, clinics were given a list of documents to be reviewed in order to be prepared. Follow-up communications were necessary for this portion of the study and took place via internet or phone communication. This portion of the study was intended to take approximately six weeks to complete visits and data collection.

Quantitative Data Analysis

The analysis of the quantitative data employed Microsoft Excel software and Statistical Package for the Social Sciences (SPSSv20). Prior to any analysis taking place, I checked all data for completeness and order. No errors were found; I checked the original source to ensure accuracy. Corrections of all errors must be completed to ensure validity (Fowler, 2009). All fields should be complete and data should be within the scoring specifications. A check and balance system was employed through all phases of data collection and data entry. If data was missing, it could be checked through reexamination of original documents to ensure its absence. If confirmed missing, the data could be treated in a variety of statistically acceptable options. Follow up with the specific clinic in an attempt to complete missing data was one option. Calculating the mean of the variable with the completed data and substituting the mean for the missing data was another option, or eliminating that clinic's data if a significant amount data was missing was also acceptable. Finally, coding the missing data as a non-response in SPSS prior to analysis was another alternative. The choice the researcher makes can depend upon the amount of missing data, the content of the data, and the origin of the missing data.

Creswell and Plano-Clark (2011) described one option in the sequential explanatory research process whereby quantitative data is collected and analyzed. The results of the quantitative analysis determine the qualitative components of the study. Qualitative data is then collected and analyzed. Integration of the qualitative and quantitative results are then integrated and interpreted to answer the overall research questions.

The quantitative data portion of the research consisted of: (a) the ACIC survey, (b) collection of clinic demographic data (Appendix D), and (c) each clinic's annual survey submitted to the OFCA (Appendix B). Descriptive statistics were used to report frequency distributions and measures of central tendency for the demographic and annual association survey data as well as each of the individual constructs of the ACIC survey. To determine the effect size (R^2) each independent variable has on the dependent variable, I conducted a backwards stepwise logistic regression. Through the process of a backwards stepwise logistic regression, independent variables were tested and removed if determined to be a weak predictor as determined by their correlation coefficient. This process determines which coefficients of the independent variables are strongest at predicting the dependent variable (Berkman & Reise, 2012; Munro, 2005; Norusis, n.d.). This process is also helpful when the sample size is small.

Qualitative Data Analysis

The qualitative portion of the study consisted of six case studies involving the three highest scoring clinics on the ACIC survey and the three lowest scoring clinics on the ACIC survey. Yin (2009) described case study analysis as one of the least developed and most difficult challenges of case study research (p. 127). The qualitative analysis involved using NVivo statistical software for coding and development of thematic groups. In addition, I used pattern matching, explanation building, and triangulation for cross-case synthesis both within group and cross-case.

Integrative Data Analysis

Lastly, the integration of the quantitative results with the qualitative results can provide inferences that answer the research questions posed for the study. Creswell and Plano-Clark (2011) suggest that meta-inferences assist in determining if the qualitative data provided more understanding of the research problem than the quantitative portion alone (p. 237). Replication logic and triangulation are other strategies used to assess the alignment of the qualitative and quantitative results (Yin, 2011). For the current study, this sequential explanatory design required that the quantitative analysis be conducted first. The results of the quantitative analysis determined the clinics chosen for the qualitative portion of the study. The qualitative portion of the study consisted of a two-tiered multi-case study series. Analysis of the qualitative portion consisted of two within case (high scoring clinics and low scoring clinics) analyses as well as a cross-case analysis comparing high scoring clinics to low scoring clinics. The final analysis showed the connection between the quantitative results and demographic characteristics of the six clinics chosen for the case studies. Additionally, the qualitative themes developed in the case studies were compared to the quantitative results to provide explanation to the identified barriers and supports present in free clinics.

Threats to Validity

The quality of any research study relies on the validity of the study. Validity is assessed in many variations in both quantitative and qualitative research (Plano-Clark & Creswell, 2008; Teddlie & Tashakkori, 2009). As a mixed methods researcher, I found the task of ensuring a high quality study to be complicated by the necessity of employing dual quality assurances to meet quantitative and qualitative standards. Triangulation or the use of multiple sources of data and procedures to both collect and analyze data is one method used in mixed methods research (Teddlie & Tashakkori, 2009, p. 27).

External validity, as defined by Yin (2009), is the domain to which a study’s findings can be generalized (p. 40). External validity is threatened in a study when: (a) the sample selection is biased or not sufficient to represent a larger population, (b) the sample is significantly different from the population, or (c) when time has elapsed so as to change the population from the outcomes of the study (Creswell, 2009; Jewell, 2011). These threats were minimized in this study by employing a methodology that accounted for the limitations associated with the sample and population of free clinics and the purposive case studies selected. Generalizations will not be made beyond the cases studied. Yin (2011) cautioned researchers that generalization in multiple case study research is not the same as case study replication. Replication logic, however, strengthens external validity garnered from the multiple case study research.

Internal validity threats exist in the experimental procedures used, the treatments provided to participants, or the experiences of the participants. Inferences to a larger population drawn from the data may be threatened if conclusions by the researcher are mistakenly drawn (Creswell, 2009). While no experimental procedures or treatments were utilized in this study, the internal threat of selection and mortality posed a minimal risk to the study. The limited time frame of the study reduced the risk of mortality. The multiple case study potion of the research employed techniques prescribed by Yin (2009) such as pattern matching, explanation building, and addressing rival explanations to strengthen the internal validity of the study.

Statistical conclusion validity is another threat to the quality of the study. The lack of adequate statistical power can lead the researcher to mistakenly state inferences about the outcomes of the data that are unsupported or false (Creswell, 2009). This threat can be accounted for by having adequate sample size and utilizing the appropriate statistical analysis procedures.

The ACIC survey, a self-reported measurement scale of fidelity to the CCM, has been primarily used as a pre-test/post-test for measuring quality improvement in healthcare delivery. In their seminal research on the ACIC, Bonomi et al. (2002)

validated the tool as responsive to changes or improvements organizations make when adopting the CCM. In this research study, the participants completed the ACIC only one time. The ACIC provided quantitative data regarding each clinic's self-reported variation in fidelity to the CCM. The ICIC, which has overseen development of the ACIC, recommends that that scoring be completed in a group consensus format.

Issues of Trustworthiness

The qualitative portion employed a case study series. Organizations were identified by their score on the ACIC survey. The case studies sought to affirm supports identified by clinics as contributing to high fidelity and barriers identified by clinics as contributing to low fidelity. Qualitative data was gathered via interviews, observation, and documents. The term trustworthiness first described by Lincoln and Guba (1985) refers to quality issues related to qualitative research (Teddlie & Tashakkori, 2009). Four indicators of quality were established for qualitative research: (a) credibility, (b) transferability, (c) dependability, and (d) confirmability. These terms and the processes to evaluate them were established to legitimize the validity of qualitative research as an alternative to quantitative research. Credibility in qualitative research is the equivalent of internal validity in quantitative research. Likewise, transferability equates to external validity, dependability equates to reliability, and confirmability equates to objectivity in quantitative research (Plano-Clark & Creswell, 2008).

The processes used in establishing trustworthiness have evolved over time. Original concepts of prolonged engagement, persistent observation, triangulation, member checks, and thick descriptions are still in use today. Qualitative researchers have established preferred techniques to enhance the quality of each concept of trustworthiness. These processes have augmented over time. Techniques used with credibility, the analogue of internal validity, include prolonged engagement, persistent observation, triangulation, member checks, negative case analysis, pattern matching, explanation building, and the use of logic models. Thick description and replication logics are the recommended techniques to establish transferability. Dependability, the equivalent to reliability, uses dependability audits and with case studies, case study protocol and replication logic. Interrater reliability and intercoder agreement are two quality measures used in quantitative and qualitative research. The premise of each measure is to determine the level of agreement or consistency among multiple people scoring the same data. Finally, confirmability uses the technique of a reflexive journal and confirmability audits (Creswell & Plano-Clark, 2011; Plano-Clark & Creswell, 2008; Teddlie & Tashakkori, 2009; Yin, 2009).

The methods I employed to conduct the case studies ensured trustworthiness of the data and subsequently the analysis or outcomes. Using stringent data collection and analysis of the quantitative data made certain that I properly selected the clinics for the case series study. The methods I chose for data collection—interviews, documents, and observation—represent diversity sufficient to capture the data necessary for triangulation and pattern matching. In addition, the use of case study protocol and replication logic aids in dependability. The analysis of the data using qualitative software and established analysis techniques assisted in establishing credibility.

Ethical Procedures

Approval from the Walden University Institutional Review Board (IRB) was obtained prior to any research data collection. The Walden IRB approval number was 12-18-14-0081479. In addition to IRB approval, all participants voluntarily signed an informed consent.

The purpose of the IRB is to ensure that the research proposed by the Walden University student is in compliance with all ethical and legal regulations set forth by the University and the Federal Government. Approval of an IRB application is evaluated on the study’s benefits as compared to the risks involved. Upon approval of the IRB application, securing the informed consent was the next step in the process of recruiting participants.

The process of obtaining informed consent centered on three main concepts: (a) the participant is provided with the information necessary to make an informed decision; (b) the participant understands the information provided; and (c) the participant’s decision to be involved is voluntarily made. The informed consent provided the purpose of the study, the expected duration of the study, and a description of the procedures. Additionally, the informed consent outlined any reasonable risks and potential benefits to the participant. The participants were assured their identities would remain confidential at all times and that all data collected by the study would be secured in a locked file cabinet in the locked office of the primary investigator. Any information or data stored on a computer was password protected. Data will be kept for a minimum of five years with the investigator, prior to being destroyed. The primary researcher and individuals associated with the student's dissertation committee at Walden University will have access to the data. The potential for other individuals to have access to data may exist. Confidentiality agreements were signed by anyone other than this researcher or Walden University representatives that may have exposure to the data (Appendix I). Finally, the informed consent provided a statement that participation in the research was totally voluntary and the subject may refuse to participate or withdraw from the study at any time without any penalty, loss of benefits or reprisals. Contact information of the researcher was provided to participants.

To avoid any conflict of interest, I excluded the clinic with which I am professionally associated from the study. No incentives were used in the study. Participation was strictly voluntary, and I have only informal association with prospective participants. Once the study is completed and the dissertation approved, each clinic will receive an executive summary of the study detailing the results.

Summary

Chapter 3 addressed the methodology used in the study. The chapter began with an introduction to the chapter followed by a description of the setting in which the research took place. An explanation of the mixed methods sequential explanatory design, as well as the rationale for the design was discussed. The role of the researcher and issues of conflict of interest and researcher bias were addressed. The instrumentation tools were explained for both the quantitative and qualitative portions of the study. The use of ACIC survey established a baseline score reflecting fidelity to the CCM. The use of multiple case studies confirmed or refuted the quantitative results portion of the study. A variety of quantitative statistical analyses was used to answer the research questions. The qualitative analyses sought to provide depth and understanding to the research questions. Issues of validity and trustworthiness were addressed and ethical concerns relating to the IRB process and informed consent were investigated. The plan as outlined in Chapter 3 allowed for in-depth analyses of the results in Chapter 4.

In Chapter 4, the quantitative data collected is analyzed to examine their relationships to ACIC scores. Clinics recording the highest scores and lowest scores on the ACIC survey were then invited to participate in a case study series. Case descriptions were developed for each group. Interpretation of the data appears in Chapter 5 of this study.

Chapter 4: Results

Introduction

The purpose of this sequential explanatory mixed methods study was to: (a) determine the level of fidelity by Ohio free clinics to the six key constructs of the CCM, (b) define the correlational relationship between demographic variables (independent) and the Assessment of Chronic Illness Care (ACIC) survey scores (dependent), and (c) conduct a two-tiered design multiple case study explaining the supports present in high ranking clinics and the barriers low ranking clinics experience.

The qualitative research questions for this study were:

> RQ4: What supports are present at Ohio free clinics with high ACIC scores that allow them to have a greater fidelity to the CCM?
>
> RQ5: What barriers exist that prevent Ohio free clinics with low ACIC scores from achieving higher ACIC scores.

This chapter is organized into six sections. In the first section, I discuss the setting. The second section includes the demographics of the participants. In the third section, I explain the data collection process. The fourth section reports data analysis of the quantitative data and follows with the two-tiered case study qualitative data. The fifth section includes the evidence of trustworthiness. Finally, the sixth section summarizes my answers to the research questions.

Research Setting

Implementation of the mandatory participation regulation of the Affordable Care Act (ACA) began in January 2014. The chaos, confusion, and delays associated with the initial enrollment process led to national criticism and skepticism among those whom the Act was intended to assist. The Supreme Court decision that allowed states to individually decide to offer Medicaid expansion to its residents only further complicated the health care picture at the time. Ohio was one of 31 states that opted to participate in the Medicaid expansion portion of the ACA. Currently, 19 states have declined to participate (Kaiser Family Foundation, 2015).

The changes occurring at both the national and state levels regarding access to health care affected all clinics in the OAFC. Clinics have experienced a loss of clientele over the past year (OAFC, 2015). The greatest impact was felt in the loss of clients served by free clinics due to expanded eligibility for Medicaid services. These decreases were so substantial in some cases that five Ohio free clinics have closed in the past two years. The remaining free clinics have had to re-examine their mission, their funding sources, and their clientele to determine sustainability in their path moving forward. The free clinic landscape has been further complicated by the shortage of or refusal of primary care doctors to accept the influx of previously uninsured patients who now have Medicaid insurance coverage (OAFC, 2015). The subsequent outcome of these changes has been that many free clinics have started the process of attaining Medicaid certification for provider status, thereby allowing the clinics to bill Medicaid for services.

This approach has put many clinics in jeopardy of losing their OAFC member status due to member restrictions on billing (Appendix C).

These tumultuous times in the Ohio health care landscape led many free clinics to decline participation in this research study. The undetermined status and organizational changes many clinics were undergoing prohibited them from having a clear clinical focus on chronic disease management.

Data Collection

Data was collected in a sequential manner whereby in Phase 1 of the study, I collected and analyzed the results of the ACIC survey and the additional demographic information. The results of Phase 1 determined the participants of Phase 2 of the study.

Quantitative Data Collection

Beginning January 5, 2014, I emailed approximately 51 participant invitation letters to the executive directors of the 51 member clinics of the OAFC as outlined in Chapter 3. Initial response was very low with only 10 clinics responding. Three clinics agreed to participate and seven declined. Follow up invitation emails were sent at 10 days and at 30 days. I followed up by phone with nonrespondents after another 30 days. Over the next six months, a total of 13 (24%) out of the 51 clinics consented to participate in Phase I of the study. Executive directors responding positively to participate then received an electronically sent, informed consent document. After electronically consenting, clinics received two surveys via email. Executive directors completed and returned all data electronically. All 13 participating clinics provided complete data sets for the ACIC survey (Appendix A) and the additional demographic survey (Appendix D). Executive directors also provided their most recent annual OAFC statistical survey (Appendix B). Data were de-identified and entered into a Microsoft excel spreadsheet. The Phase 1 data collection period was extended beyond the outline provided in Chapter 3 due to the circumstances referred to in the previous setting section.

Qualitative Data Collection

A two-tiered case study series comprised the qualitative portion of the study. I chose a case study methodology in order to gain an understanding of the complex social phenomena of free clinics. Case studies answer the questions of *how* and *why* while capturing evidence from a variety of sources in a natural environment (Yin, 2009).

Six clinics were identified for Phase 2 of the study. The three clinics identified as having the highest mean scores on the ACIC survey and the three clinics identified as having the lowest mean scores on the survey were chosen to participate in the case study phase of the study. All six clinics positively responded to participate in Phase 2 and received electronically an informed consent for all Phase 2 participants as identified in Chapter 3.

Qualitative data collection consisted of three methods: (a) interviews with key clinic personnel, (b) review of evidence supporting documents, and (c) observation of three key processes.

Interviews took place at all six clinics with key personnel identified in Chapter 3. A total of 20 interviews were conducted. I conducted and audiotaped the interviews in private offices and conference rooms. The focused interviews were structured according to the established questions in Table 2. I extended opportunities for elaboration and explanation to the interviewee and for follow-up questions from me. I made field notes during the interviews to capture subjective insights and highlight the importance of particular responses.

Table 2

Qualitative Interview Questions

1. What criteria do you use to base your hours of operation?
2. What barriers limit your hours of operation?
3. What supports enable your hours of operation
4. How do you recruit/attract professional health care providers? (Dr, RN, etc)
5. How does the clinic assure for continuity with inconsistency in staffing?
6. Does the lack of particular HCP disciplines prevent you from providing certain services?
7. How has your annual operating budget influenced your service delivery model?
8. Does your clinic dedicate specific operational money for chronic disease management?
9. What health information technology does the clinic use?
10. How has it been integrated into your service delivery model?
11. What processes have been implemented to accommodate to your volume of patient visits?
12. How does staff provide input into operational issues, such as scheduling?
13. How is the service delivery model different / same for chronic disease patients as acute episodic patients?
14. How has the clientele you serve changed over time?

Documents providing evidence that supported elements of CCM fidelity were reviewed during site visits. Field notes included a description of the type of document and how it supported CCM fidelity. The particular ACIC construct the document supported was also noted. The documents listed covered all six constructs of the model.

Table 3 lists the documents requested at each clinic. Clinics were provided the list of documents ahead of the site visit in order to prepare them for review.

Table 3

Document Review

Evidence Item
• Mission, Vision and Values Statements
• Policies and Procedures
• Strategic Planning
• Self-Assessment
• Board Minutes
• Process Improvement Team
• Use of outside Consultants including OAFC/NAFC
• Community Collaboratives Established
• Clinical Outcomes
• Operational Outcomes
• Patient Input and Feedback
• Resources Needed for Operations of the Clinic
• Use of Protocols/EBM
• Patient Education Instructional and Written
• Use of Informational Technology

Observation of three key processes of the CCM—Delivery System Design, Self-Management Support, and Clinical Information Systems—took place at each site visit. I followed an observation protocol (Appendix K). Field notes involved both descriptive and reflective notes.

Data Collection Summary

Data were collected from 13 clinics during Phase 1 of the study. Data included the ACIC survey, additional demographic information, and the OAFC annual statistical report. Phase 2 of the study involved the three clinics with the highest mean on the ACIC survey and the three clinics with the lowest mean score on the ACIC survey. Data collected from these six clinics included interviews, document reviews, and observations.

Data Management

The management of data collected during this study was addressed in a confidential and secure manner. The participants' privacy and anonymity were not compromised. All requirements of the Walden IRB for the preservation of data will be observed for the time period of five years as all data will be kept in the secure (locked) file cabinet and home office of the researcher.

Quantitative Data Management

All forms returned electronically from the executive directors during Phase 1 of the study were complete with no missing data. I downloaded the data onto a removable disk used exclusively for this research study. The disk required password access to enter the database. The forms were checked for completeness, and the data were then entered into an Excel spreadsheet. All data were then erased from the email section of the computer and the removable disk became the permanent repository for the study data.

Qualitative Data Management

The data collected from the qualitative portion of the study included audio taped interviews that were transcribed by a local transcriptionist who signed a confidentiality agreement (Appendix I), and the tapes were labeled in such a manner that de-identified both the clinic and the participant. The transcriptionist returned the transcribed tapes and sent the transcripts electronically via email; I then downloaded the transcripts and stored them on the removable disk.

Field notes collected from the document review and observation protocol were secured in each clinic's assigned folder located in my home office.

Data Analysis

Quantitative Demographic Data Analysis

Prior to formal analysis, I examined the data set to ensure the accuracy and completeness of the data entry to determine the appropriateness of the proposed analyses. No missing data were found.

A summary of the descriptive statistics collected from the additional demographic survey (Appendix D) are provided in Table 4. Participating clinics showed a wide range in years of operation with four (*n* = 31%) in operation for less than 10 years and the oldest participating clinic in existence for 44 years. The range in variation carried through in average weekly hours of operation with four (*n* = 31%) clinics operating 10 hours or less per week while 5 (*n* = 38%) clinics operated in excess of 35 hours per week. Annual operating budgets also reflected extreme variation with six (*n* = 46%) clinics operating on a budget of less than $100,000 while three (*n* = 23%) operated on a budget in excess of $500,000. One clinic had an annual budget in excess of $1,000,000.

Participating clinics represented urban, suburban, and rural settings. The urban setting had the highest representation with 7 (*n* = 54%). Rural clinics had the second highest representation with four (*n* = 31%) and suburban clinics had the lowest representation with two (*n* = 15%). Technology integration was fairly consistent among the sample with a mean score of 3.6 and standard deviation of (1.1) in responses to the eight questions asked. All clinics positively responded that they used some form of computer-based health care information technology in the operation of the clinic (Question 5). Twelve (*n* =92%) of the clinics responded they used some form (partial/full) of an electronic medical record (Question 9), while 10 (*n* = 77%) indicated they keep disease registries of patients with chronic disease (Question 11).

Table 4

Clinic Demographics

Variable	Mean (*SD*) *N*=13	Median (25%, 75%)
Years of operation	16.3 (10.7)	11.0 (9.0, 21.0)
CCM knowledge	0.5 (0.5)	1.0 (0.0, 1.0)
ACIC knowledge	0.2 (0.4)	0.0 (0.0, 0.5)
Geographic setting	1.7 (0.9)	1.0 (1.0, 3.0)
Average weekly hours of operation	22 (15.9)	17 (7.0, 40.0)
Operation budget ($)	328,461 (348193)	169,000 (64,000, 598,500)
Technology integration	3.6 (1.1)	4.0 (3.0, 4.0)

Table 5 provides a summarization of the ACIC survey (Appendix A) from the participating clinics. Six (*n* = 46%) clinics reported no previous knowledge of the chronic care model and only 3 (*n* = 23%) clinics reported knowledge of the ACIC survey.

The ACIC survey consisted of six construct sections and one integration section for a total of seven sections. Each construct varied from three to six components to be scored. Each component was scored on a Likert scale of 0-11. The higher the score for each component, the more fidelity that component had to the CCM. A mean score for each construct was calculated as well as a mean score for all seven constructs. The overall mean score per clinic allowed a rank order to be established for each participating clinic.

Construct 2 of the ACIC (Community Linages) and ACIC 1 (Organization of the Health care Delivery System) reflected the highest fidelity to the CCM while ACIC 7 (Integration of the Chronic Care Model Components) and ACIC 6 (Clinical Information Systems) reflected the lowest fidelity to the model. The overall mean of the sample for the seven sections was 5.9 with a *SD* (1.2).

The Improving Chronic Illness Care project (2012) reported in their completing and scoring the ACIC scores "between 3 and 5 = basic support for chronic illness care" while scores "between 6 and 8 = reasonably good support for chronic illness care." (para. 4)

Table 5

ACIC survey results

Category	N	Mean (SD)	Rank
ACIC 1	13	6.6 (1.1)	2
ACIC 2	13	7.2 (1.6)	1
ACIC 3	13	5.7 (1.4)	4
ACIC 4	13	5.2 (1.5)	5
ACIC 5	13	6.4 (1.4)	3
ACIC 6	13	5.04 (1.7)	6
ACIC 7	13	5.02 (1.8)	7
ACIC total		5.9 (1.2)	n/a

Table 6 illustrates each individual clinic's mean ACIC data and rank order.

Table 6

Individual clinic scores

	Mean ACIC Score	Rank
1	5.8	7
2	6.4	4
3	6.8	3
4	5.6	8
5	4.1	13
6	5.2	10
7	8.6	1
8	6.1	5
9	5.9	6
10	5.6	9
11	4.4	12
12	4.9	11
13	7.3	2

The three clinics with the highest ACIC mean score and the three clinics with the lowest mean score were selected to participate in Phase 2 of the study. The Phase 2 portion consisted of a two-tiered design multiple case study series. Phase 2 of the study aimed to identify the supports that allowed clinics to adopt the key constructs of the CCM and identify barriers in clinics scoring low in fidelity to the key constructs of the CCM.

Quantitative Research Questions

Since a backward stepwise linear regression was proposed, I performed assumptions for regression analysis to ensure violations would not affect the results. Technology integration, annual operating budget, and weekly hours of operation were the primary variables of interest as predictor variables and the average ACIC score as the outcome variable.

I assessed the variables of interest for outliers by creating *z* scores and verifying that none of the standardized scores were significant at the $p < 0.001$ level, which corresponds to a z score of 3.29. The assumption of linearity was tested with simple scatter plots and found to display mild to moderate violations at the univariate level. Normality was assessed by analyzing skewness and kurtosis statistics for each variable of interest and dividing by the standard error of each statistic using a ratio of 3:1 as the threshold of significance. None of the variables of interest were found to be significant. I further assessed normality using the Shapiro-Wilk test for each variable of interest. I employed a significance value of $p = 0.01$ in accordance with the recommendation of Tabachnick and Fidell (2012) for small sample sizes. All variables were found to be nonsignificant with $p > 0.01$.

At the multivariate level, bivariate scatter plots of the standardized versus the predicted residuals were observed to assess linearity, normality, and homoscedasticity.

The scatter plot demonstrated that the residuals appeared linear and normally distributed with mild to moderate violation of homoscedasticity.

In addition, the predictor variables were tested to determine if multicollinearity might be a problem. Each of the proposed predictor variables—(a) technology integration, (b) annual operating budget, and (c) weekly hours of operation—were tested for multicollinearity through an analysis of the variance inflation factor (VIF). I employed an acceptable threshold of 5 for VIF. No VIF for any combination of IVs exceeded 2.5, suggesting that multicollinearity would not impact this data set.

The multiple linear backward stepwise regression was run with the ACIC average as the outcome variable and (a) weekly hours of operation, (b) annual operating budget, and (c) technology integration as predictor variables. The probability of the predictor variables was entered at 0.05 and removed at 0.10. Weekly hours of operation and technology integration were removed from the model, and annual operating budget was the final model. Annual operating budget does not significantly predict ACIC average, $R^2 = 0.259$, $R^2_{\text{adj}} = 0.192$, $F(1,11) = 3.84$, $p = .076$. In follow-up analyses, I ran individual single entry regressions of both weekly hours of operation, $R^2 = 0.103$, $R^2_{\text{adj}} = 0.021$, $F(1,11) = 1.26$, $p = .286$, and technology integration, $R^2 = 0.247$, $R^2_{\text{adj}} = 0.179$, $F(1,11) = 3.62$, $p = .084$, and found that neither variable significantly predicted ACIC average. A significant limitation of this analysis is the lack of appropriate sample size to perform multiple regressions. In regression modeling, different authors have reported several general guidelines for adequate statistical power. A simple rule of thumb is 10-15 cases per predictor variable; however, Green (1991) proposed $N \geq 50 + 8m$ where m is the number of predictor variables. With only 13 cases for returned surveys, an attempted regression model with three predictors is inappropriate; therefore the results should be regarded with caution.

In an attempt to better understand these data, I performed a simple correlation between the variables in order to examine the simple relationships between the predictor variables.

RQ1. Do the weekly average hours of operation at Ohio free clinics significantly contribute to increased compliance with the CCM?

$H_0$1: The weekly average hours of operation do not significantly predict compliance with the CCM at Ohio free clinics.

H_a1: The weekly average hours of operation do significantly predict compliance with the CCM at Ohio free clinics.

Correlation analysis of the data demonstrated a weak relationship between the weekly hours of operation and ACIC average adherence. The Pearson correlation value for this analysis was $r = 0.320$ with a two-tailed *t*-test significance value of $p = 0.29$.

RQ2. Does the size of the annual operating budgets of Ohio free clinics significantly contribute to increased compliance with the CCM?

$H_0$2: The size of the operating budget does not significantly predict compliance with the CCM at Ohio free clinics.

H_a2: The size of the operating budget does significantly predict compliance with the CCM at Ohio free clinics.

Correlation analysis of the data demonstrated a weak relationship between the annual budgets and ACIC average adherence. The Pearson correlation value for this analysis was $r = 0.509$ with a two-tailed *t*-test significance value of $p = 0.08$.

RQ3. Does the amount of electronic health record integration significantly contribute to increased compliance with the CCM at Ohio free clinics?

H_03: Electronic health record integration does not significantly predict compliance with the CCM at Ohio free clinics.

H_a3: Electronic health record integration does significantly predict compliance with the CCM at Ohio free clinics.

Correlation analysis of the data demonstrated a weak relationship between the electronic health record integration and ACIC average adherence. The Pearson correlation value for this analysis was $r = 0.497$ with a two-tailed *t*-test significance value of $p = 0.08$.

Correlation values using Pearson's correlation coefficient of all three IVs to the ACIC were weak and non-significant. Since all three demonstrated weak correlational values and nonsignificance, I analyzed the relationship of the three IVs to each other. All three variables (hours of operation, operating budget, and technology integration) showed a strong correlation to each other and were statistically significant.

Table 7

Correlation Coefficients of the Inferential Variables

Variables	1	2	3	4	5	6
1. ACIC Knowledge	1					
2. CCM Knowledge	.507	1				
3. Work Hours	-.404	-.191	1			
4. Operating Budget	-.093	-.082*	.777**	1		
5. Technology Integration	-.356	.167	.663*	.664*	1	

*Correlation significant at 0.05 level (2-tailed); **Correlation significant at the 0.01 level (2-tailed)

The variables were then analyzed non-parametrically using Kendall's tau. Results from this analysis were the same as Pearson's analysis. All three variables had a weak correlation to the ACIC scores, but all three variables were strongly correlated to each other and were statistically significant.

Qualitative Data Analysis

Thirteen Ohio free clinics participated in the quantitative phase of this mixed methods sequential explanatory research study. The quantitative phase resulted in the identification of a total of six clinics to participate in the qualitative phase of the study. Clinics with the three highest and three lowest mean ACIC scores relating to CCM fidelity were chosen. I conducted case studies on all six clinics in order to collect evidence and data to substantiate answers to my qualitative research questions. Evidence from the case studies was collected using three methods: interviews, documents, and observation. Each method provided a different source of evidence that allowed data triangulation. Information corroborated from multiple sources provides solid construct validity to qualitative studies (Yin, 2009).

Twenty in-depth interviews were conducted across the six clinics. I conducted interviews with the key personnel identified in Chapter 3. Manuscripts from the transcribed interviews were separated into two categories: low scoring clinics and high scoring clinics. Each category of interviews was analyzed separately. I coded manuscripts for key words and phrases. These words and phrases were then combined into groups. Groups with similar meanings were then joined together to form categories. Themes evolved from the bigger categories.

Clinics were given a list of potential documents (Appendix G) for review. I correlated the requested documents to the six constructs of the ACIC survey, which provided corroboration of evidence. Documents reviewed included: educational materials, statistical reports, governance documents, administrative reports, policies and procedures, and outcomes. Documents were reviewed during on-site visits, and field notes reflected the level of evidence and corroboration.

Observation protocols were used during on-site visits. In particular, I observed three processes in their natural occurrence. I detailed delivery system design, self-management support, and clinical information systems with both descriptive notes and reflective notes. These three processes also correlated with the ACIC survey and provided corroborative evidence.

Theme One - High Scoring Clinics: Progressive Vision

The theme Progressive Vision emerged in all sources of evidence in all three high scoring (HS) clinics. The theme permeated all facets of the organizations and their processes. Evidence showed that all three clinics had knowledge of the CCM and two of the three had knowledge of the ACIC survey tool. Knowledge of these instruments is imperative to advancing care for chronic disease management (ICIC, 2012). Scores for the ACIC from the three HS clinics showed above mean scores for the majority of the seven ACIC constructs. Clinic A was above the mean in all seven categories while Clinic B was above in six out of seven and Clinic C in four out of seven. Groups and categories supporting the theme of Progressive Vision are represented in Figure 4.

Qualitative data collected from interviews is represented in Figure 4. The smaller circles represent groups that were generated from similar code words. Groups that represented similar meaning and importance were organized into categories. These are represented by larger circles. The theme Progressive Vision emerged from the categories and is represented by the largest circle.

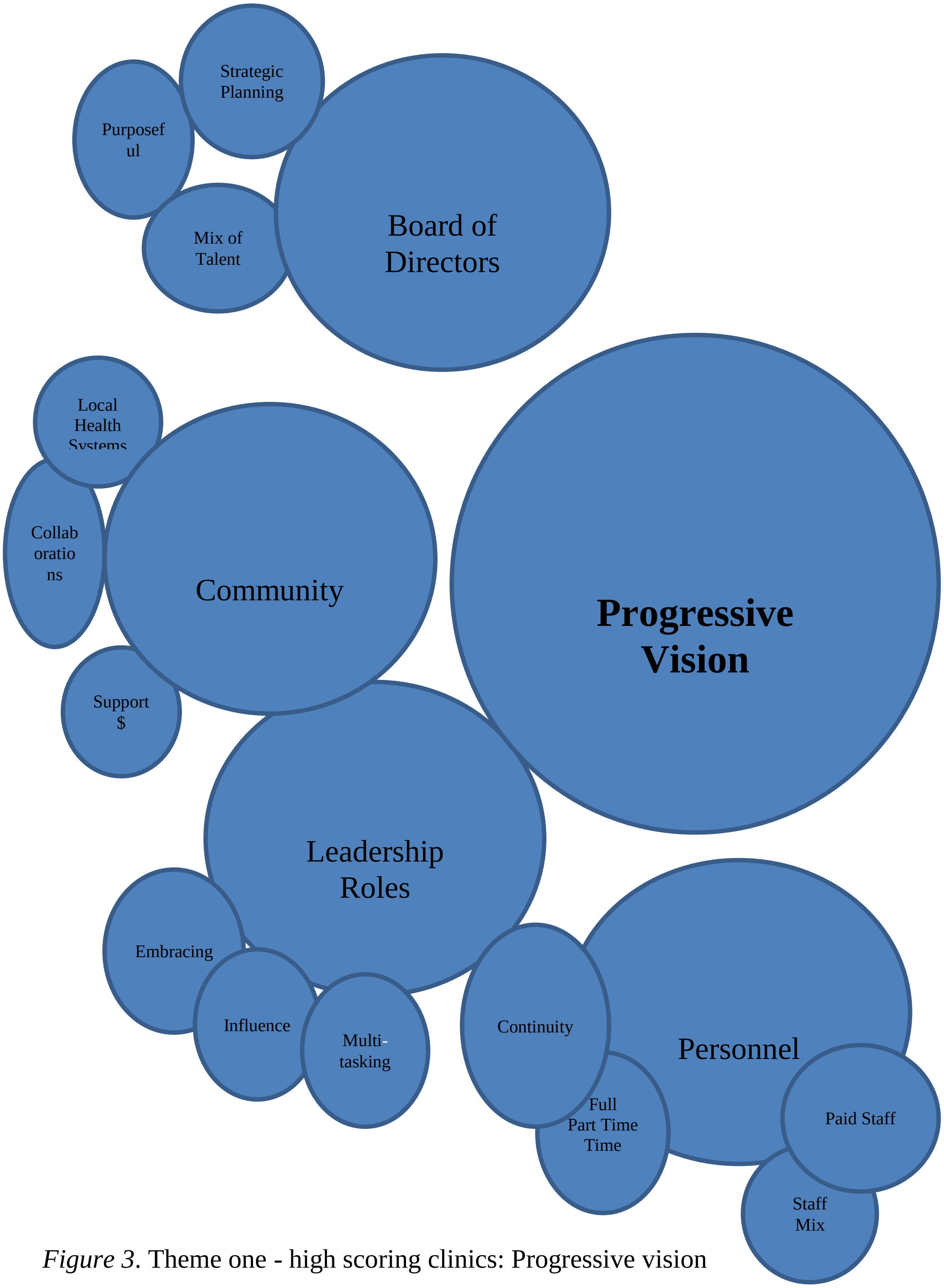

Figure 3. Theme one - high scoring clinics: Progressive vision

High scoring Clinic A. Participants from Clinic A were enthusiastic when discussing their clinic's future as evidenced by the following remarks.

Mary, A3:

> We continually have challenges before us but the leadership from our Board and executive staff combined with the dedicated work of our staff and volunteers allow us to identify and strategize our path forward while maintaining the mission and vision or our clinic.

John, A2:

> This clinic has been around awhile and we have seen many changes in the health care landscape. The access problem still exists, just not to the degree it did before. Our challenge now is to figure out our place in the landscape with all the changes the ACA is bringing.

These comments reflect the reality that change is inevitable both in the broad health care arena and in free clinics. Anticipating change and proactively working to adapt was evident in the strategic plan document of the clinic. The document laid out a set of strategies to be adopted and enacted over the period of 12 to 18 months. While strategic planning was not new to the organization, the need to shorten the time between plans and the speed to enact the plan has changed.

Mary, A3:

> When I first came to the clinic we would create a strategic plan with a 5-year lifespan, then it became a 3-year lifespan and now we are operating on a 1-2-year

> plan. The scope of our strategic plan hasn't changed much but implementing the plan has become more challenging given our time projections.

The challenge to generate information (data) in a timely manner to keep the clinic operating efficiently and effectively has resulted in process changes. Observation of the clinic's use of health information technology (HIT) reflected an efficient process. Observation of HIT use revealed a variety of reports for statistical tracking and efficient patient scheduling that allowed health care providers access to view information in real time. The electronic medical record provided HIPAA compliance for confidentially and security. Providers were able to track patient care and follow up on orders. Staff was able to communicate with outside providers via the HIT system, saving time and money.

Bob, A4:

> The financial investment into HIT was significant. However, we knew this was the future and that we had to jump in at some point. The difficulty is keeping current. Hardware and software seem to change so fast that as soon as we begin using something a newer, better version is coming out…. Another challenge is keeping everyone trained. We have so many volunteers working at the clinic that we have to be mindful not to overburden them with too many changes in technology.

High scoring Clinic B. The structure and operation of Clinic B provided for a progressive vision. Since its inception, the clinic's mission and vision has been to meet the needs of the uninsured. Its large contingent of volunteer health care providers ensured it had the capacity to meet the needs of this busy clinic.

Fred, B3:

> We began as a community collaboration to address a growing health care problem here. We knew this was not a temporary problem so we tried to structure it to ensure sustainability for the long haul….We've adjusted over the years but stayed true to the mission.

Clinic B also operated off a strategic plan (document) that focused in one part on building and maintaining its community collaborations. The clinic viewed its sustainability as the resources the community could provide, specifically, the volunteer manpower of health care providers and the economic resources provided through donations and grants. The involvement of the local health care systems was evident in board representation (document).

Sally, B4:

> The expectation in this community as a health care provider is to contribute to the overall health of the community. This clinic is an option many choose. These providers want to provide the same level of care here at the clinic that they do elsewhere. While that is not always possible, we strive to achieve that.

The large contingent of volunteer health care providers contributed a level of care to the patient that reflected current acceptable practice within published guidelines. The expectation expressed above is a quality issue often associated with free clinics. The clinical outcomes reports (documents) provided by the clinics, however, dispel the quality myth as evidenced by the effectiveness of the care provided.

Mary, B1:

> We offer a variety of educational programs to our clients. The clients often do not understand their health problem. Lifestyle adjustments to problems like diabetes need to be taught or else the medical interventions are useless. We can’t assume our clients know how to make these changes.

Clinic B made a vast array of education materials (documents) related to chronic disease available to patients. The observed process used to sign up patients for formal education classes was evident in the patient scheduling process and physician orders.

High scoring Clinic C. The third HS clinic operated on a smaller scale than the previous two clinics. While operating fewer hours per week with fewer patients, the clinic was able to achieve above mean scores in 6 out of 7 ACIC sections. These scores are attributable to the key personnel in place at the clinic.

Barbara, C5:

> This clinic was founded with a mission for this community. The dedicated work of our executive director, medical director, board, and volunteers allows us to fulfill our role in the community. Their leadership and knowledge provide the right direction we need to be heading. We feel we are really making a difference in our patient’s lives.

That difference was evident in the process patients experienced at Clinic C. The medical staff completed thorough assessments of the patients to identify risk factors affecting their health (documents). These assessments then become the plan of care (documents) for the healthcare providers. Observation of the scheduling system discovered a purposeful plan for patient visits for reassessments of lab work, pharmaceutical interventions, and compliance with educational interventions. The care provided was purposeful and directed.

Rob, C3:

> We try very hard to involve our patients in their care. By that I mean they have to take some ownership in trying to make themselves healthier. Pills alone don't make every problem better. Because we're a smaller clinic we have more flexibility to give our patients the time and attention needed to educate them about their problems. Not only are we their health providers but we're their health coaches as well.

Clinic C, similar to Clinics A and B, relied on community volunteers for staffing the clinic. However, Clinic C used a considerable number of resources to provide paid positions (document) to key providers in the clinic. This delivery model has proven to be effective at this clinic.

Sue, C2:

> It's our philosophy that in order to provide high quality care to these patients we need to have as much continuity as possible. It's difficult to make progress if

> every time they come to the clinic they are seeing different providers. Our goal is to have consistency with our staffing by having them see the same patients as much as possible.

This model differed from the way most free clinics operate. While this may not be feasible in larger clinics due to excessive volume, Clinic C has developed a model in their community that has been working (ACIC scores). I observed that this model required more time for the scheduling process due to matching patient and provider.

Theme Two - High Scoring Clinics: Patient-Centered Care

The second theme to emerge from the data and evidence was that of patient-centered care. The initial impetus for the free clinic phenomenon was to provide safety net access for the uninsured. The number of individual’s uninsured nationwide has dramatically decreased over the past two years. The implementation of the ACA with its marketplace mandate and Medicaid expansion has been the main contributor to this decrease. The free clinic movement has matured from providing access to primary care to a more comprehensive medical model. Health care providers who work in the insurance driven health care market comprise the majority of the volunteers who work at free clinics. Their experiences with health care changes in the private market have slowly migrated to the free clinic model. As free clinics continue to adapt to health care changes, they have begun to provide more patient-centered care. The Patient Centered Medical Home (PCMH) model closely aligns with many standards of the CCM model. Figure 5 represents the groups and categories that emerged to form this patient-centered care theme within the HS clinics.

Qualitative data collected from interviews were represented in Figure 5. The smaller circles represent groups that were generated from similar code words. Groups that represented similar meaning and importance were organized into categories. These are represented by larger circles. The theme Patient-Centered Care emerged from the categories and is represented by the largest circle.

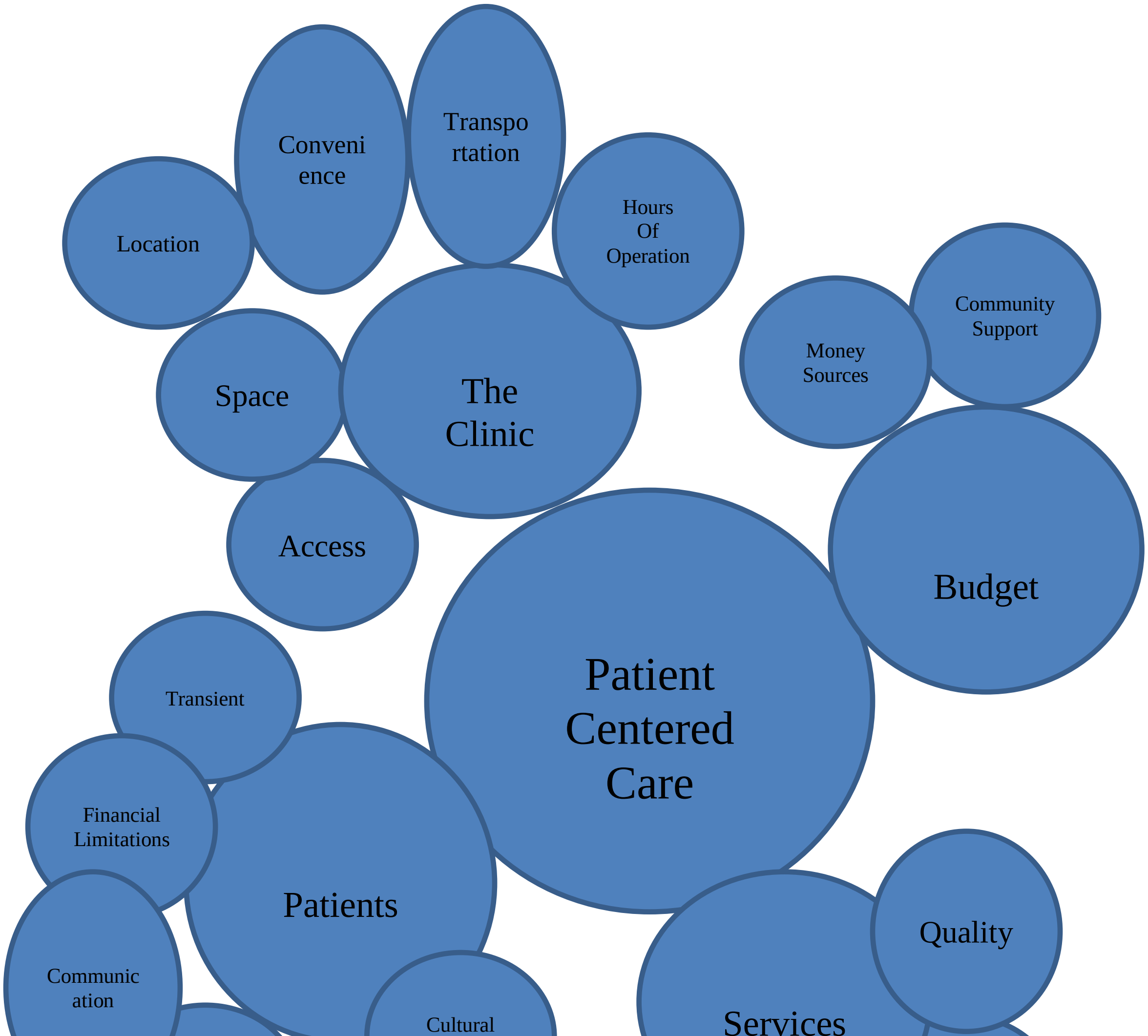

Figure 4. Theme two - high scoring clinics: Patient centered care

High scoring Clinic A. Quality assurance (QA) processes were one facet of patient-centered care. Determining what services must be provided to patients and whether they are effective are two cornerstones of any QA program. Clinic A incorporated its HIT to track data better (documents), which assists in analyzing if the clinic is meeting the needs of its patients. Observation of reports generated for disease registries, patient profiles for age, ethnicity, primary language, and income all provided information that allowed for more educated decision making.

Bob, A4:

> We have a schedule of reports that we run weekly, monthly, quarterly, and annually that give us snapshots of who we are treating. When fluctuations become trends, we know we need to act. We've added and dropped services over the years based on this information.

Quality assurance programs can also identify areas of deficit that may need to be remedied.

Mary, A3:

> We strive for timely provision of our services. At times, we become backlogged in certain areas. For example, sometimes we have longer than acceptable waiting lists to see a specialist. When this problem becomes persistent, we have gone out and recruited more specialists to alleviate it.

High scoring Clinic B. Clinic B demonstrated patient-centered care by meeting the many needs of the patients they serve. Clinic B, an urban based clinic, served a diverse cultural population. The ability to provide care and educational material to an array of ethnicities in their native language (documents) requires resources and coordination.

Betty, B2:

> For our non-English speaking patients, we first ask if an English speaking family member can be with the patient to interpret. That's not always possible and we then need to provide interpreter services. This is an expensive service and requires much more time during the visit.

Transient and homeless individuals make up part of any free clinic clientele. These individuals present with unique challenges beyond just their health care problems. Social issues often range from lack of permanent housing to lack of food. This population may also have criminal issues or addiction and mental health issues. The process of making referrals to other community agencies more suited to helping the patient was observed.

Mary, B1:

> As a health care clinic, we are not able to address all the problems our patients have outside of their health problems. Our network of community agencies are resources to send these individuals to just as we are a resource to them for individuals with health problems.

High scoring Clinic C. Transportation is often a problem for the vulnerable population. Clinic C was experiencing high no-show/cancellation rates for clinic appointments. After tracking the problem for a period of months (documents), the clinic analyzed the problem and generated possible solutions. The observed solution outcome was collaboration with a community agency that provided transportation to the underserved.

Sue, C2:

> We try to meet the basic needs of our patients. Small things like bus tokens or agency transportation often impact a patient’s health status. Missing an appointment may mean they don’t get a prescription refilled or lab work delayed.

The mission statement of Clinic C stated that it “provide services with care and compassion” to patients (document).

Theme One – Low Scoring Clinics: Capacity Building

Low scoring (LS) clinics should be acknowledged for providing a valuable service to the communities and individuals they serve. Many are the only safety net health provider for their particular community. Two of three LS clinics were located in rural communities. The third clinic was an urban clinic that had specialized services for a small population. Results of ACIC scoring showed all three clinics scored below the mean in each of the seven categories. All three clinics reported no knowledge of the CCM or the ACIC. The major categories of staffing, resources, mission, and technology supported the theme of Capacity Building as represented in Figure 6.

Qualitative data collected from interviews is represented in Figure 6. The smaller circles represent groups that were generated from similar code words. Groups that represented similar meaning and importance were organized into categories. These categories are represented by larger circles. The theme Capacity Building emerged from the categories and is represented by the largest circle.

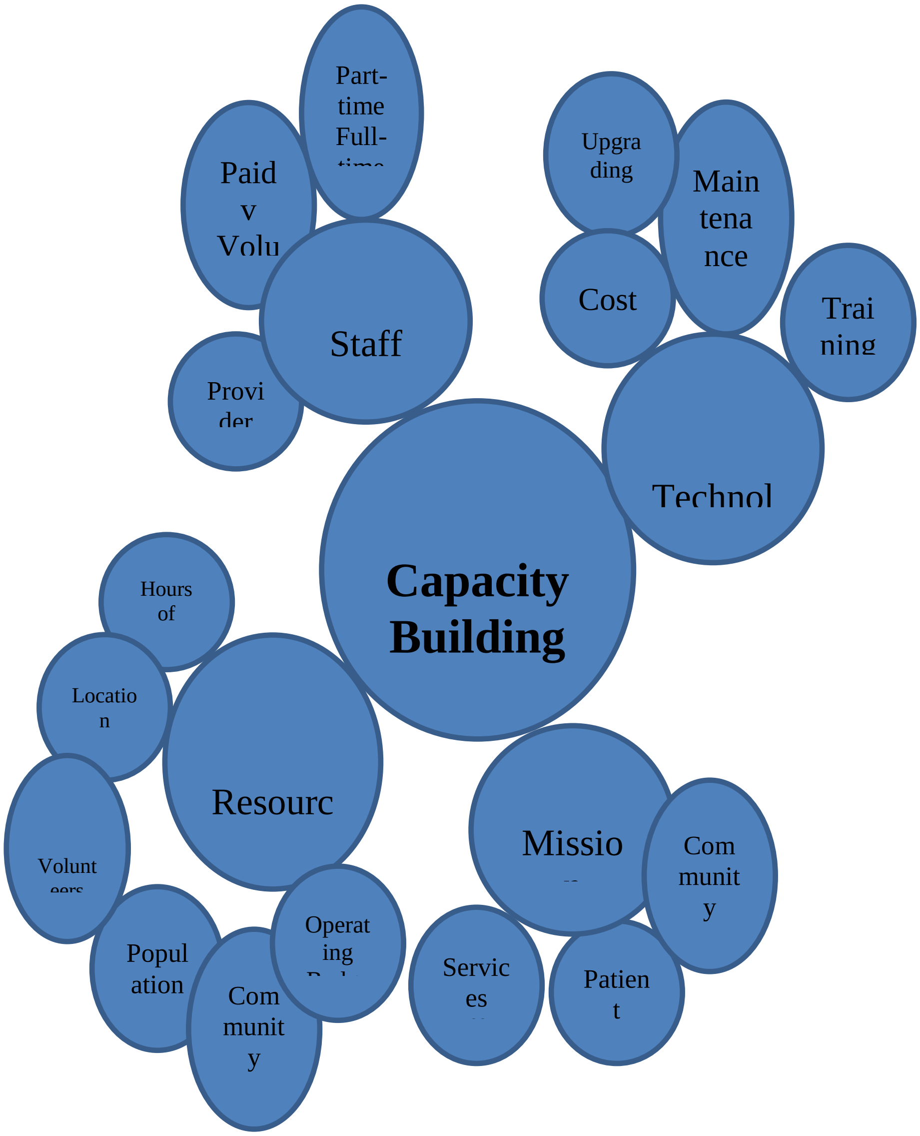

Figure 5. Theme one – low scoring clinics: Capacity building

Low scoring Clinics X, Y, and Z. Clinics X, Y, and Z were not totally devoid of the evidence and outcomes present in HS clinics. Evidence of the Patient Centered Care and Progressive Vision themes was present in the LS clinics, just on a smaller scale. The LS theme of Capacity emerged from the categories of Mission, Resources, and Staffing.

Central to all three LS clinics was the category of Mission. Mission is often described as the purpose of the organization. All three LS clinics had very specific mission statements that narrowly describe their purpose (documents). That description limits the scope of the free clinic by either population or geography or need of the community. Joe's words represent the scope of free Clinic X.

Joe, X1:

> We started this clinic to serve a specific purpose for our county. We didn't open this clinic with the vision of growing it into a large health facility. We don't have a population to support that and we don't have the medical professionals to support it either. We know our purpose.

Documents viewed at Clinic X revealed that it was a small, rural free clinic that operated primarily for the individuals residing in that county. It offered primary care medicine and a limited variety of ancillary services. It had a small paid staff of part-time and full-time employees and a small core group of volunteers. Many of the services offered at the LS clinics were provided based on the historical needs of the individuals they had served. The actual size of the clinic was another factor where all three were similar. Space was limited in the clinics, and although operations were not cramped, there was limited room for expansion of services. Two of the three clinics shared space with another agency, organization, or community service.

There was a sense of contentment in all three clinics that they were serving their mission to the community and their focus was more on sustaining their presence rather than changing, growing, or expanding.

The second common category the three LS clinics exhibited was limited resources. This category arose from groupings such as: limited fundraising capabilities, small operating budgets, few community collaboration opportunities, range of services provided, transportation, and use of technology.

Access to health services in small, rural communities differs from access to health services in large urban cities. Many of the small, rural free clinics arose out of a community awareness and sense of responsibility to assist “their own”. The needs and services required by the rural patients differ from those of patients treated at large urban clinics. While health problems such as diabetes, high blood pressure, or COPD may be similar between the two settings, the supports and social issues between the two groups may differ dramatically. Issues such as transportation, language differences, and homelessness add complexity to successfully treating those individuals.

The challenges exhibited by Clinics X, Y, and Z were many. Two of the three clinics operated on an annual budget of less than $60,000. Limited funds equates to limited services and staff. Clinics not able to assist in lab work, imaging, and pharmacy costs must rely on other community agencies and resources for that assistance if it exists.

The reality experienced by Clinics X, Y, and Z was that fewer health services were provided in rural areas as compared to large urban communities. The opportunities for collaboration with outside agencies and health systems were less available. The availability of community education classes for particular health issues such as diabetes or COPD was often non-existent.

The use of health information technology in LS clinics was observed to be significantly less than that in the HS clinics. Volume of patients and costs were two common denominators all three LS clinics cited for their minimal use of HIT.

Bill, Z2:

> The cost of purchasing software and the continual upgrades is just not a good way to spend the limited money we have. Our staff feels they can function using a paper system rather than an electronic medical record….Besides they all detest learning a new computer system.

Limited funds equates to less staff. Continuity of care is essential for chronic disease management and consistent staffing is the backbone to continuity of care. Hilda from Clinic X expressed these thoughts.

Hilda, X4:

> I feel our clinic is successful because of the caregivers we have. We all live in this community and we have been at this clinic for a long time. Our patients begin to feel like family to us. We really care about their health.

LS clinics see their size and scope more as an asset than a hindrance. Jody expressed these sentiments.

Jody, X2:

> I have been a nurse here for a long time and you learn to wear many hats in this job. I fill many roles from caregiver to educator. We give our patients very individualized care and they seem to like that. I try to keep on top of everything.

Intracase Comparisons of High Scoring Clinics

Table 8

Intracase Comparison HS Clinics

Standard	Clinic A	Evidence Present Y/N	Clinic B	Evidence Present Y/N	Clinic C	Evidence Present Y/N
ACIC #1 – Organization of the Health System	Interview Evidence	Y	Interview Evidence	Y	Interview Evidence	Y
	Document Evidence	Y	Document Evidence	Y	Document Evidence	Y
	Observational Evidence	N/A	Observational Evidence	N/A	Observational Evidence	N/A
ACIC #2 – Community Linkages	Interview Evidence	Y	Interview Evidence	Y	Interview Evidence	Y
	Document Evidence	Y	Document Evidence	Y	Document Evidence	Y
	Observational Evidence	N/A	Observational Evidence	N/A	Observational Evidence	N/A
ACIC #3 – Self-management Support	Interview Evidence	Y	Interview Evidence	N	Interview Evidence	Y
	Document Evidence	Y	Document Evidence	N	Document Evidence	Y
	Observational Evidence	Y	Observational Evidence	N	Observational Evidence	Y
ACIC #4 – Decision Support	Interview Evidence	Y	Interview Evidence	N	Interview Evidence	N
	Document Evidence	Y	Document Evidence	N	Document Evidence	N
	Observational Evidence	N/A	Observational Evidence	N/A	Observational Evidence	N/A
ACIC #5 – Delivery System Design	Interview Evidence	Y	Interview Evidence	Y	Interview Evidence	Y
	Document Evidence	Y	Document Evidence	Y	Document Evidence	Y
	Observational Evidence	Y	Observational Evidence	Y	Observational Evidence	Y
ACIC #6 – Clinical Information Systems	Interview Evidence	Y	Interview Evidence	Y	Interview Evidence	Y
	Document Evidence	Y	Document Evidence	Y	Document Evidence	Y
	Observational Evidence	Y	Observational Evidence	Y	Observational Evidence	Y
CCM knowledge		Yes		Yes		Yes
ACIC knowledge		Yes		Yes		No

Supports Identified

1. HS clinics demonstrated continual commitment both clinically and organizationally to improvement and sustainability.

2. HS clinics provided services that were responsive to the needs of the patients and the community.
3. HS clinics employed models of staffing for paid/volunteer, full-time/part-time, and a mix of health care providers that allowed the organization to cover patient care and organization objectives.
4. HS clinics demonstrated the ability to identify and attain necessary monetary, personnel, and community collaboration resources.
5. HS clinics’ organization of care was current, evidence-based, and patient-focused.

Intracase Comparisons of Low Scoring Clinics

Table 9

Intracase Comparison LS Clinics

Standard	Clinic X	Evidence Present	Clinic Y	Evidence Present	Clinic Z	Evidence Present
ACIC #1 – Organization of the Health System		Y/N		Y/N		Y/N
	Interview Evidence	Y	Interview Evidence	Y	Interview Evidence	Y
	Document Evidence	N	Document Evidence	Y	Document Evidence	N
	Observational Evidence N/A		Observational Evidence N/A		Observational Evidence N/A	
ACIC #2 – Community Linkages		Y/N		Y/N		Y/N
	Interview Evidence	Y	Interview Evidence	Y	Interview Evidence	Y
	Document Evidence	Y	Document Evidence	Y	Document Evidence	N
	Observational Evidence N/A		Observational Evidence N/A		Observational Evidence	N/A
ACIC #3 – Self-management Support		Y/N		Y/N		Y/N
	Interview Evidence	Y	Interview Evidence	N	Interview Evidence	Y
	Document Evidence	Y	Document Evidence	N	Document Evidence	Y
	Observational Evidence	Y	Observational Evidence	N	Observational Evidence	Y
ACIC #4 – Decision Support		Y/N		Y/N		Y/N
	Interview Evidence	Y	Interview Evidence	N	Interview Evidence	N
	Document Evidence	N	Document Evidence	N	Document Evidence	N
	Observational Evidence N/A		Observational Evidence N/A		Observational Evidence N/A	
ACIC #5 – Delivery System Design		Y/N		Y/N		Y/N
	Interview Evidence	Y	Interview Evidence	Y	Interview Evidence	Y
	Document Evidence	Y	Document Evidence	Y	Document Evidence	N
	Observational Evidence	Y	Observational Evidence	Y	Observational Evidence	Y
ACIC #6 – Clinical Information Systems		Y/N		Y/N		Y/N
	Interview Evidence	Y	Interview Evidence	Y	Interview Evidence	Y
	Document Evidence	N	Document Evidence	Y	Document Evidence	N
	Observational Evidence	Y	Observational Evidence	Y	Observational Evidence	Y
CCM knowledge		No		No		No
ACIC knowledge		No		No		No

Barriers Identified

1. LS clinics lack knowledge of the CCM as a blueprint to organized care for chronic disease management.
2. LS clinics employ a low use of technology to assist in organization of care.

3. LS clinics demonstrate limited capacity to increase monetary, community and personnel resources to expand scope of services.
4. LS exhibit decreased awareness and use of evidence-based guidelines in the provision of chronic disease management.

Evidence of Trustworthiness

Credibility

Attempts to establish credibility were carried out during the interview phase of the study via a structured format that provided the interviewee many opportunities to express their opinions. I also had many opportunities to ask follow up questions when ambiguity existed or when further clarification was needed. I also took field notes to capture the essence of the interview not available by audio recording. Interview participants received a transcribed copy for review with the opportunity to correct or clarify themselves. In addition, I provided the interviewees with observation protocols for the three system processes observed, sharing both the descriptive notes taken as well as the reflective notes for accuracy. With these steps, I attempted to accurately and credibly reflect the participants' perspective of the research.

Transferability

The ability to generalize the results or transfer the results from this study to other settings is limited. Free clinics in general are not a homogenous group. This study attempted to qualify those differences by studying both HS clinics as well as LS clinics to distinguish the differences. However, there were differences within each group of the HS and LS clinics. General characteristics of the HS and LS clinics were identified, but transferability of these characteristics would not ensure similar outcomes.

Dependability

Dependability is based on the quantitative concept of reproducibility. The free clinic landscape is a very fluid, changing environment due to the significant and constant changes taking place in health care. I tried to reflect how these changes were affecting the free clinics studied. Specifically, the LS clinics were more impacted and their sustainability was in question based on their present operational model. The case study protocol provided consistent sources of evidence across all the clinics in attempts to improve dependability.

Confirmability

Data collected during the study were handled in a systematic manner that assured confidentiality and security. Each step of data collection followed a procedure to check and recheck the data. Interviews were audio taped, and I used a professional transcriptionist to transcribe the document. I read the transcripts and flagged any section that appeared unclear. Re-listening to the audio tapes cleared any misinterpretations. Transcripts were provided to participants for further confirmation and interpretation. Transcripts were then coded, grouped, and categorized. The emergence of themes resulted from this process. Document review provided a descriptive list of documents, confirming their use in clinic administration, patient care, and operations. Observational protocols allowed for observation of three key processes at the clinics. The process of continual triangulation of the data from the three distinctive sources, as well as field notes that documented personal observations, importance, and incidental occurrences, allowed me to confirm the dependability of that data.

Summary

Thirteen member clinics of the OAFC out of 51 clinics (25%) participated in this sequential explanatory mixed methods study. Phase 1 of the study consisted of executive directors completing two surveys. The ACIC survey measured the clinics' fidelity to the CCM while a demographic survey provided background data such as: (a) years of operation, (b) geographic setting, and (c) technology integration. Clinics also provided their annual statistical report.

Descriptive statistics analysis revealed a wide range of variation among the clinics for most variables. Prior knowledge of the CCM was only 46% and prior knowledge of the ACIC survey was only 23%. A summary of the ACIC survey showed a mean score for all 13 clinics to be 5.9/11. The Improving Chronic Illness Care project (2012) reported in their completing and scoring of the ACIC that scores "between 3 and 5 = basic support for chronic illness care" while scores "between 6 and 8 = reasonably good support for chronic illness care". (para. 4) The Assessment of Chronic Illness Care construct 2 (Community Linages) and ACIC 1 (Organization of the Healthcare Delivery System) reflected the highest fidelity to the CCM while ACIC 7 (Integration of the Chronic Care Model Components) and ACIC 6 (Clinical Information Systems) reflected the lowest fidelity to the model. The overall mean and standard deviation of the sample for the seven sections was 5.9, *SD* (1.2).

The three clinics with the highest and lowest ACIC mean score then participated in a two-tiered case study series. Evidence collection consisted of interviews, document review, and observation. Data collected was corroborated through a process of triangulation. Two main themes emerged from the high scoring clinics: Progressive Vision and Patient Centered Care. One central theme emerged from the low scoring clinics: Capacity Building. Intercase and crosscase analyses were also completed. In addition, Chapter 4 also described data collection and management techniques.

Chapter 5 discusses the interpretation of the findings, limitations to the study, my recommendations, and implications for positive social change.

Chapter 5

Introduction

The purpose of my sequential explanatory mixed methods study was to: (a) determine the level of fidelity by Ohio free clinics to the six key constructs of the CCM, and (b) define the correlational relationship between demographic variables (independent) and the Assessment of Chronic Illness Care (ACIC) survey scores (dependent). Additionally, I conducted a two-tiered design multiple case study series explaining the supports present in high-ranking clinics and the barriers low-ranking clinics experience.

Vulnerable populations, described as low-income, uninsured, racial and ethnic minorities, rural and immigrant populations, and the undereducated, have been shown to have a disproportionately higher incidence of chronic diseases such as diabetes, cardiovascular disease, and obesity (Bahls, 2011; Hoffman & Paradise, 2008; Kirby & Kaneda, 2010). In an effort to provide better quality care and control health care costs associated with chronic disease, the CCM was developed in the late 1990s. It has become the benchmark model for chronic disease management (Robert Wood Johnson Foundation, 2011).

Community safety nets are one option the uninsured population has to access health services. Free clinics are one community safety net option to the uninsured. Free clinics began in the late 1960s and early 1970s as a community safety net for substance abusers and ethnic minorities (Weiss, 2006). Over time, free clinics evolved to provide primary medical care. Their popularity grew as the number of individuals without health insurance grew. Free clinics quickly became a viable option for access and affordability to health care services for the uninsured.

Health care research literature to date involving free clinics has been scarce due to: (a) the historical lack of identification of free clinics as legitimate providers of health care services; (b) the lack of uniformity of services provided among free clinics; and (c) the less rigorous reporting and accountability standards to which free clinics are held (Brennan, 2013).

These factors have led to gaps in the research literature identifying how chronic disease management is conducted in the free clinic settings. My purpose for this study was to identify the fidelity that Ohio free clinics have to the six key constructs of the CCM. Additionally, the most compliant clinics to the CCM were compared to the clinics that had the least amount of fidelity. Supports and barriers were identified that may provide free clinics with information, resources, and strategies to better enable them to meet the health care needs of their constituents.

Summary of Key Findings

Supports identified at HS clinics:

1. HS clinics demonstrated continual commitment both clinically and organizationally to improvement and sustainability.

2. HS clinics provided services that were responsive to the needs of the patients and the community.
3. HS clinics employed models of staffing for paid/volunteer, full-time/part-time, and mixed healthcare providers that allowed the organization to cover patient care and organization objectives.
4. HS clinics demonstrated the ability to identify and attain necessary monetary, personnel, and community collaboration resources.
5. HS clinics' organization of care was current, evidence-based, and patient focused.

The supports identified at HS clinics align with findings from the literature review. HS clinic support 3 aligned with successful implementation of the CCM is often attributed to patients' being actively involved in their own care, staff understanding and use of clinical guidelines, and adequate resources for staffing and technology. The flexibility for changes in staff roles and clinical management were identified as key components to successful implementation (Lemay, Beagan, Ferguson, & Hargraves, 2010; Leykum et al., 2011; Nutting et al., 2011).

HS clinic support 4 aligned with the evidence from the literature that large physician organizations, especially those operating within a HMO, were more likely to have success implementing the various subcomponents. These organizations had more financial resources, were already computer equipped and integrated, and typically had a wider representation of the workforce necessary for case management teams (Wagner et al., 1999).

HS clinic support 5 was reflected in the literature by use of evidence-based medicine in the delivery of care has grown in acceptance and usage in the health care system. Access to research information and its dissemination via the internet has broadened the knowledge base (Agency for Health Care Research and Quality, 2012; Spigel, 2008; Sackett et al., 1996).

Barriers identified at LS clinics:

1. LS clinics lacked knowledge of the CCM as a blueprint to organized care for chronic disease management.
2. LS clinics employed a low use of technology to assist in organization of care.
3. LS clinics demonstrated limited capacity to increase monetary, community, and personnel resources to expand scope of services.
4. LS exhibit decreased awareness and use of evidence-based guidelines in the provision of chronic disease management.

The barriers identified at LS clinics also align with findings from the literature review. Not all studies supported the CCM in its early stages. The process of changing care delivery and philosophical beliefs of health care roles were not always readily accepted (Hanratty et al., 2008; Oswald, 2001; Spigel, 2008).

LS clinic barrier 1 reflected the complexity of the model was often seen as overwhelming to health care organizations to adopt as a whole, resulting in competing priorities, lack of organizational readiness for change, and commitment (motivation) to change (Hroscikoski et al., 2006; Lemmens, Strating, Huijsman & Nieboer, 2009).

LS clinic barriers 2 and 4 reflected literature identifying common themes that evolved among health organizations attempting to implement the CCM. Significantly noted were: changing culture, limited resources to fund required technology changes, additional personnel required for team processes, limited resources for patient education and self-management, and reimbursement not reflective of services provided (Bodenheimer et al., 2004; Oswald, 2001; Wagner et al., 1999).

Finally, LS clinic barrier 3 was addressed in the literature reflecting independent practice associations, which represent solo or small physician practice groups, experienced greater difficulty implementing the CCM. They argued that the CCM benefitted large providers and insurance companies more than small providers due to the significant cost savings for reduced hospitalizations. The insurance companies' reluctance to change reimbursement to more adequately reflect the resources being extended in the CCM by physician groups led to active resistance by some providers (Oswald, 2001).

Interpretation of the Findings

Interpretation of ACIC Survey

The ACIC survey consisted of six construct sections and one integration section for a total of seven sections. Each construct varied from three to six components to be scored. Each component was scored on a Likert scale of 0-11. The higher the score for each component, the more fidelity that component had to the CCM. A mean score for each construct was calculated as well as a mean score for all seven constructs. The overall mean score per clinic allowed a rank order to be established for each participating clinic.

Results showed ACIC 2 (Community Linages) mean 7.2, SD (1.6) and ACIC 1 (Organization of the Healthcare Delivery System) mean 6.6, *SD* (1.1) reflected the highest fidelity to the CCM while ACIC 7 (Integration of the Chronic Care Model Components) mean 5.02, *SD (*1.8) and ACIC 6 (Clinical Information Systems) mean 5.04, *SD* (1.7) reflected the lowest fidelity to the model. The overall mean of the sample for the seven sections was 5.9, *SD* (1.2).

The Improving Chronic Illness Care project (2012) reported in their completing and scoring of the ACIC that scores “between 3 and 5 = basic support for chronic illness care” while scores “between 6 and 8 = reasonably good support for chronic illness care”. (para. 4)

Interpretation of Qualitative Data

In this study, qualitative case study data was collected from three separate sources: interviews, document reviews, and observation of specific processes. Each data source provided evidence that was identified with a specific CCM construct. The triangulation of data evidence from the three sources provided a strong foundation for the reliability of the findings.

High scoring clinics theme 1—progressive vision. HS clinics consistently demonstrated characteristics that reflected organized and purposeful care in this study. Review of documents supported the level of involvement of the board, administration, leaders, and key personnel in strategic planning for the organization and care planning for the patients. These traits were supported by observed evidence of key processes. I observed the use of technology to coordinate care and subsequently how it allowed the HS clinics to more efficiently provide a greater scope of services without significant changes in staffing. The use of an electronic health record, disease registries, scheduling of appointments, education, and testing benchmarks were examples of technology use. Wagner et al. (1996) reported that the systems and processes in place at that time were not adequate to meet the needs of patients with chronic diseases. The coordination of care for follow-up visits, referrals, test results, and patient education was labor and time intensive. In addition, record keeping was poor and uncoordinated, communication with care providers was not timely, and continuity suffered. Fidelity to the six constructs reflects an organization that is committed to providing services and care in a manner that will optimize the resources of the organization while providing evidence-based care that produces quality outcomes.

HS clinics had a palpable team concept. They represented a diversification and expansion of healthcare providers that would normally not be seen in a regular primary care doctor’s office. Margolius and Bodenheimer (2010) outlined this evolution in chronic disease management as well as the primary care doctor evolving from the sole care provider to a delegator role.

My observations revealed that because free clinics do not bill for uninsured patients, the constraints of cost, time, and personnel resources required for adopting the CCM model do not exist. Those same observations also revealed that adopting the CCM model was difficult for free clinics due to inconsistencies and unpredictability of volunteer staffing on which the majority of clinics rely.

High scoring clinics theme 2—patient centered care. High scoring clinics offered a scope of services that included specialist care, disease education programs, resource assistance, and disease monitoring tests. Documents reviewed at HS clinics showed that quality measure outcome standards were routinely collected. Patient education programs aimed at increased health literacy of chronic disease as well as available health resources. Enrollment in pharmacy prescription assistance programs was observed in the HS clinics. Rittenhouse et al. (2010) reported that healthcare organizations that were required to report quality measures to external compliance organizations were more likely to use care management processes than those not obligated to report. This tended to be reflected in the HS free clinic environment.

The services provided to patients with a chronic disease at HS clinics reflected the use of national guidelines for the management of that disease. These guidelines include not only medical interventions but also ancillary services and lifestyle modifications. Spigel (2008) reported that the Cochrane library, host to a collection of systematic reviews of medical studies, has produced over 1,000 practice guidelines and that the dissemination and adoption of evidence-based guidelines in clinical practice has flourished tremendously with the growth of the internet. The proliferation of medical journals converting to electronic subscriptions, web-based search engines of scholarly work, and social media outlets have all contributed to the evidence-based medicine movement.

Low scoring clinics theme 1— capacity building. LS clinics, while delivering quality services, lacked the ability to match HS clinics is size and scope. Their overall ACIC score fell within the “basic support for chronic illness care.” More reflective is that all three LS clinics were below the mean score for each of the seven constructs of the ACIC survey. The clinics’ limited ability to recruit resources, both monetary and non-monetary, influenced the organizational size and structure. This phenomenon is not new to the CCM. The complexity of the model is often seen as overwhelming for health care organizations to adopt as a whole, resulting in competing priorities, lack of organizational readiness for change, and lack of commitment (motivation) to change (Hroscikoski et al., 2006; Lemmens, Strating, Huijsman & Nieboer, 2009). Likewise, Hanratty et al. (2008) identified barriers that potentially prohibit community safety net organizations from developing registries: (a) poor financial resources, (b) poor information technology resources, (c) inconsistent client base due to high turnover of patients, and (d) decreased financial incentives for increased health outcomes.

A path forward towards successful implementation of the CCM is often attributed to patients' actively involved in their own care, staff's use of clinical guidelines, and availability of adequate resources for staffing and technology. The flexibility for changes in staff roles and clinical management were identified as key components to successful implementation (Lemay, Beagan, Ferguson, & Hargraves 2010; Leykum et al., 2011; Nutting et al., 2011).

Limitations of the Study

The low participation level of member clinics in the OAFC was a limitation to my study. Thirteen out of 51 clinics participating did not provide a full and comprehensive picture for quantitative analysis. Correlational analysis of variables was thereby affected. Extenuating circumstances of Medicaid coverage to vulnerable populations in Ohio contributed to the low participation. As a result of the low participation in the study, the external validity of the study was compromised. The ability to generalize findings from this study to other like settings is not applicable.

Recommendations

Fifty-one free clinics comprise the members of the OAFC. The association offers members multiple opportunities for education seminars, member sharing, and resource sharing. In addition, the association provides members grant opportunities, resource discounts, and staffing resources through the Federal Vista and Navigator programs. It is recommended that member clinics take a more active role and participate in these opportunities. The association might also provide capacity building education, mentoring, and resources specific to smaller clinics in a manner that addresses their needs. In addition, membership in the National Association of Free and Charitable Clinics is recommended for access to additional resources for organizational operations and clinical care. The recommendation for member clinics to pursue Patient Center Medical Home (PCMH) certification through the National Committee for Quality Assurance at the basic level would meet compliance with many of the CCM constructs.

Recommendations for future research would be based upon higher participation from member clinics. Free clinics have always been a diverse grouping of organizations bound by a common objective to assist the uninsured. The ACIC survey provided an instrument that permitted diversity but allowed organizations to be measured on the same standards. The mixed methods sequential explanatory model proved valuable in capturing the diversity of different clinics. Future research focusing on meaningful use of technology in the clinic may provide opportunities for clinics to improve their service delivery model.

Implications for Positive Social Change

There is no possession a person takes more for granted until it is lost than their health. The current study focused on vulnerable populations that were uninsured. Vulnerable populations comprise the majority of Americans who live without health insurance. This statistic has been steadily increasing for the past decade. The consequences of living without health insurance have been shown to be detrimental not only to the individual but also to the communities in which they live (Bahls, 2011).

Improving the scope and quality of services provided at free clinics to those experiencing chronic disease will move health care in the direction of reducing health disparities in at-risk populations. The uninsured face barriers to accessible, affordable, and quality health services and often rely on community safety net services, when available, for their health care.

Free clinics have long served communities by providing health services at no cost to individuals who lack health insurance. This is a great benefit not only to the uninsured but also to the community. Free clinics have served as a valuable community safety net by providing access to health services not readily available to the uninsured. It is documented that these services alone have decreased morbidity and mortality of the vulnerable population they serve. This study aimed to understand how the process of chronic disease management is provided to the uninsured patient at Ohio free clinics. While some variation of services is a normal expectation across health care providers, this study intended to understand why that happens to patients with chronic disease. This study identified three clinics with high fidelity to the CCM, the gold standard of chronic disease management. The study also identified three clinics with low fidelity. Through a series of case studies, I identified the supports present at HS clinics and barriers present in LS clinics.

By identifying barriers present at LS clinics, the organization can begin to plan, strategize, and implement actions to reduce or eliminate the barriers. Increased services and quality of the care will directly benefit the individual being served. The supports identified in the HS clinics can be used as educational tools and models to be implemented across the Ohio free clinics. While it is inconceivable that all free clinics will operate similarly, it is conceivable that all free clinics attempt to implement more of the components of each CCM construct. The main purpose of the ACIC survey was to provide organizations a feedback tool regarding compliance with the model. Adoption of the model provided free clinics in Ohio a framework by which to improve the quality of health services for the uninsured. By providing a more comprehensive scope and depth of services, free clinics may empower patients to strive for improved health status. Changes in the quality of health services may result in an improvement not only to the health status of the individual but the communities in which they live through reductions in disease, disability, and premature deaths.

Conclusion

The implementation of the Affordable Care Act provided states a process to expand healthcare services to vulnerable populations previously not eligible for Medicaid services. However, the ACA is not a universal health insurance program and a significant sector of the population is still uninsured. Free clinics remain a viable option for this population within the community safety net. Uninsured individuals diagnosed with a chronic disease experience a wide fluctuation of services and care for their disease management. Fidelity to the CCM should be the aspiration of each clinic. The supports identified in clinics with high fidelity should be evaluated for implementation when possible. The clinics with barriers present should organize a path forward with achievement goals set within realistic time frames.

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Appendix A: Assessment of Chronic Illness Care

Assessment of Chronic Illness Care

Version 3.5

Please complete the following information about you and your organization. This information will not be disclosed to anyone besides this researcher. I would like to get your phone number and e-mail address in the event that I need to contact you the future.	
Your name:	**Date:** ________/________/________ Month Day Year
Organization & Address:	
Your phone number: (______) __ __ __ - __ __ __ __	**Your e-mail address:**

Directions for Completing the Survey

This survey is designed to help systems and provider practices move toward the "state-of-the-art" in managing chronic illness. The results can be used to help your team identify areas for improvement. Instructions are as follows:

1. **Answer each question** from the perspective of one physical site (e.g., Free Clinic) that supports care for chronic illness.

2. **Answer each question** regarding how your organization is doing with respect to chronic disease

3. For each row, **circle the point value** that best describes the level of care that currently exists in the site. The rows in this form present key aspects of chronic illness care. Each aspect is divided into levels showing various stages in improving chronic illness care. The stages are represented by points that range from 0 to 11. The higher point values indicate that the actions described in that box are more fully implemented.

4. **Sum the points in each section** (e.g., total part 1 score), calculate the average score (e.g., total part 1 score / # of questions), and enter these scores in the space provided at the end of each section. Then sum all of the section scores and complete the average score for the program as a whole by dividing this by 7.

For more information about how to complete the survey, please contact:

Jim Benedict
330-881-5964 (cell)
330-941-3227 (work)
james.benedict@waldenu.edu

Assessment of Chronic Illness Care, Version 3.5

Part 1: Organization of the Healthcare Delivery System. Chronic illness management programs can be more effective if the overall system (organization) in which care is provided is oriented and led in a manner that allows for a focus on chronic illness care.

Components	Level D	Level C	Level B	Level A
Overall Organizational Leadership in Chronic Illness Care Score	…does not exist or there is a little interest. 0 1 2	…is reflected in vision statements and business plans, but no resources are specifically earmarked to execute the work. 3 4 5	…is reflected by senior leadership and specific dedicated resources (dollars and personnel). 6 7 8	…is part of the system's long term planning strategy, receive necessary resources, and specific people are held accountable. 9 10 11
Organizational Goals for Chronic Care Score	…do not exist or are limited to one condition. 0 1 2	…exist but are not actively reviewed. 3 4 5	…are measurable and reviewed. 6 7 8	…are measurable, reviewed routinely, and are incorporated into plans for improvement. 9 10 11
Improvement Strategy for Chronic Illness Care Score	…is ad hoc and not organized or supported consistently. 0 1 2	…utilizes ad hoc approaches for targeted problems as they emerge. 3 4 5	…utilizes a proven improvement strategy for targeted problems. 6 7 8	…includes a proven improvement strategy and uses it proactively in meeting organizational goals. 9 10 11
Incentives and Regulations for Chronic Illness Care Score	…are not used to influence clinical performance goals. 0 1 2	…are used to influence utilization and costs of chronic illness care. 3 4 5	…are used to support patient care goals. 6 7 8	…are used to motivate and empower providers to support patient care goals. 9 10 11
Senior Leaders Score	…discourage enrollment of the chronically ill. 0 1 2	…do not make improvements to chronic illness care a priority. 3 4 5	…encourage improvement efforts in chronic care. 6 7 8	…visibly participate in improvement efforts in chronic care. 9 10 11
Benefits Score	…discourage patient self-management or system changes. 0 1 2	…neither encourage nor discourage patient self-management or system changes. 3 4 5	…encourage patient self-management or system changes. 6 7 8	…are specifically designed to promote better chronic illness care. 9 10 11

Total Health Care Organization Score ________ Average Score (Health Care Org. Score / 6) _________

Part 2: Community Linkages. Linkages between the health delivery system (or provider practice) and community resources play important roles in the management of chronic illness.

Components	Level D	Level C	Level B	Level A
Linking Patients to Outside Resources	…is not done systematically.	…is limited to a list of identified community resources in an accessible format.	…is accomplished through a designated staff person or resource responsible for ensuring providers and patients make maximum use of community resources.	… is accomplished through active coordination between the health system, community service agencies and patients.
Score	0 1 2	3 4 5	6 7 8	9 10 11
Partnerships with Community Organizations	…do not exist.	…are being considered but have not yet been implemented.	…are formed to develop supportive programs and policies.	…are actively sought to develop formal supportive programs and policies across the entire system.
Score	0 1 2	3 4 5	6 7 8	9 10 11
Regional Health Plans	…do not coordinate chronic illness guidelines, measures or care resources at the practice level.	…would consider some degree of coordination of guidelines, measures or care resources at the practice level but have not yet implemented changes.	…currently coordinate guidelines, measures or care resources in one or two chronic illness areas.	…currently coordinate chronic illness guidelines, measures and resources at the practice level for most chronic illnesses.
Score	0 1 2	3 4 5	6 7 8	9 10 11

Total Community Linkages Score ___________ Average Score (Community Linkages Score / 3) _________

Part 3: Practice Level. Several components that manifest themselves at the level of the individual provider practice (e.g. individual clinic) have been shown to improve chronic illness care. These characteristics fall into general areas of self-management support, delivery system design issues that directly affect the practice, decision support, and clinical information systems.

Part 3a: Self-Management Support. Effective self-management support can help patients and families cope with the challenges of living with and treating chronic illness and reduce complications and symptoms.

Components	Level D	Level C	Level B	Level A
Assessment and Documentation of Self-Management Needs and Activities	…are not done.	…are expected.	…are completed in a standardized manner.	…are regularly assessed and recorded in standardized form linked to a treatment plan available to practice and patients.
Score	0 1 2	3 4 5	6 7 8	9 10 11
Self-Management Support	…is limited to the distribution of information (pamphlets, booklets).	…is available by referral to self-management classes or educators.	…is provided by trained clinical educators who are designated to do self-management support, affiliated with each practice, and see patients on referral.	…is provided by clinical educators affiliated with each practice, trained in patient empowerment and problem-solving methodologies, and see most patients with chronic illness.
Score	0 1 2	3 4 5	6 7 8	9 10 11
Addressing Concerns of Patients and Families	…is not consistently done.	…is provided for specific patients and families through referral.	…is encouraged, and peer support, groups, and mentoring programs are available.	…is an integral part of care and includes systematic assessment and routine involvement in peer support, groups or mentoring programs.
Score	0 1 2	3 4 5	6 7 8	9 10 11
Effective Behavior Change Interventions and Peer Support	…are not available.	…are limited to the distribution of pamphlets, booklets or other written information.	…are available only by referral to specialized centers staffed by trained personnel.	…are readily available and an integral part of routine care.
Score	0 1 2	3 4 5	6 7 8	9 10 11

Total Self-Management Score_______ Average Score (Self Management Score / 4) _______

Part 3b: Decision Support. Effective chronic illness management programs assure that providers have access to evidence-based information necessary to care for patients--decision support. This includes evidence-based practice guidelines or protocols, specialty consultation, provider education, and activating patients to make provider teams aware of effective therapies.

Components	Level D	Level C	Level B	Level A
Evidence-Based Guidelines	…are not available.	…are available but are not integrated into care delivery.	…are available and supported by provider education.	…are available, supported by provider education and integrated into care through reminders and other proven provider behavior change methods.
Score	0 1 2	3 4 5	6 7 8	9 10 11
Involvement of Specialists in Improving Primary Care	…is primarily through traditional referral.	…is achieved through specialist leadership to enhance the capacity of the overall system to routinely implement guidelines.	…includes specialist leadership and designated specialists who provide primary care team training.	…includes specialist leadership and specialist involvement in improving the care of primary care patients.
Score	0 1 2	3 4 5	6 7 8	9 10 11
Provider Education for Chronic Illness Care	…is provided sporadically.	…is provided systematically through traditional methods.	…is provided using optimal methods (e.g. academic detailing).	…includes training all practice teams in chronic illness care methods such as population-based management, and self-management support.
Score	0 1 2	3 4 5	6 7 8	9 10 11
Informing Patients about Guidelines	…is not done.	…happens on request or through system publications.	…is done through specific patient education materials for each guideline.	…includes specific materials developed for patients which describe their role in achieving guideline adherence.
Score	0 1 2	3 4 5	6 7 8	9 10 11

Total Decision Support Score_______ Average Score (Decision Support Score / 4) _______

Part 3c: Delivery System Design. Evidence suggests that effective chronic illness management involves more than simply adding additional interventions to a current system focused on acute care. It may necessitate changes to the organization of practice that impact provision of care.

Components	Level D	Level C	Level B	Level A
Practice Team Functioning	…is not addressed.	…is addressed by assuring the availability of individuals with appropriate training in key elements of chronic illness care.	…is assured by regular team meetings to address guidelines, roles and accountability, and problems in chronic illness care.	…is assured by teams who meet regularly and have clearly defined roles including patient self-management education, proactive follow-up, and resource coordination and other skills in chronic illness care.
Score	0 1 2	3 4 5	6 7 8	9 10 11
Practice Team Leadership	…is not recognized locally or by the system.	…is assumed by the organization to reside in specific organizational roles.	…is assured by the appointment of a team leader but the role in chronic illness is not defined.	…is guaranteed by the appointment of a team leader who assures that roles and responsibilities for chronic illness care are clearly defined.
Score	0 1 2	3 4 5	6 7 8	9 10 11
Appointment System	…can be used to schedule acute care visits, follow-up and preventive visits.	…assures scheduled follow-up with chronically ill patients.	…are flexible and can accommodate innovations such as customized visit length or group visits.	…includes organization of care that facilitates the patient seeing multiple providers in a single visit.
Score	0 1 2	3 4 5	6 7 8	9 10 11
Follow-up	…is scheduled by patients or providers in an ad hoc fashion.	…is scheduled by the practice in accordance with guidelines.	…is assured by the practice team by monitoring patient utilization.	…is customized to patient needs, varies in intensity and methodology (phone, in person, email) and assures guideline follow-up.
Score	0 1 2	3 4 5	6 7 8	9 10 11
Planned Visits for Chronic Illness Care	…are not used.	…are occasionally used for complicated patients.	…are an option for interested patients.	…are used for all patients and include regular assessment, preventive interventions and attention to self-management support.
Score	0 1 2	3 4 5	6 7 8	9 10 11
Continuity of Care	…is not a priority.	…depends on written communication between primary care providers and specialists, case managers or disease management companies.	…between primary care providers and specialists and other relevant providers is a priority but not implemented systematically.	…is a high priority and all chronic disease interventions include active coordination between primary care, specialists and other relevant groups.
Score	0 1 2	3 4 5	6 7 8	9 10 11

(From Previous Page)

Total Delivery System Design Score_______

Average Score (Delivery System Design Score / 6) _______

Part 3d: Clinical Information Systems. Timely, useful information about individual patients and populations of patients with chronic conditions is a critical feature of effective programs, especially those that employ population-based approaches.[7, 8]

Components	Level D	Level C	Level B	Level A
Registry (list of patients with specific conditions)	…is not available.	…includes name, diagnosis, contact information and date of last contact either on paper or in a computer database.	…allows queries to sort sub-populations by clinical priorities.	…is tied to guidelines which provide prompts and reminders about needed services.
Score	0 1 2	3 4 5	6 7 8	9 10 11
Reminders to Providers	…are not available.	… include general notification of the existence of a chronic illness, but does not describe needed services at time of encounter.	…includes indications of needed service for populations of patients through periodic reporting.	…includes specific information for the team about guideline adherence at the time of individual patient encounters.
Score	0 1 2	3 4 5	6 7 8	9 10 11
Feedback	…is not available or is non-specific to the team.	…is provided at infrequent intervals and is delivered impersonally.	…occurs at frequent enough intervals to monitor performance and is specific to the team's population.	…is timely, specific to the team, routine and personally delivered by a respected opinion leader to improve team performance.
Score	0 1 2	3 4 5	6 7 8	9 10 11
Information about Relevant Subgroups of Patients Needing Services	…is not available.	…can only be obtained with special efforts or additional programming.	…can be obtained upon request but is not routinely available.	…is provided routinely to providers to help them deliver planned care.
Score	0 1 2	3 4 5	6 7 8	9 10 11
Patient Treatment Plans	…are not expected.	…are achieved through a standardized approach.	…are established collaboratively and include self management as well as clinical goals.	…are established collaborative an include self management as well as clinical management. Follow-up occurs and guides care at every point of service.
Score	0 1 2	3 4 5	6 7 8	9 10 11

Total Clinical Information System Score_______ Average Score (Clinical Information System Score / 5) ________

Integration of Chronic Care Model Components. Effective systems of care integrate and combine all elements of the Chronic Care Model; e.g., linking patients' self-management goals to information systems/registries.

Components	Little support	Basic support	Good support	Full support
Informing Patients about Guidelines	…is not done.	…happens on request or through system publications.	…is done through specific patient education materials for each guideline.	…includes specific materials developed for patients which describe their role in achieving guideline adherence.
Score	0 1 2	3 4 5	6 7 8	9 10 11
Information Systems/Registries	…do not include patient self-management goals.	…include results of patient assessments (e.g., functional status rating; readiness to engage in self-management activities), but no goals.	…include results of patient assessments, as well as self-management goals that are developed using input from the practice team/provider and patient.	…include results of patient assessments, as well as self-management goals that are developed using input from the practice team and patient; and prompt reminders to the patient and/or provider about follow-up and periodic re-evaluation of goals.
Score	0 1 2	3 4 5	6 7 8	9 10 11
Community Programs	…do not provide feedback to the health care system/clinic about patients' progress in their programs.	…provide sporadic feedback at joint meetings between the community and health care system about patients' progress in their programs.	…provide regular feedback to the health care system/clinic using formal mechanisms (e.g., Internet progress report) about patients' progress.	…provide regular feedback to the health care system about patients' progress that requires input from patients that is then used to modify programs to better meet the needs of patients.
Score	0 1 2	3 4 5	6 7 8	9 10 11
Organizational Planning for Chronic Illness Care	…does not involve a population-based approach.	…uses data from information systems to plan care.	…uses data from information systems to proactively plan population-based care, including the development of self-management programs and partnerships with community resources.	…uses systematic data and input from practice teams to proactively plan population-based care, including the development of self-management programs and community partnerships, that include a built-in evaluation plan to determine success over time.
Score	0 1 2	3 4 5	6 7 8	9 10 11
Routine follow-up for appointments, patient assessments and goal	…is not ensured.	is sporadically done, usually for appointments only.	is ensured by assigning responsibilities to specific staff (e.g., nurse case manager).	is ensured by assigning responsibilities to specific staff (e.g., nurse case manager) who uses the

Components	Little support	Basic support	Good support	Full support
planning	0 1 2	3 4 5	6 7 8	registry and other prompts to coordinate with patients and the entire practice team. 9 10 11
Guidelines for chronic illness care	…are not shared with patients. 0 1 2	…are given to patients who express a specific interest in self-management of their condition. 3 4 5	…are provided for all patients to help them develop effective self-management or behavior modification programs, and identify when they should see a provider. 6 7 8	…are reviewed by the practice team with the patient to devise a self-management or behavior modification program consistent with the guidelines that takes into account patient's goals and readiness to change. 9 10 11

Total Integration Score (SUM items): __________ ➢ Average Score (Integration Score/6) = __________

Scoring Summary
(bring forward scoring at end of each section to this page)

Total Org. of Health Care System Score _______
Total Community Linkages Score _______
Total Self-Management Score _______
Total Decision Support Score _______
Total Delivery System Design Score _______
Total Clinical Information System Score _______
Total Integration Score _______

Overall Total Program Score (Sum of all scores) _______

Average Program Score (Total Program /7) _______

Appendix B: Ohio Association of Free Clinics Annual Statistical Survey

CLINIC INFORMATION			
Clinic Name			
Street Address			
City, State, Zip			
Phone Number			
Contact Person(s)			
Address as you want it displayed on the OAFC website (if different from above)			
Phone Number you want displayed on the OAFC website (if different from above)			
Counties served by your clinic in 2012 (list all)			
Total January 1 through December 31, 2012 Operating Budget (do NOT include in-kind contributions)			
Hours of operation			
Please indicate your hours of operation and whether hours are clinical, administrative, or both			
	Time	Type	

Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			
Sunday			
	YES	NO	
Do you plan to add additional clinic hours in 2013?			
If yes, how many hours?			
If yes, what type of hours? (clinic, admin, both)			
Does your clinic purchase medical liability insurance?			
Does your clinic purchase general liability insurance?			
Does your clinic purchase D&O insurance?			
Does your clinic have a pharmacy license?			
Does your clinic purchase medications through the State Pharmacy Service Center (ODMH)?			
Is your clinic participating in a drug repository program?			
Does your clinic have a CLIA license?			

How do you qualify your patients?			
Is your clinic accepting new patients?			
If no, why?			
Do you have scheduled appointments, walk-in or both			
What is the average wait time to get a scheduled appointment for a **new patient**?			
What is the average wait time to get a scheduled appointment for a **follow-up patient**?			
If you track the number of patients turned away, what is that number for 2012?			
Do you see patients with health insurance?			
How many of your patients seen in 2012 had health insurance? (give actual number)			
Do you ask patients to pay for visits, prescriptions or any other service?			
If yes, what services do you collect money for?			
If yes, how much did you receive from patients?			

Do you bill your patients?			
Do you accept contributions from patients?			
PATIENT INFORMATION:			
How many **unduplicated** patients did you see on-site (at clinic)?			
How many **unduplicated** patients did you refer for off-site (referrals)?			
Total Patients (2012) – UNDUPLICATED	0		
How many patient **visits** did you see on-site?			
How many patient **visits** did you see off-site?			
Total Patient Visits (2012) – DUPLICATED	0		
Patients seen in 2012 by sex/age (**unduplicated**)			
# Infants (less than 1)			
# children (1 - 18)			
# adult Men (19 and older)			
# adult Women (19 and older)			
Total	0		
Please indicate the number of PATIENT VISITS for the following: (**duplicated**)			
	# visits on-site	# visits off-site	Total

Primary Care			0
Specialty Care			0
Dental Care			0
Mental Health Care			0
Total	0	0	0
INFORMATION ABOUT YOUR SERVICES			
Which best describes the type of care your clinic provides?			
Acute Care Only			
Chronic Care Management Only			
Both Acute and Chronic Care			
Does your clinic provide prenatal care for pregnant women?			
Does your clinic provide mental health services?			
Does your clinic provide dental services?			
Does your clinic provide immunizations for children?			
Does your clinic provide immunizations for adults?			
Does your clinic provide patient education?			

If yes, what types of patient education do you provide?			
Does your clinic provide services to the community outside of your clinic (such as health fairs, student activities, corporate staff training, Medicare Education for those turning 65, etc.)?			
If yes, please list those activities along with community impact.			
How many prescriptions did you dispense in 2012?			
How many people received prescriptions?			
What was the value of those prescriptions?			
How many lab tests did you provide in 2012?			
How many patients received labs?			
What was the value of those lab services?			
What laboratories participated in providing labs?			
How many diagnostic tests did you provide in 2012?			
How many people received diagnostic tests?			
What was the value of those diagnostic tests?			
What providers participated in providing diagnostic tests?			

How many people received hospital care through your clinic in 2012?			
What types of care did they receive?			
What was the $ value of those services?			
What hospitals partnered with you to provide services?			
VOLUNTEERS			
Please complete the grid below for volunteer involvement:	# on-site volunteers (individuals)	# off-site volunteers (Individuals)	Total Volunteer hours for 2012
Administrative Staff			
Board Member			
Cardiologist			
Chiropractor			
Dentist			
Development Director			
Family Medicine/Internal Medicine			
Gastroenterologist			
Lay (non-medical) volunteer			
Massage Therapist			
Medical Assistant			
Medical Resident			
Medical Student			
Mental Health Counselor			
Neurologist			

Nurse Practitioner			
Nurse (LPN)			
Nurse (RN)			
Ob/Gyn			
Occupational Therapist			
Optometrist			
Orthopedist			
Pharmacist			
Physical Therapy			
Primary Care Physician (do not include psychiatrists)			
Psychiatrist			
Radiologist			
Social Worker			
Surgeon			
Others			
PAID STAFF			
Please complete the grid below for paid staff involvement:	# on-site staff (individuals)	# off-site staff (Individuals)	Total Paid Staff hours for 2012
Administrative Staff			
Board Member			
Cardiologist			
Chiropractor			
Dentist			
Development Director			
Family Medicine/Internal Medicine			

Gastroenterologist			
Lay (non-medical) volunteer			
Massage Therapist			
Medical Assistant			
Medical Resident			
Medical Student			
Mental Health Counselor			
Neurologist			
Nurse Practitioner			
Nurse (LPN)			
Nurse (RN)			
Ob/Gyn			
Occupational Therapist			
Optometrist			
Orthopedist			
Pharmacist			
Physical Therapy			
Primary Care Physician (do not include psychiatrists)			
Psychiatrist			
Radiologist			
Social Worker			
Surgeon			
Others			
FUNDING SOURCES			
Please indicate the amount of revenue that your clinic generated from the following sources in 2012:			

Local Foundations			
Local Government			
United Way			
State Government (include UCF funds here)			
Federal Government			
Individual Donors			
Corporate Donors			
Clinic Fees			
Special Events (including fundraisers)			
Churches/Religious Organizations			
Hospitals			
Civic Groups			
Universities/Colleges			
Misc/Interest			
Total	$0.00		
Legislation			
Have any legislators visited your clinic?			
If yes, please list who has visited your clinic.			
When was the most recent visit?			
Do you regularly communicate with your legislator?			
If yes, who on a local, state and federal level?			
If yes, how do you communicate? (newsletters, regular meetings, etc.)?			

Appendix C: Ohio Association Free Clinics Membership Criteria

Ohio Association of Free Clinics

The following membership criteria apply:

- The free clinic must be a nonprofit organization with a primary mission of providing free health care services to people with limited resources.
- A free clinic facilitates the delivery of these services through volunteer health care professionals and voluntary care networks.
- If a free clinic requests an administrative fee from patients, patients are not denied care or billed if they cannot pay this fee.
- If a free clinic bills Medicaid, Medicare or other third-party payers, no more than 25% of the clinic's annual operating revenue can come from these sources.
- Free clinics do not perform operations. (Although procedures that do not require general anesthesia are typically performed in an office setting and are within the scope of the health care professional are permitted.)

Appendix D: Additional Demographic Information from Ohio free clinics

1. The number of years Clinic has been in operation. ______________________
2. Do you have previous knowledge of the Chronic Care Model? Yes / No
3. Do you have previous knowledge of the Assessment of Chronic Illness Care (ACIC) survey? Yes / No
4. The geographical setting that best describes your clinic is:
    1. Urban
    2. Suburban
    3. Rural

Healthcare Information Technology Integration

5. Does your clinic use any computer based healthcare information technology in the operation of the clinic? Yes / No
6. Does your clinic have a designated person that coordinates informational technology hardware and software? Yes / No
7. Electronic scheduling Yes / No
8. Electronic billing Yes / No
9. Does your clinic use an electronic medical record? No / Partially / Fully
10. Does your electronic information technology communicate with other health provider systems? (ie. Hospitals, Doctor's offices) Yes / No
11. Do you keep disease registries for your patients with chronic disease? (ex. List of all patients with diabetes) Yes / No
12. Do you have e-prescription capability Yes / No

Appendix E: Ohio Association of Free Clinic Member Listing

AAPIO Clinic
3671 Hyatts Road (Bharatiya Temple)
Powell, Ohio 43065
AAPIOCLINIC@yahoo.com

Ashland Christian Health Center
380 E. 4th Street
Ashland, Ohio 44805
419.903.0475

Asian Health Initiative/AACS
2231 N. High Street
Columbus, Ohio 43214
614.220.4023 x224

Berger Health Foundation
1280 N. Court Street
Circleville, Ohio 43311
740.477.9590

The Breathing Association
1520 Old Henderson Road
Columbus, Ohio 43220
614.437.1520

By The Way, Inc. Medical Mission - Free Clinic
1029 S. Broad Street
Lancaster, Ohio 43130
740.653.5734

Clinic at Faith Mission
315 E. Long Street
Columbus, Ohio 43215
614.224.6617

Columbus Free Clinic
2231 N. High St.
Columbus, Ohio 43212
www.ColumbusFreeClinic.com
614.404.8417

Columbus Medical Association Physicians Free Clinic
240 Parsons Avenue
Columbus, Ohio 43215
www.goodhealthcolumbus/pfc
614.240.7430

Community Health Clinic
144 W. Main Street
Newark, Ohio 43055
740-345-1113

Compassion Medical Clinic of Williams County
614 E. Edgerton Street
Bryan, Ohio 43506
419.630.0313

Compassionate Care of Shelby County
124 North Ohio Avenue
Sidney, Ohio 45365
www.ccsccares.org
937.492.9400

The Free Medical Clinic of Greater Cleveland
12201 Euclid Avenue
Cleveland, Ohio 44106
www.thefreeclinic.org
216.721.1667

Free Clinic of Clinton County, Inc.
62 East Sugartree Street
Wilmington, Ohio 45177
937.383.3382

Good Neighbor House
844 S. Patterson Boulevard
Dayton, Ohio 45402
www.goodneighborhouse.org
937.224.3003

Hartville Migrant Ministries
3980 Swamp Street
Hartville, Ohio 44632
www.hartvillemigrantministries.org
330.877.2983

Health Partners of Miami County
1300 N. County Road 25A
Troy, Ohio 45373
www.healthpartnersclinic.org
937.332.0894

Helping Hands Health & Wellness Center
1421 Morse Road
Columbus, Ohio 43229
www.helpinghandsfreeclinic.wetpaint.com
614.262.5094

Jefferson County 4th Street Health Center

701 North Fourth Street
Steubenville, Ohio 43952
740.283.2856

Lake County Free Clinic
54 South State Street, Room 302
Painesville, Ohio 44077
440.352.8686

Lorain County Free Clinic
3323 Pearl Avenue
Lorain, Ohio 44055
www.lcfreeclinic.org
440.277.7602

Madison County Health Partners
210 North Main Street
London, Ohio 43140
740.845.7286

Medina Health Ministry
425 West Liberty St. Suite 1
Medina, Ohio 44256
330.764.9300

Midlothian Free Clinic
388 East Midlothian Blvd
Youngstown, Ohio 44507
330.788.3330

North Coast Health Ministry
16110 Detroit Avenue
Cleveland, Ohio 44107
www.nchealthministry.org
216.228.7878

Ohio University College of Osteopathic Medicine,
Community Health Programs
055 Grosvenor Hall
Athens, Ohio 45701
740.593.9364

OPEN M's Summit County Free Clinic
941 Princeton Street
Akron, Ohio 44311
www.openm.org
330.434.0110

Oxford College Corner Clinic
P.O. Box 390
Oxford, Ohio 45056
513.524.5426

Parma Health Ministry
7000 Ridge Road
Parma, Ohio 44129-5621
440.843.8087

Reach Out of Montgomery County
25 E. Foraker Street
Dayton, Ohio 45409
www.daytonreachout.org
937.258.2000

Southwest General Neighborhood Care Center
17951 Jefferson Park Drive
Cleveland, Ohio 44130
440.816.4039

Toledo/Lucas County CareNet
3231 Central Park West, Suite 200
Toledo, Ohio 43617
419.842.0800

Total Living Center Ministries, Inc.
2221 9th Street SW
Canton, Ohio 44706
www.totallivingcenter.org
330.455.3663

Townhall II Medical Clinic
155 N. Water Street, Suite 210
Kent, Ohio 44240
www.townhall2.com
330.678.3006

Tuscarawas Clinic for the Working Uninsured
614 N. Tuscarawas Avenue
Dover, Ohio 44622
www.tuscarawasclinic.org
330.362.1583

University Family Physicians Race Track Clinic
2123 Auburn Avenue, Suite 340
Cincinnati, Ohio 45219
513.721.2221 Ext. 15

Vineyard Free Health Clinics
6000 Cooper Road
Westerville, Ohio 43081
171 E. 5th Avenue (Wednesday)
Columbus, Ohio 43201

614.259.5428
Viola Startzman Free Clinic
1874 Cleveland Road
Wooster, Ohio 44691
www.startzmanfreeclinic.org
330.262.2500

Washington County Free Clinic
P.O. Box 804 Marietta,
Ohio 45750
740.376.0261

Western Stark Free Clinic, Inc.
820 Amherst Road NE
Massillon, Ohio 44646
330.834.1546

Wheeling Health Right
61 29th Street
Wheeling, West Virginia 26003
www.wheelinghealthright.com
304.233.9323

Xenos Free Clinics
40 N. Chicago Avenue (Tuesday)
Columbus, Ohio 43222
1934 N. Fourth Street (Monday)
Columbus, Ohio 43201
614.823.6510 x840

Appendix F: Qualitative Questions

Question	Corresponding Quantitative Question #
1. What criteria do you use to base your hours of operation?	1
2. What barriers limit your hours of operation?	1
3. What supports enable your hours of operation	1
4. How do you recruit/attract professional health care providers? (Dr, RN, etc)	2
5. How does the clinic assure for continuity with inconsistency in staffing?	2
6. Does the lack of particular HCP disciplines prevent you from providing certain services?	2
7. How has your annual operating budget influenced your service delivery model?	3
8. Does your clinic dedicate specific operational money for chronic disease management?	3
9. What health information technology does the clinic use?	4
10. How has it been integrated into your service delivery model?	4
11. What processes have been implemented to accommodate to your volume of patient visits?	5
12. How does staff provide input into operational issues, such as scheduling?	5
13. How is the service delivery model different / same for chronic disease patients as acute episodic patients?	6
14. How has the clientele you serve changed over time?	6

Appendix G: Case Study Evidence

Evidence Item	Qualitative/Quantitative Classification	ACIC Construct #
Mission, Vision and Values Statements	Qual- Documents	1
Policies and Procedures	Qual- Documents	1
Strategic Planning	Qual- Documents	1
Self-Assessment	Qual- Documents	1
Board Minutes	Qual- Documents	1
Process Improvement Team	Qual- Documents	3C
Use of outside Consultants including OAFC/NAFC	Qual- Documents	1
Collaboratives established	Qual-Documents	2
Clinical Outcomes	Qual- Documents and Reports	3B & 3D
Operational Outcomes	Qual- Documents and Reports	3C
Patient Input and Feedback	Qual- Observation of process used, Documentation	3A
Resources Needed for Operations of the Clinic	Quant-Budget Documentation	1
Use of Protocols,EBM	Qual-Documentation	3B
Patient Education Resources	Qual- Documentation and Direct Observation of Material	3B
Use of Informational Technology	Quan- Documentation and Direct Observation of Material	3D

Appendix H: CCM Model Permissions

ACP
American College of Physicians
internal medicine | *Doctors for Adults*

WAECP1418376

Walden University
100 Washington Avenue South, Suite 900
Minneapolis, MN 55401

Dear Mr. Benedict;

Thank you for your request to print (dissertation proposal) the following from *Effective Clinical Practice:*

Figure 1: Wagner EH, Chronic Disease Management: What Will It Take to Improve Care for Chronic Illness? Effective Clinical Practice, 1998, Vol1

Permission is granted to print the preceding material with the understanding that you will give appropriate credit to *Effective Clinical Practice* as the original source of the material. Any translated version must carry a disclaimer stating that the American College of Physicians is not responsible for the accuracy of the translation. This permission grants non-exclusive, worldwide rights for this edition in print (dissertation proposal) for not for profit only. ACP does not grant permission to reproduce entire articles or chapters on the Internet unless explicit permission is given. This letter represents the agreement between ACP and Walden University for request WAECP1418376 and supersedes all prior terms from the requestor. The Annals of Internal Medicine wants to encourage users to go to the original article on the website for scientific integrity, in the event there are retractions and corrections.

Thank you for your interest in Annals of Internal Medicine. If you have any further questions or would like to discuss the matter further, please contact me at 856-489-8555 or fax 856-489-4449.

Sincerely,
Gina Brown
Permissions Coordinator

Appendix I: Confidentiality Agreement

Name of Signer:

During the course of my activity in collecting data for this research: "Chronic Disease Management of the Uninsured Patient at Ohio Free Clinics, a Mixed Methods Sequential Explanatory Study" I will have access to information, which is confidential and should not be disclosed. I acknowledge that the information must remain confidential, and that improper disclosure of confidential information can be damaging to the participant.

By signing this Confidentiality Agreement I acknowledge and agree that:

1. I will not disclose or discuss any confidential information with others, including friends or family.
2. I will not in any way divulge, copy, release, sell, loan, alter or destroy any confidential information except as properly authorized.
3. I will not discuss confidential information where others can overhear the conversation. I understand that it is not acceptable to discuss confidential information even if the participant's name is not used.
4. I will not make any unauthorized transmissions, inquiries, modification or purging of confidential information.
5. I agree that my obligations under this agreement will continue after termination of the job that I will perform.
6. I understand that violation of this agreement will have legal implications.
7. I will only access or use systems or devices I'm officially authorized to access and I will not demonstrate the operation or function of systems or devices to unauthorized individuals.

Signing this document, I acknowledge that I have read the agreement and I agree to comply with all the terms and conditions stated above.

Signature: **Date:**

Appendix J: Permission to the ACIC Survey

Thursday, February 07, 2013 8:37 AMSchaefer, Judith [schaefer.jk@xxxx.org]
Hello Jim,
Congratulations on choosing such a worthy topic for your dissertation. We are delighted that you choose the ACIC for your work. Please consider this permission to use it. If you make any changes to tailor the instrument to your study, please send us a copy of the revisions for approval.

Thank you and good luck,
Judith Schaefer, MPH
MacColl Center for Health Care Innovation
206-287-2077

From: James A Benedict [jbenedict@xxxx.edu]
Sent: Wednesday, February 06, 2013 10:20 AM
To: Schaefer, Judith
Subject: Permission to the ACIC survey

Judith,

I am seeking permission to use the ACIC 3.5 version survey as part of my Ph.D doctoral dissertation. I am a student at Walden University in the School of Public Policy and Administration. My doctoral dissertation will examine chronic disease management among uninsured patients at Ohio free clinics. If you require additional information I will be happy to supply what you need. I can be reached at this email address or at 330-xxx-1111.

Thank you for consideration of my needs.

Jim Benedict, PT

Appendix K: Observation Protocol

Clinic______________________ Location_________________________
Date_______________

Activity Description: Delivery System Design Processes

Descriptive Notes	Reflective Notes
Planned patient visits include…. 1. Specific providers? 2. Format of visit note 3. Frequency of visits Continuity of care is accomplished by….. 1. Communication aides between providers 2. Documentation – paper v electronic Team meetings are conducted….. 1. Who attends 2. How often held 3. Format of the meeting	

Clinic______________________ Location_________________________
Date_______________

Activity Description: Self-Management Support Processes

Descriptive Notes	Reflective Notes
Educational classes are scheduled and provided…. 1. How many, how often 2. Format 3. Style – hands on, lecture? Peer support is conducted…. 1. How often, how many 2. How is it assessed for effectiveness Health literacy is assessed and documented… 1. How assessed 2. How reassessed 3. How documented	

Clinic______________________ Location_________________________
Date_______________

Activity Description: Clinical Information Systems Processes

Descriptive Notes	Reflective Notes
Patient Scheduling: 1. Electronic? 2. Provider specific? 3. No shows/Cancellations ? Patient registries generated and used for…. 1. Scheduling? 2. How are multiple chronic diseases handled? 3. Is compliance recorded and measured? Treatment plans are generated…. 1. By whom? 2. Who follows up? How? 3. What happens with non-compliance?	