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The Patient-Centered Medical Home and Diabetes Mellitus Outcomes: A Systematic Review

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has been found to be complete and satisfactory in all respects,
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Abstract

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MSN, Walden University, 2010

BSN, University of South Carolina- Aiken, 2003

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Project Submitted in Partial Fulfillment

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Abstract

Ineffectively managed chronic diseases such as diabetes mellitus (DM) increase overall health care expenditures and negatively affects health outcomes such as exacerbations, functional decline, disability, and death. The purpose of this systematic review (SR) was to review the DM outcomes reported by patient-centered medical homes (PCMHs). The goal was to determine how care coordination and evidence-based clinical management impacted financial and health outcomes. The SR followed the Cochrane protocol and complied with the PRISMA evidence-based minimum set for reporting. Overall, DM management in the PCMH demonstrated statistically significant completion rates for essential screenings and preventive care, including HgA1c ($p = 0.0013$), lipid management ($p < 0.0001$), foot exam ($p < .0001$), referral for eye exam ($p < .0001$), pneumococcal vaccine ($p = <0001$), influenza vaccine ($p < .0001$), and urine micro albumin ($p < 0.001$). Statistically significant improvement ($p = 0.000$) was found in care effectiveness measures such as HgA1c, low density lipids, cholesterol, triglycerides, high density lipids, and systolic blood pressure ($p = 0.010$). There were improvements in pre- and post-test effectiveness and data information set (HEDIS) measures, including HgA1c (56% to 97%), LDL (56% to 94%), micro albumin (68% to 94%), and referral for eye exam (41% to 68%). Finally, decreased emergency room visits and inpatient admissions were reported. The implications for positive social change include advancing chronic care management within a PCMH to further improve care coordination of care, improve patient outcomes, reduce unwarranted admissions and emergency room visits, and decrease overall health care costs.

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Dedication

I would like to dedicate this project to my late brother, Chad Eric Sullivan (11/15/1974 -10/26/2016), who was killed by a drunk driver on 10/26/2016. Chad always provided encouragement and support throughout my DNP journey. I will miss our conversations and being able to share the final phase of this journey with him. You were such an inspiration to everyone you encountered. I love you and until we meet again.

I would also like to dedicate this project to the case managers, care managers, patient care coordinators, care team members, and physicians in the primary care setting. Thanks for your hard work and dedication to ensure patients receive coordinated quality care especially when financial resources and reimbursement are limited. I admire your continued commitment to providing patient-centered holistic care.

Acknowledgments

I would like to thank Dr. Patrick Palmieri for his continued support and guidance. A special thanks to Michele Stanek for her support, guidance and friendship throughout this journey. I would also like to thank my wonderful husband and best friend, Michael McManus, for his continued support, encouragement, and pushing me to pursue a terminal degree. Thanks for being so understanding and for tolerating the countless late nights as I worked on the dissertation and other activities for the DNP degree. I am looking forward to another trip to Hawaii or somewhere tropical soon. I would like to thank my wonderful parents, Thomas and Myrtle Sullivan, for instilling the importance of pursuing advanced educational opportunities and for their prayers, support, and encouragement. Thank you.

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Section 1: Nature of the Project

Introduction

Care management and coordination of care are not new concepts to improving quality of health services and patient outcomes; however, penalties and withholding reimbursement for poor quality services is an industry-wide standard. The Patient Protection and Affordable Care Act (ACA) radically changed the health systems landscape. The implementation of the ACA allowed uninsured individuals an opportunity to purchase affordable health insurance. The ACA is responsible for removing barriers such as preexisting clauses, which often resulted in denial of coverage, extended waiting periods, and/or higher premiums and allowing continuation of coverage under a parent's health plan until the age of 25. During the first year of the ACA, an estimated 1 million young adults ages 19 to 25 were covered under their parent's health plan and 30,000 individuals previously denied for insurance due to preexisting conditions were able to obtain coverage (Seibelius, 2011). In addition, new health plans under the ACA are required to provide essential health benefits, that include coverage for prescription drugs, hospitalization, emergency, ambulatory care, behavioral health, maternity, newborn, pediatric, disease management, and preventive and wellness services (Bagley & Levy, 2014). The ACA removes financial barriers for preventative services such as vaccinations, preventative screenings, and wellness counseling in an effort to improve patient outcomes (Health and Human Services, 2009). In 2010, the ACA went into effect to ensure individuals have access to insurance and receive quality health care by tying reimbursement to quality improvement

initiatives such as care coordination, case management and other activities to improve outcomes and decrease healthcare costs (Health and Human Services, 2009).

Patient-centered medical homes (PCMHs) evolved from the ACA. The purpose of the PCMH is to provide high quality, coordinated, patient-centered, holistic care. Implementation of care coordination and care management initiatives by PCMHs are influential in decreasing healthcare costs and improving patient outcomes (Collins, Piper, & Owens, 2013). Providing quality healthcare involves safe, efficient, and patient-centered care (Ball et al., 2011).

Poorly managed chronic conditions contribute to rising healthcare costs, which results in multiple readmissions, increased length of stay, frequent utilization of emergency room (ER) services, and disabilities. Poor medical management of diabetes mellitus in the can lead to amputations, vision loss, renal failure, and neuropathy. Diabetes mellitus and associated complications in the Medicare population are estimated at $174 billion (Caspersen, Thomas, Boseman, Beckles, & Albright, 2012). Approximately 10.9 million people 65 years or older are affected by diabetes. This is anticipated to triple by 2050 (Caspersen et al., 2012). Chronic conditions such as diabetes, hypertension, coronary artery disease, and hyperlipidemia place an individual at risk for increased morbidity, disability, and mortality. Retinopathy and nontraumatic limb amputations are the leading complications associated with diabetes. (Johnson & Raterink, 2009). For example, in 2010 a reported 60% of nontraumatic limb amputations were related to diabetes (World Health Organization, 2013). Additionally, diabetic patients

have a 15% increase of developing leg or foot ulcers due to diabetic neuropathy or infections (Markuson et al., 2009).

The role of the care manager in primary care is a central driver for effective chronic care management programs. The care manager serves as a liaison, educator, advocate, and facilitator to ensure patients receive recommended preventative and routine care. The care manager is responsible for navigating a quagmire of issues to include compliance with regulations, documentation standards, working with patients with multiple comorbidities, limited financial and community resources. The ultimate goal for care managers is to educate patients and families, implement strategies to contain costs, promote multidisciplinary collaboration, and empower the patient through self-care strategies to prevent hospital readmissions and ER visits (Parsons et al., 2012).

Chronic diseases are the leading cause of death and disability (Draper, Draper, & Bresick, 2014). Chronic diseases in the United States are responsible for 7 out of 10 deaths and one fourth of disabilities associated with limitations on activities of daily living (Zamosky, 2014). In addition, chronic diseases are responsible for two thirds of deaths worldwide (Bauer, Briss, Goodman, & Bowman, 2014). In the United States, diabetes is the seventh leading cause of death (Centers for Disease Control and Prevention, 2014b). The leading complications associated with diabetes include retinopathy, nephropathy, and heart and renal disease (Zamosky, 2014).

The Centers for Medicare and Medicaid (CMS) have continued to move away from fee for service reimbursement and towards reimbursement based on the delivery of quality healthcare (Aroh, Collela, Douglas, & Eddings, 2015). As of January 1, 2015,

Medicare began reimbursing providers for non-face-to-face chronic care management consultations for patients identified with two or more chronic conditions. Non-face-to-face care management by a health care provider includes communications with the patient, the patient's family, or authorized representative, which are conducted via telephone, secure e-mail, patient portal or other asynchronous modalities (Centers for Medicare and Medicaid, 2014). These non-face-to-face activities may include, but not be limited to, prescription refills, updates to care plan, referrals, medication reconciliation, and coordination of care. Other non-face-to-face activities include telephonic follow-up after hospitalization or emergency room visits. Overall, the purpose of this initiative is to improve care coordination between providers and increase patient self-care to decrease ER utilization and decrease admissions and complications associated with chronic diseases (McManus, 2014). Furthermore, the care coordination also provides an opportunity to identify potential gaps in care, access to care, and other potential barriers.

Problem Statement

Rising healthcare costs associated with chronic health conditions within the Medicare population are estimated to be $4.2 trillion annually (Erdem, Prada, & Haffer, 2013). Over two thirds of Medicare dollars are spent on five or more chronic diseases (Lochner, Goodman, Posner, & Parekh, 2013). Chronic conditions are associated with overutilization of resources such as ER visits and inpatient admissions contributing to continued rising healthcare costs. The cost of health services for a person with chronic conditions is 4 times more for than those without chronic conditions (Christensen et al., 2013). Healthcare costs associated with management of chronic conditions exceeds $400

billion (Foote, 2009). Disabilities associated with chronic diseases are another contributing factor to escalating healthcare costs. For example, diabetes retinopathy is a leading cause for blindness or vision loss (Haley & Richards, 2014). This condition is preventable by following the American Diabetes Association (ADA, 2014) recommendations, including an annual eye exam for early detection and treatment of retinopathy. Furthermore, a comprehensive eye exam in diabetics can reduce the risk of total vision loss by 90% (Brown et al., 2013).

In an effort to improve patient outcomes, provide quality healthcare, and control costs, innovative approaches and care management programs are being implemented in various settings. PCMHs are a contemporary approach to address complex patients through a team-based approach to improve health services coordination and provide holistic care (Taliani, Bricker, Adelman, Cronholm, & Gabbay, 2013). PCMHs utilize care managers to support patients with care transitions, care coordination, referrals, and connections to community resources (Daaleman, Hay, Prentice & Gwynne, 2014). The *PICOT* framework is utilized to formulate the questions. The acronym PICOT stands for population/problem, intervention, comparison, outcome, and time frame / type (Schardt, Adams, Owens, Keitz, & Fontelo, 2007).

P - Patients treated in a PCMH with chronic conditions such as diabetes.

I - Chronic care coordination-care management strategy (or model or framework or program). Coordination of care between providers, facilitation of referrals, patient education on disease process

C - Comparison of data from research studies regarding the effectiveness of PCMH care management on ER visits, inpatient admissions, HgA1c, body mass index (BMI), and blood pressure.

O - Improvement in HgA1c, blood pressure, BMI results, a decrease in hospital admissions and ER visits related to chronic conditions.

T - A systematic review was performed over a 5-year span of time from 2010 to 2015 to determine the effectiveness PCMHs have on chronic conditions and outcomes.

Purpose Statement

The overall purpose of chronic care management models is to improve patient self-management, provide appropriate resources, and improve outcomes. This is accomplished through the utilization of key concepts from Wagner's chronic care model (CCM) (Wagner, 1998), Pender's health promotion model (HPM) (Pender, Murdaugh, & Parsons, 2011), and Orem's self-care deficit (Sürücü & Kizilci, 2012). The baby boomer population, individuals born between 1946 to 1964, is the fastest growing age group ("Healthy People," 2014; Winston & Barnes, 2007). Older adults, 65 years and older, are at higher risk of suffering from falls, disabilities, functional decline, and increased morbidity (Han, Ferris, & Blaum, 2014). In addition, more than two thirds of patients eligible to receive Medicare benefits have two or more chronic health conditions ranging from diabetes, hypertension, depression, and/or heart disease (Lochner et al., 2013). The purpose of this project was to systematically review the current chronic care management research literature to understand the clinical and financial outcomes.

Goals and Objectives

Effective goals are specific, measurable, achievable, relevant, and time framed (SMART; Kelly, 2011). The goal of PCMH is to reduce health care expenditures by providing preventative health services, effectively manage chronic health conditions, limit inappropriate utilization of inpatient and emergency room services, and improve patient outcomes. DeVries et al. (2012) found a PCMH commercial insurance pilot program resulted in improved HgA1c testing (82.1% vs 77.7%; $P < .001$), LDL control of less than 100 (64.7% vs. 57.3; $P < .001$), a 12% to 23% decrease in hospitalization ($P < .001$), and a 11% to 17% decrease in ER visits ($P < .001$) when compared to non-PCMH cohorts. Complications and comorbidities associated with diabetes mellitus indicated a 10% to 50 % increase indirect health care cost (Rui et al., 2013).

PCMH care management programs are anticipated to provide education, care coordination, telephonic outreach, and referrals to appropriate community resources. The CCM program requires individual contributions from a multidisciplinary team, including medical assistants (MAs), diabetes educators, nurses, physicians, pharmacists, and ancillary personnel. Naughton, Adelman, Bricker, Miller-Day, and Gabbay (2013) discuss the various roles of MAs in PCMHs, which have been shown to positively impact the patient and the practice. For example, MAs can be utilized as care managers, health coaches, and outreach workers to name a few (Naughton et al., 2013). The objective of this project was to evaluate the research literature to determine the PCMH outcomes. A Level 3 PCMH revealed care management services demonstrated a decrease of

emergency department visits by 8 visits per month and inpatient admissions by 7.5 per month (Daaleman et al., 2014).

Theoretical Foundation and Conceptual Models

Theoretical underpinnings guide nursing praxis, the convergence of theory and clinical practice. Proactive health management by health care professionals enhance quality care (McEwen & Ellis, 2011). For example, telephonic chronic care management reported a statistically significant decrease in readmissions (6.9%; $P < .001$) for those participating in the program as compared to a 14.9% increase for those not participating (Hamar et al., 2010). Orem's self-care deficit theory often informs chronic disease management strategies, programs, and processes (Burks, 1999; Denyes, Orem, & SozWiss, 2001; Kumar, 2007; Markuson et al., (2009); Sousa & Zauszniewski, 2005; Sürücü & Kizilci, 2012; Swanlund, Scherck, Metcalfe, & Jesek-Hale, 2008). Orem's theory assists with self-management of chronic conditions (Evans, 2010) by providing a model to facilitate the development of self-care interventions. Although self-care deficit theory is an important and relevant theory for chronic disease management, the HPM moves the theory to practice for the specific population in this project.

Nola Pender's HPM extends self-care deficit theory to focus on health promotion activities (Ho, Berggren, & Dahlborg-Lyckhage, 2010), which coincides with the goals of the chronic care management (McManus, 2014). Health promotion enhances the quality of life and with a focus on self-care activities such as accountability, nutrition, physical activity, and well-being (Easom, 2003). The goal of health promotion activities in the

elderly population is to promote independence and self-efficacy (Hosseini, Torkani, & Tavakol, 2013).

Edward Wagner developed the CCM model in the 1990s. Wagner's CCM model focuses on improving the health care system at the patient, community, physician, and organizational levels in order to provide quality care (Walters, Adams, Nieboer & Bal, 2012). Chronic care management involves coordinated care interventions and should be multifaceted (Taylor & Lahey, 2008). While the HPM moves theory into practice, the patient-centered concepts of Wagner's CCM will focus on patient engagement and satisfaction for the population in this project (Mirzaei et al., 2013).

The concepts from the PCMH model are somewhat similar to various concepts of Wagner's CCM, Orem's self-care deficit, and Pender's HPM. The PCMH conceptual framework consists of seven joint principles. These joint principles focus on the physician/patient relationship, team-based care, patient-centered care, improving coordination of care, quality, access, and payment supporting PCMH (Braddock, Snyder, Neubauer & Fischer, 2013; Mead, Andres, & Regenstein, 2014). The implementation of the PCMH model into practice has demonstrated improved access to care, a decrease in emergency utilization, improvement in patient compliance, and reduction in spending (Moran, Burson, Critchette, & Olla, 2011). The concepts of the PCMH model include elements aligned with meeting the goals of the triple aim. The triple aim was introduced in 2008 in an effort to improve quality health care in the United States (Block, 2014). The triple aim focus is geared towards improving the patient experience, improving health of populations, and reducing healthcare costs for populations (Block, 2014).

Project Questions

1. What are the physiological patient outcomes resulting from the care coordination and chronic care management at the PCMH, including HgA1c, blood pressure, and BMI?
2. What impact does chronic care management at the PCMH have on diabetes mellitus related emergency department visits and/or hospital readmissions?

Evidence Based Significance of Project

Evidence-based practice (EBP) can improve patient outcomes by guiding health services, with substantiated and clinical practices (Mark, Latimer & Hardy, 2010). EBPs can be organized into a framework to guide clinical practice, reducing variations that lead to poor quality. The successful implementation of EBP is dependent on clinicians because they have first-knowledge of the population and culture of the organization (Mark et al., 2010).

The significance of the project is demonstrated by the potential to decrease costs, improve patient outcomes, and replicability across multiple populations and payer groups. Care coordination models seek to improve communication, reduce gaps in care, and decrease resource utilization through managing exacerbations (Baker et al., 2013). Through a quality improvement initiative, the CMS provide higher reimbursement for primary care providers and medical homes to offset reductions in reimbursement for preventable readmissions (Ferman, 2010). CMS (2014) has proposed to provide higher reimbursement to primary care providers for non-face-to-face visits in 2015 for improved care coordination and chronic care management. The project was guided by Wagner's

CCM, Pender's HPM, and Orem's self-care deficit theory. Robeznieks (2013) discussed how utilizing chronic care management model will improve patient outcomes, quality of care, and decrease costs. A longitudinal study on care management revealed a 15% reduction in mortality and an 18% reduction in hospital admissions (Baker et al., 2013). The Ashville and Hickory project demonstrated how implementation of a CCM can decrease overall expenditures while improving compliance with prescribed treatment regimens (Bunting, Lee, Knowles, Lee, & Allen, 2011). The individualized counseling and goal setting resulted in a substantial reduction of health care dollars spent from 85% to 43% (Bunting et al., 2011). The CCM is intended to improve patient and provider relationships to transform to proactive care versus reactive (Coleman, Austin, Brach, Wagner, 2009). A multidisciplinary team for a practice to transform to proactive care. For example, proactive care in a practice involves information technology, decision support and support for self-management (Coleman et al., 2009).

The CCM initiatives implemented within a PCMH will evaluate the influence on patient adherence to treatment plan, outcomes, and overall healthcare costs. PCMHs provide health services through a multidisciplinary approach, led by physicians, focused on providing comprehensive patient care (Christensen et al., 2013). The CCM program will focus on the Medicare payer population, and those patients with two or more chronic conditions. Furthermore, CMS is proposing additional reimbursement to providers to improve care coordination and improve patient outcomes. The Comprehensive Primary Care initiative is an example that will increase reimbursement or provide bonuses for

PCMHs that improve care coordination through better management of chronic conditions (Stockbridge, Philpot, & Pagán, 2014).

In order to increase the patient homogeneity for the project, the inclusion criteria specify patients diagnosed with diabetes mellitus. The inclusion criteria also further specify patients 18 years and older treated within the PCMH. Additional inclusion criteria consist of all payer sources such as Medicare, Medicaid, private, military insurance, and self-pay. The exclusion criteria includes patients not being treated by a PCMH, patients less than 20 years of age, and pediatric patients within a PCMH.

Implications of Social Change

The care management programs can be expanded to other age groups, diseases, insurance plans, and geographic populations to improve self-care, care coordination, care quality, and cost containment. Reimbursing practitioners for non-face-to-face care activities such as referrals, medication management, and care plan revisions will improve quality healthcare. Overall, the new reimbursement strategy facilitates resource allocations tailored to the specific complexity of the patient population. Non-face-to-face chronic care management programs are required to have asynchronous modalities to connect the patient with the practitioner and the care team as requirement for reimbursement. The use of information technology (IT) such as portals, secure texting, secure e-mails, websites, and telephonic communications are a few of the ways to satisfy this requirement. Information technology (IT) applications allow a patient the opportunity to be interactive, manage their chronic diseases, and communicate with care team members and their practitioner (Soloman, 2008).

Definitions of Terms

The following terms were utilized in defining the chronic care disease management program.

Care manager: A nurse, social worker, or community health worker acting as the primary liaison for patients. The care manager is responsible for education, scheduling appointments, coordinating care, and documenting activities.

Chronic care management: Management of those health conditions which are expected to last at least 12 months or until death, increase the patient's risk for complications, exacerbations, functional decline or decompensation (CMS, 2014).

Chronic care model (CCM): A model utilized in chronic care management. This model was developed in 2001 by Wagner and utilizes six major concepts to improve quality of care for patients with chronic diseases (Dancer & Courtney, 2009).

Patient-centered medical home (PCMH): A model that emphasizes team based, coordinated, and holistic care (Henderson, Princell, & Martin, 2012).

Licensed practical nurse (LPN): A licensed practical nurse is an individual meeting the necessary course requirements and passed the national licensure exam.

Gap in care: A term referring to a delay or omission in care as designated by normal standards of care.

Value-based-purchasing: A strategy intended to incentivize providers through reimbursement based on delivery of quality health care resulting in improved outcomes and decreased costs (Aroh et al., 2015).

Assumptions

Assumptions are defined as statements as true without supporting evidence to support them (Grove, Burns & Gray, 2013). The assumptions for the CCM systematic review include the following:

- Care management administered by PCMHs will show an improvement in care coordination and/or patient outcomes (HgA1c, BP, weight, depression screening).
- Management of chronic diseases by PCMHs will increase overall patient satisfaction.
- The management of chronic conditions within a PCMH will show a reduction in readmissions and emergency room visits related to those chronic conditions.

Limitations

Limitations include weaknesses or barriers that can diminish the findings of the study (Grove et al., 2013). The initial limitations anticipated for the systematic review regarding the effect PCMHs have on diabetes mellitus include the following:

- The limited research on effect PCMHs has on the management and clinical outcomes of diabetes mellitus.
- The variation of research designs.
- The small sample sizes of research studies meeting the inclusion criteria.

Summary

Providing patient-centered coordinated care is one step to improving patient outcomes. Care management activities by PCMH are anticipated to improve quality of life and control costs by decreasing complications associated with chronic diseases resulting in readmissions and preventable ER visits. According to the World Health Organization (2013), diabetes mellitus is responsible for more than 80% of all deaths and is anticipated to be the leading cause of death by 2030. In Section 2, I will discuss the scholarly evidence and theoretical frameworks often associated with care management programs.

Section 2: Background and Context

Literature Search

An electronic literature search was performed from Thoreau and multiple databases simultaneously, such as Medline, CINAHL, PubMed, Proquest, and Cochrane Library. The search strategy consisted of limiting data to the most current literature with publication date ranges from 2010 to 2015. The only exception to the date range that I considered was if the work was considered seminal. The key search terms utilized included *patient centered medical home, PCMH*, *diabetes mellitus*, or *DM*. Boolean terms "and" and "or" were utilized to combine terms such as *patient centered medical home* or *PCMH* with a focus on peer-reviewed randomized control trials, quasi-experimental, quantitative, qualitative, and cohort studies to produce articles that contained one or more of the terms.

Effectiveness of PCMH

The PCMH model of care focuses on improving access, efficiency, and quality of care provided to the patient (Ackroyd & Wexlar, 2014). The Institute of Medicine (as cited in Block, 2014) discussed the importance of improving population health, controlling health care costs for population health, and improving the patient experience, which is referred to as *the triple aim*. The PCMH demonstration projects have shown improvements in care coordination, HgA1c, cholesterol, and reductions in emergency room and inpatient admissions (Bojadzievski & Gabbay, 2011).

Quality of Healthcare by PCMH

The PCMH model is anticipated to improve quality of healthcare. Quality measures are typically aligned with clinical practice guidelines and best practices (Paustain et al., 2014). There are various quality metrics that can be utilized to measure the effectiveness and quality of the care being provided. For example, the HgA1c of the diabetic patient population are monitored to improve quality of care the patient is receiving by ensuring they are treated appropriately based on these results.

Paustain et al. (2014) compared the quality of care received by providers implementing the full PCMH model versus the partial PCMH model. This study was conducted over an 11-month time frame and focused on the effect of PCMH quality measures on quality of care and medical costs (Paustain et al., 2014). The full implementation of the PCMH model reported a 3.5% higher score on quality measures, 5.1% on health prevention, while decreasing health care costs by $26.37 per patient (Paustain et al., 2014).

Conceptual Models and Theoretical Frameworks

As previously discussed, conceptual models and theoretical frameworks guide practice. The PCMH model was based on the CCM (Ackroyd & Wexler, 2014). Other theories that are often associated with empowering patients and improving self-management include Orem's self-care deficit theory and Pender's HPM. Although there are similarities between the three theories/models, there also are notable differences.

Orem's Self-Care Deficit Theory

Orem's theory assists with closing self-care deficits through the identification of barriers that prevent the patient from complying with the prescribed treatment plan (Shahady, 2013). Incorporating the concepts of Orem's self-care deficit theory in chronic care management programs will be essential in empowering the patient and providing the necessary resources for self-management of chronic diseases. Patients that take a more active role in their health care through self-management have improved outcomes (Shahady, 2013). Scholars typically use Orem's self-care deficit nursing theory when opportunities to improve patient outcomes are identified. Practitioners and health care providers have a responsibility to empower and educate the patient on how to manage their health and chronic conditions effectively. Orem's self-care deficit nursing theory framework is strikingly similar to the nursing process of assessment, planning, implementation of interventions, and evaluation.

Pender's HPM

Pender's HPM takes into account a person's individuality, experiences, behavior and outcomes associated with those behaviors (Ho et al., 2010). In addition, Pender's HPM model focuses on the individual's current behaviors and the readiness for change in order to manage their health effectively. The HPM also considers the individual's perceptions of their current health state and their willingness to manage their health. The goal of the HPM is to assess, empower, and develop interventions that meet the needs of the patient to achieve the desired outcomes (Ho et al., 2010). The HPM model allows flexibility to accommodate each individual, setting, and situation.

Chronic Care Model

Providing holistic care takes into consideration the whole patient by considering the medical, social, and psychological needs (Shahady, 2013). This is one reason for selecting Edward Wagner's CCM. The six elements of the CCM include patient support for self-management, redesign of healthcare delivery system, clinical information systems, decision support, and community and organizational resources (Dancer & Courtney, 2010). The utilization of the CCM has been widely accepted and embedded within the PCMH to improve quality. The CCM is illustrated in Figure 1 (Wagner, 1998).

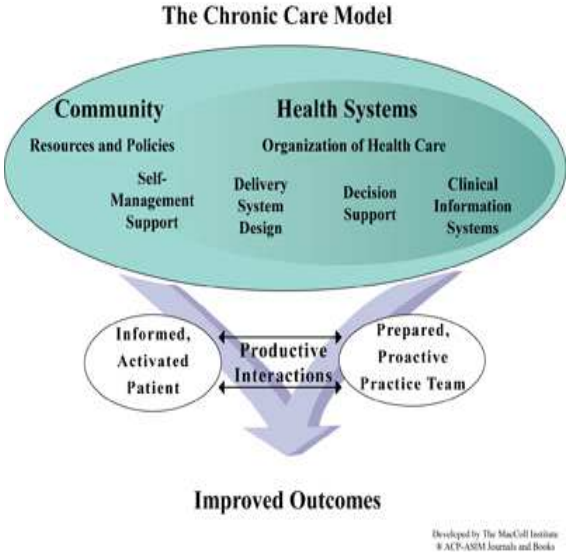

Figure 1. The CCM. From "Chronic Disease Management: What Will It Take to Improve Care for Chronic Illness?" by E. H. Wagner, 1998, *Effective Clinical Practice, 1*(1), 3. Copyright 1998, American College of Physicians; American Society of Internal Medicine. Reprinted with Permission.

PCMH Model

The PCMH model is a framework that guides practices in improving access and delivering patient-centered quality health care. The guiding principles include team-based care, patient-centered care, care coordination, safety and quality, increased access to care,

and improving the relationship with the primary care provider(s) (Braddock et al., 2013). In the United States, the National Committee for Quality Assurance (NCQA) PCMH model are the frequently utilized set of standards to assist practices with obtaining recognition as a PCMH (Braddock et al., 2013). The categories within the NCQA standards align with the PCMH framework. These standards focus on enhancing access and continuity, team-based care, management of patient populations, care management, coordination of care, and performance measurement and quality improvement (NCQA, 2014). The PCMH adopted the concepts of the CCM (Bojadzievski & Gabbay, 2014). The PCMH model depicts the various concepts and Figure 2 provides and illustration of the model.

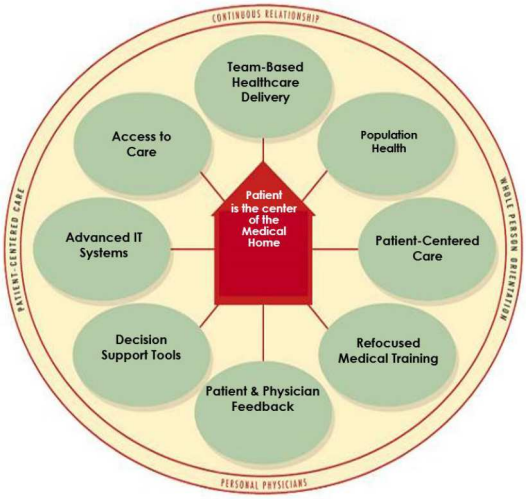

Figure 2. The PCMH. From "National Naval medical center patient-centered medical home: A partnership committed to improving healthcare", by K. A. Dorrance, 2009, *Healthtechnet.net.* Copyright 2003 by the National Naval Medical Center. Reprinted with permission.

Section 3: Collection and Analysis of Evidence

Method

The method is the systematic literature review to evaluate the impact PCMHs have on chronic diseases, such as diabetes. Cochrane protocol is one protocol utilized to perform systematic reviews (Higgins & Green, 2011), and the details of the protocol are outlined in Appendix A. The systematic review of randomized controlled trials, quantitative, qualitative, and cohort research studies evaluating the effectiveness of PCMH initiatives in improving a patient's self-management, HgA1c, blood pressure, lipids, cholesterol, weight, renal function, readmission rates, emergency room visits, and lifestyle changes such as smoking cessation, weight loss, dietary changes, and weight loss or management. After approval by the DNP Project Committee and the Walden University's Institutional Review Board, I completed the systematic review and have reported the findings. The Institutional Review Board approval number was 04-12-16-0147987. A systematic review is a step-by-step process that groups empirical evidence to answer the research question (Higgins & Green, 2011). I extrapolated quantitative data from the relevant research literature in the search. Review of quantitative data assists with the identification of specific patterns or themes for the identified population (Terry, 2012).

I performed the literature review of the research studies and a professor with the local university served as the second reviewer. The search strategies and key word searches were documented and provided to the second reviewer to ensure the search can be replicated and to avoid omission of relevant research studies. A review of the abstracts

assisted with elimination of research studies that did not meet the inclusion criteria. The remaining research studies were reviewed to determine if they were appropriate based on the population, interventions, and outcomes. The second reviewer and I reviewed all eligible studies remaining to identify themes, interventions, and outcomes. The data from the remaining studies were collected, analyzed, and reported.

Inclusion criteria included research studies of patients currently being managed within the PCMH with a diagnosis of diabetes mellitus that resulted in exacerbations or functional decline. Exclusion criteria included pediatric patients, patients with gestational diabetes, without confirmed diagnosis of diabetes mellitus, depression, research studies performed outside of the United States, and non-PCMH practices. A systematic review using the Cochrane protocol is outlined in Appendix A, which I performed to identify and isolate research studies meeting the inclusion and exclusion criteria for the DNP project. The Cochrane protocol includes background, objectives, methods for selecting studies, data collection and analysis, acknowledgements, references, tables and figures, and supplementary information (Higgins & Green, 2011). The methods section of the protocol will elaborate on the types of studies, participants, interventions, outcomes and search strategies (Higgins & Green, 2011). The systematic review will include randomized control trials and cohort studies. The DNP capstone project will be submitted to committee members for review and revisions.

Program Design

Program planning and design allows the researcher to systematically evaluate the needs and develop interventions to meet the needs of the identified population (Kettner,

Moroney, & Martin, 2013). I used the Cochrane protocol to perform the systematic review (Higgins & Green, 2011). The Cochrane protocol is outlined in Appendix A.

Data Collection

The initial data collection included research studies meeting the inclusion criteria. The data from the randomized control trials and cohort studies were reviewed to determine if there were statistically significant differences to interventions by the PCMH based on race, age, and socioeconomic status. The systematic review of the literature measured patient outcomes based on interventions provided for their chronic conditions. These outcomes included, but were not limited to, blood pressure, HgA1c, weight, renal function, lipid panel, utilization of emergency department, and inpatient admissions. Additional themes that would be worthy of measuring include lifestyle changes, such as smoking cessation, weight loss, dietary changes, and increasing physical activity.

Data Analysis

Research studies meeting the inclusion criteria were selected and reviewed. A local university professor and researcher agreed to be the second reviewer and to assist with data analysis. Data from the selected studies were analyzed and discussed. Themes from the selected studies were analyzed and extrapolated. The analysis revealed interventions often utilized within a PCMH to improve clinical outcomes and assist patients with diabetes mellitus to improve self-management.

Project Evaluation Plan

Ongoing evaluation of program goals, objectives, and activities are needed to identify barriers or limitations of the program design (Hodges & Videto, 2011). Program

evaluation is key to determining if established goals and objectives are being met as intended by the program design. The program evaluation provides information on strengths, limitations, biases, and cost effectiveness (Hodges & Videto, 2011). For this project the data from the systematic review were analyzed to determine the types of program evaluations commonly utilized in the research studies.

Evaluation plans should be incorporated in program planning. The purpose of an evaluation plan is to obtain feedback on the progress and impact of the program to determine if changes need to be made (Kettner et al., 2013). Chronic care improvement goals and objectives include improvement of care coordination and quality of care (Fagen et al., 2010). Ongoing program evaluation is needed to reevaluate the program, the services offered, and the sustainability of the CCM program.

The long-term impact is improved patient outcomes as a result of self-management and care coordination. Empowering patients to be active in their healthcare is essential in improving compliance and outcomes (Shahady, 2013). Primary care providers and care team members are key in ensuring the care provided is coordinated, appropriate, and cost effective in order to meet the needs of the patient (Mirabito & Berry, 2010). While health care professionals play a central role to engage and empower, the patient is ultimately responsible for assuming responsibility for lifestyle choices and behaviors (Christensen et al., 2013). Decreasing costs associated with chronic conditions and associated disabilities is another long-term impact. Approximately 6.6 million patients with diabetes will suffer from visual impairments. Rowley and Bezold (2012) estimated costs associated with diabetes complications at $514 billion dollars.

Care coordination and CCMs have shown promise in decreasing gaps in care. Preventable exacerbations of chronic conditions will decrease the inappropriate use of emergency room (Baker et al., 2013). According to Spoorenberg and colleagues(2015), the intent of care management by a PCMH is to provide proactive and patient-centered health care to effectively manage chronic diseases and make the necessary lifestyle changes.

Timeline for Evaluation

The evaluation of the data from the systematic review was conducted between April 2016 to September 2016. The systematic review provided data regarding the feasibility of moving forward with the current PCMH's chronic care management program, which was postponed in October 2015. The postponement of the initial DNP care management program was due to fierce salary competition from local nursing homes, and the practicum site has struggled to find a licensed practical nurse. The program has been postponed until a care coordinator can be hired and trained. My plan was to perform a systematic review to determine the impact PCMHs have on chronic conditions and care management. In addition, the systematic review provided information regarding specific interventions implemented by the PCMH, which resulted in statistically significant improved outcomes, lifestyle choices, or cost containment.

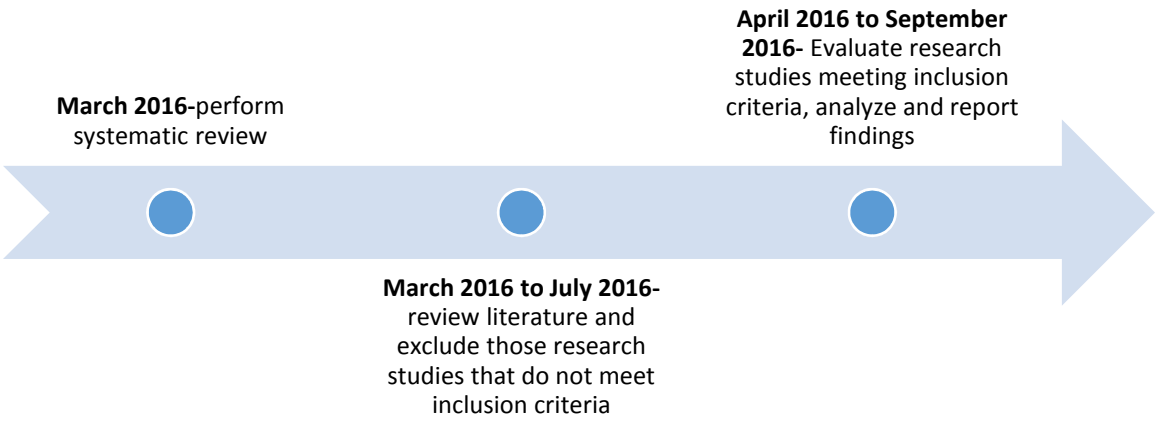

Figure 3. Evaluation time line.

Summary

Coordination of care and chronic care management coupled with empowering patients to self-manage those chronic care conditions effectively are a few interventions to decrease overall health care costs, disabilities, reduce readmissions, ER visits associated with chronic diseases, and increase compliance with treatment regimen.

Section 4: Findings and Recommendations

Introduction

Primary care practices utilize the PCMH model for practice transformation to improve care coordination, access, and quality health care. Defining elements of a PCMH include (a) patient-centered care, (b) team-based care, (c) care coordination, (d) systematic evidence based approach, and (e) performance measurement and quality improvement (Jackson et al., 2013). The concepts of the PCMH have shown improvement in clinical outcomes and management of chronic diseases, such as diabetes mellitus. A systematic review of research studies was performed to determine what impact the PCMH model has on clinical outcomes for patients diagnosed with diabetes mellitus.

Summary and Evaluation of Findings

A systematic review was performed using the following keyword search strategies *patient centered medical home* or *pcmh* and *diabetes mellitus* or *dm* or *adult onset diabetes* and *randomized control trials, cohorts, quantitative, qualitative* or *quasi-experiment* on CINAHL, MedLine, Proquest, PubMed, Cochrane, and Thoreau databases. The results included various research designs in the primary care setting. The research studies evaluated for this systematic review included mixed method, observation, survey, data collections, cross sectional analysis, nonrandomized cohort, prospective quasi-experimental, retrospective review, randomized control trial, pretest/posttest, and a systematic review. Research methods are ranked according to the quality of evidence. Figure 4 illustrates the hierarchy of research designs based on quality of evidence.

Systematic reviews and critically appraised topics and articles are in the top tiers followed by randomized control trials, cohort studies and case-controlled studies or reports. Expert opinion is ranked the lowest. For the purposes of this systematic review, the second review and I attempted to utilize the higher tiers and avoided expert opinions and background information. However, the inclusion criteria and focus for this systematic review resulted in cohort studies being utilized. There was one systematic review with the remainder between the randomized control trials and case controlled studies.

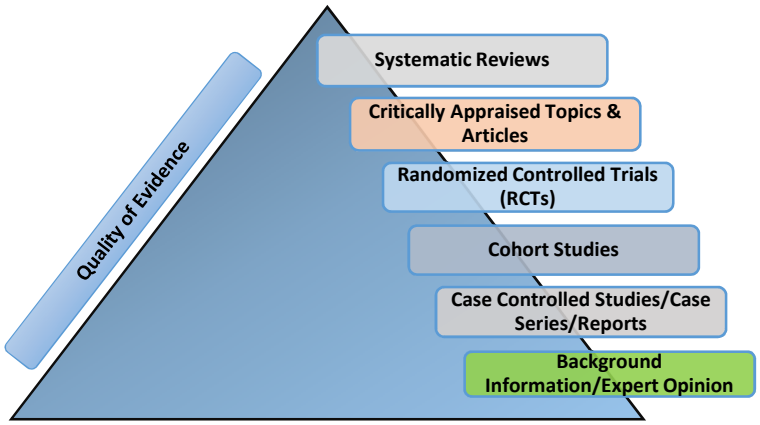

Figure 4. Pyramid of evidence.

Grading the quality of evidence is the degree of confidence in the evidence. The Cochrane protocol utilizes this approach to grade the quality of evidence. There are four grade levels of evidence: high, moderate, low, and very low quality of evidence. The higher the level of quality, the more reliable (Higgins & Green, 2011). Typically, randomized control trials start out as high and observational studies are low quality. There are five specific factors that can lower the quality of evidence, and these include limitations in detailed design and execution, inconsistency, indirectness of question or PICOT, and imprecision and publication bias (Higgins & Green, 2011). The three factors

that may increase the quality of evidence include an increased magnitude of effect, confidence in the effect, and the results of the effect (Higgins & Green, 2011).

The search criteria pulled 434 research studies and three studies from other sources. After duplicates were removed, 411 remained. The remaining titles were reviewed for inclusion and 267 were excluded as not meeting the inclusion criteria. One hundred forty-four abstracts were screened for eligibility and 94 of these were excluded based on the content within the abstract. A full text review was performed on 50 research studies and 34 were excluded based on the inclusion and exclusion criteria. The reasons for exclusion varied from diagnosis other than diabetes mellitus, ages less than 18 or no age mentioned, type of practice, non-PCMH, and non-English or United States studies. The remaining 16 studies were included as meeting the inclusion criteria. Three research articles were added from review of the bibliographies of the studies. Appendix B illustrates the research, screening, exclusion, and inclusion numbers utilizing the PRISMA table (Moher, Liberati, Tetzlaff, & Altman, 2009).

The research studies were reviewed independently and various themes within the studies were identified. The emerging themes identified during the systematic review included team-based care, PCMH interventions on clinical outcomes, costs and completion of standards of care for diabetic patients, and self-management. There were various interventions utilized within the PCMH that contributed to noted improvements of clinical outcomes, self-management, documentation of completing standards of care, and improving the patient experience. These interventions included group medical visits,

pharmacist-led interventions, registered nurse certified diabetes educator (RN-CDE), and care coordination.

The interventions discussed in the research studies focused on the impact of pharmacist interventions, group medical visits, self- management, electronic messaging, registered nurse certified diabetes educator, and care coordination on patient outcomes within the PCMH. The evidence indicated the PCMH positively affected clinical outcomes and showed improvement in self-management, HgA1c, low density lipids (LDL) and blood pressure. Based on the data from the studies meeting inclusion criteria, there were no statistically significant reductions in emergency room visits and hospitalizations in patients with diabetes mellitus.

Team-Based Care

One element of the PCMH is team-based care (Ackryod & Wexlar, 2014; Berdine & Skomo, 2012; Bojadzievski & Gabbay, 2011; Edwards, Webb, Scheid, Britton, & Armor, 2012). The integration of multidisciplinary team members such as pharmacist and registered nurses was discussed in 5 of the 16 research studies reviewed. Team-based care is instrumental in effectively managing the complexities and co-morbidites associated with chronic diseases, such as diabetes mellitus. Effective communication and care coordination is crucial in team-based care within the PCMH (Bojadzievsk & Gabbay, 2010).

The integration of pharmacist in PCMH team-based models demonstrated improvements in completion of diabetes standards, patient care, medication adherence, and self-management (Berdine & Skomo, 2012; Edwards et al., 2012; Lamb, Baker, &

McFarland, 2015). The ADA (2016) has recommended measurement of HgA1c, lipids, micro/macro albumin, foot exam, eye exam, pneumococcal, and influenza vaccines. Pharmacist integration and interventions on patients with diabetes (n = 94) within the PCMH demonstrated statistically significant improvements in completion rates for screening and measurements of HgA1c (p = 0.0013), lipid measurement (p = < 0.0001), foot exam (p =< 0.0001), referral for eye exam (p = < .0001), pneumococcal vaccine (p = < 0.0001), influenza vaccine (p = < 0.0001) and urine micoalbumin (p = < 0.0001; Edwards et al., 2012). The utilization of a diabetes assessment service (DAS) by pharmacist contributed to higher completion rates of ADA standards of measuring and documenting HbA1c, lipid panel, foot exam, referral for eye exam, microalbumin, and pneumococcal and influenza vaccinations (Edwards et al., 2012).

A nonrandomized cohort study reviewed the effectiveness of pharmacist interventions within the PCMH for diabetes self-management and medication adherence (Berdine & Skomo, 2012). Pharmacist integration and interventions were measured over 1-, 2- and 3-year periods and showed statistically significant improvements in outcomes of recommended ADA (2016) standards of care. The first year illustrated statistically significant improvements were noted in HgA1c (p = 0.000), systolic blood pressure (p = 0.010), LDL (p = 0.000), total cholesterol (p = 0.000), triglycerides (p = 0.000), and high density lipids (HDL; p = 0.000) after the pharmacist interventions. The second year demonstrated statistically significant improvements in HgA1c (p = 0.006), BMI (p = 0.000), LDL (p = 0.000), total cholesterol (p = 0.000), triglycerides (p = 0.000), and HDL (p = 0.000). Statistically significant improvements remained steady 3 years after the

pharmacist-led intervention and integration in total cholesterol ($p = 0.007$), LDL ($p = 0.000$), triglycerides ($p = 0.008$), HDL ($p = 0.000$) cholesterol, and BMI ($p = 0.000$; ADA, 2012).

A quasi-experimental, prospective research study evaluated integration of pharmacists as part of the PCMH interdisciplinary team to determine the impact on the clinical outcomes, such as HgA1c, LDL, and blood pressure for patients with diabetes (Lamb et al., 2015). The eligible population included patients with diabetes mellitus, mean age of 65.13, and HgA1c > 7%, LDL > 100, systolic blood pressure > 130, and/or diastolic blood pressure > 80 ($n = 24$; Lamb et al., 2015). Statistically significant improvements were noted from baseline in HgA1c ($p = 0.0122$), LDL ($p = 0.0156$), systolic blood pressure ($p = 0.0302$), and diastolic blood pressure ($p = 0.0012$) within 6 months of pharmacist interventions (Lamb et al., 2015).

Health care costs associated with diabetes are approximately $198 billion and expected to increase to exceed $500 billion each year by 2020 (Moran et al., 2011). Another approach to team-based care is the integration of registered nurse (RN)-certified diabetes educator (CDE) in the PCMH. The integration of the RN-CDE has demonstrated improvements in clinical outcomes, patient satisfaction, and Healthcare Effectiveness Data Information Set (HEDIS) measures in patients with diabetes (Moran et al., 2011). A pretest-posttest research design evaluated the impact of RN-CDE's had on patients ages 18-80 years of age diagnosed with diabetes mellitus (Moran et al., 2011). Thirty-four eligible participants ($n = 34$) demonstrated statistically significant improvements in HgA1c ($p = 0.000$), fasting blood glucose ($p = 0.002$), and LDL ($p = 0.04$) based on the

RN-CDE intervention focusing on glucose control. There were no statistically significant improvements noted in microalbumin, blood pressure, and BMI, and this was mainly attributed to the focus on glucose control (Moran et al., 2011).

Team-based care and the relationship between the provider and patient is an important aspect for patient engagement. A mixed method study with a qualitative approach was performed to capture the relationship between the four PCMH clinics and their effect on patients with diabetes (n = 1,301) (Hall, Webb, Scuderi, Tamayo-Friedel, & Harman, 2014). The patients rated their experiences with access, care coordination, communication, knowledge, health promotion, trust, and interpersonal relationships. There were noted differences between the clinics; however, statistically significant differences were not appreciated.

Effectiveness on Clinical Outcomes

Supporting evidence indicates diabetic patients managed by PCMHs are more likely to receive preventive services and experience improvements in clinical outcomes and reductions in emergency room visits (Coleman, Austin, Brach, & Wagner, 2009). A review of the literature revealed six of the 16 studies, meeting the inclusion criteria, showed improvements in HgA1c, LDL, blood pressure, and BMI for diabetic patients managed by PCMHs. One goal of the PCMH is to optimize care for the chronically ill patients through team-based care, improved access, care coordination, and delivery of quality health care (Coleman et al., 2009). Various interventions, such as group medical visits, registered nurse-certified diabetes educators (RN-CDE), self-management

programs, and pharmacist-led interventions within a PCMH have reported success in improved control of HgA1c, LDL, BMI, and blood pressure.

A cross sectional study of a pilot project reviewed 25 (n = 25) PCMH practices to evaluate clinical improvements of diabetic patients in higher and lower performing practices (Gabbay et al., 2013). Practices considered higher performing demonstrated improvements in three outcomes. Higher performing practices (n = 5) showed higher overall improvements in HgA1c < 7% (8.8%) BP < 130/80mg/Hg (19.5%) and LDL < 100 mg/dl (14.9%) than lower performing practices (n = 5; Gabbay et al., 2013). The higher performing practices also communicated more effectively with diabetic patients regarding testing and appointments. The limitations of this study were the small sample sizes, the study design, and surveys were performed during the last year and not throughout the study. This study did provide valuable information regarding the variations of diabetic outcomes dependent on the PCMH's performance. Higher performing PCMHs had better diabetic outcomes than did their lower performing counterparts.

In a cohort study, Seiber, Fiorella, and Mantila (2012) evaluated the effectiveness of group medical visits on clinical outcomes for patients with diabetes. Seiber et al. focused on the effectiveness of group medical visit interventions on clinical outcomes on 62 diabetic patients (n = 62) led by a family practice physician and psychologist. Five 2-hour sessions focused on goal setting, physical activity, portion control, dietary information, food preparation, and stress management (Seiber et al., 2012). There were improvements noted in pre- and post-interventions of group medical visits group (n =

62). However, these improvements were not statistically significant when compared to the control group (n = 137).

Emerson et al. (2016) used a pilot randomized controlled trial to evaluate effectiveness of multidisciplinary interventions and modalities of communication on diabetic outcomes. The study consisted of an intervention (n = 12) and control group (n = 8) in the initial group. However, attrition in both groups over time resulted in four patients in each group. Both intervention and control groups received usual care from the PCMH. Additional technology was provided to the intervention group, which allowed for virtual visits with a health coach and remote glucose monitoring (Emerson et al., 2016). The intervention group had fewer office visits and more phone and virtual contacts than the intervention group. The intervention group (n = 4) had an initial HgA1c of 10.2% prior to the intervention and 8.1% post intervention. The control group demonstrated similar improvements in HgA1c from 11% to 8.4%. The main limitation of this pilot study was attrition of participants and the small sample size of the intervention and control group.

The integration of a registered nurse certified diabetes educator (RN-CDE) within the PCMH has shown promise for diabetic patients to achieve their clinical goals (Moran et al., 2011). The pretest-posttest design was conducted on 34 patients (n = 34) with type 2 diabetes with a HgA1c greater than 8% from two PCMHs. The posttest results revealed statistically significant improvements in HgA1c from 9.6% to 8% (p = 0.000), LDL from 122.22mg/dl to 106.11mg/dl (p = 0.04), and fasting blood glucoses from 208.20 to 129.56 (p = 0.002) (Moran et al., 2011). Although not statistically significant, there were

slight improvements in BMI from 34.9 to 34.54 ($p = 0.26$) and patients with LDLs less than 100 to begin with from 94.43mg/dl to 90.86 ($p = 0.53$). There were no improvements noted in blood pressure or microalbumin. The integration of the RN-CDE had a positive impact on improving HEDIS measures, such as HgA1c, LDL, retinal eye exam, mircroalbumin, and documented blood pressure. The improvements in the diabetic HEDIS measures are noted in Table 1. The integration of the RN-CDE within the PCMH did not demonstrate statistically significant decreases in emergency room visits ($p = 0.65$) and inpatient admission (0.70; Moran et al., 2011). The identified limitations of the study were the nonrandomized sample, small sample size, and the limited time period of the study.

Table 1

HEDIS Measures for Diabetes

HEDIS Measure	Pretest #	Pretest %	Post Test #	Post Test %
HgA1c	19	56%	33	97%
LDL	19	56%	32	94%
Microalbumin	23	68%	32	94%
Retinal eye exam	14	41%	23	68%

Note. Adapted from "Exploring the Cost and Clinical Outcomes of Integrating the Registered Nurse-Certified Diabetes Educator into the Patient-Centered Medical Home," by K. Moran, R. Burson, J. Critchette, and P. Olla, 2011, *The Diabetes Educator, 37*(6), 780-793. http://doi.dx.org/10.1177/0145721711423979

Calman et al. (2013) performed a retrospective study on diabetic patients ($n =$ 4,595) over a 9-year period revealing improvements in HgA1c from baseline based on

PCMH model interventions. The interventions consisted of patient outreach, diabetes education, psychosocial, and care by primary provider (Calman et al., 2013). The study revealed the HgA1c decreased by 2% from 10.72% to 8.34% for those patients with a baseline HgA1c of 9% (Calman et al., 2013). The study also revealed a slight increase in the HgA1c of 0.34% from baseline. The study provided evidence that PCMHs are demonstrating improvements in HgA1c. The limitations noted for this study included the use of a nonrandomized convenience sample and the singular focus on the HgA1c.

A nonrandomized cohort study evaluated the effectiveness of integration of pharmacists within the PCMH on patients with chronic diseases such as diabetes mellitus, hypertension, and chronic heart failure (Berdine & Skomo, 2012). There were 200 patients (n = 200) included in the study with multiple diagnosis. Patients with a diagnosis of diabetes mellitus made of 37% of the population (n = 75). Pharmacist integration has shown statistically significant improvements in HgA1c (p = 0.000), BMI (p = 0.000), LDL (p = 0.000), HDL (p = 0.000), total cholesterol (p = 0.000), triglycerides (p = 0.000), and systolic blood pressure (p = 0.000) within the first year after implementation (Berdine & Skomo, 2012). Two years after the pharmacist-led interventions, patients continued to show statistically significant improvements in their HgA1c (p = 0.006), LDL (p = 0.000), total cholesterol (p = 0.000), HDL (p = 0.000), triglycerides (p = 0.002), and BMI (p = 000). The participants did not maintain statistically significant improvements in HgA1c (p = 0.132), systolic blood pressure (p = 0.777), diastolic blood pressure (p = 0.968) 3 years after the pharmacist interactions. However, statistically significant improvements from baseline 3 years after the pharmacist interventions were

noted in LDL ($p = 0.007$), total cholesterol ($p = 0.000$), triglycerides ($p = 0.008$), and HDL ($p = 0.000$) (Berdine & Skomo, 2012). Pharmacist-led interventions within the PCMH appear to be effective in managing diabetic outcomes. The limitations of this study were it was nonrandomized cohort study and the small sample size. The study did provide valuable data of how pharmacist-led interventions can contribute to improved diabetic outcomes.

Health Care Utilization and Costs

The costs associated with diabetes mellitus were estimated at $198 billion annually (Moran et al., 2011). The costs are expected to more than double by 2020. The ineffective management of diabetes can result in overutilization of services, which can continue to drive the costs upward. The multidisciplinary approach of the PCMH has shown improvements in managing the clinical outcomes of diabetes mellitus. According to DeVries et al. (2012), PCMH demonstration projects had shown reductions in hospitalizations ranging from 6% to 40% and ER visit reductions ranging from 7.3% to 29%. The cost savings per patient were estimated from $71 to $640 (DeVries et al., 2012). Five of the 16 studies reviewed discussed healthcare utilization and costs.

In a retrospective cross sectional analysis, Flottemesch, Anderson, Solberg, Fontaine, and Asche (2012) evaluated the total costs and potentially avoidable costs. The population consisted of diabetic patients ($n = 2,008$) receiving 50 of their care from the PCMH. The study indicated a $126 reduction per patient for practices engaged in quality improvement and performance improvement initiatives (Flottemesch et al., 2012). Of the 2,008 patients, 781 had episodes of utilization and potentially avoidable costs of $2,623.

The limitations of this study include the design of the study, focus on costs of patients with diabetes in patients with other chronic conditions, and restricted geographical area (Flottemesch et al., 2012). The study did provide information on how the PCMH can be influential in decreasing health care costs associated with diabetes care and possibly other chronic diseases.

An observational study using a difference-in difference approach to determine the effect PCMH practices had on ER visits. The study involved included more than 460,000 patients from 280 practices (David, Gunnarsson, Saynisch, Chawla & Nigam, 2015). The PCMH model has shown to play a role in the reduction in overall healthcare costs through improved management and reduction of unwarranted inpatient admissions or ED visits (DeVries et al., 2012; Flottemesch et al., 2012). The categories monitored four categories of ED visits among diabetic patients (n = 100,679) as well as those with chronic diseases (n = 393,317; David et al., 2015). The patients monitored in the four categories included non-emergent care (n = 100,679), emergent care (n = 50,015), preventable emergent care (n = 100,679) and nonpreventable emergent care (n = 50,015). There were statistically significant differences spanning all four categories of ED visits emergent, non-emergent, preventable and non-preventable ($p < 0.001$) for diabetic patients managed by PCMH (2015). This study illustrated the positive effect PCMHs have on reducing ED visits and the associated healthcare costs. The limitations of this study focuses on solely on ED utilization.

The pretest-posttest research design evaluated the effect the RN-CDE within the PCMH had on ED visits and inpatient admissions (Moran et al., 2011). The results did

not demonstrate statistically significant reductions in ED visits ($p = 0.65$) or inpatient admissions ($p = 0.70$; Moran et al., 2011). One limitation is the short time span of 6 months, which may not have be sufficient to truly evaluate the effectiveness of PCMH on decreasing ED visits or inpatient admissions for diabetic patients.

A meta-analysis which included 48 cluster randomized trials and 94 patient level trials revealed PCMH strategies decreased inpatient admissions by 18% ($p < .001$) and readmissions by 36% ($p < 0.02$) for diabetic patients (Ackroyd & Wexler, 2014). The cost associated with interventions was estimated at $337.93 reduction per patient per year (Ackroyd & Wexler, 2014). In addition, overall health care costs was reduced by $245 per patient (Ackroyd & Wexler, 2014). Ongoing studies would be beneficial to determine the long-term reductions in admissions and associated healthcare costs.

DeVries et al. (2012) performed an observational cohort study to determine what impact PCMH had on reducing health care costs associated with hospitalizations and emergency room visits. There were statistically significant reductions for inpatient hospital admissions ($p = .003$) and emergency room visits ($p < 0.001$) of PCMH patients ages 18 to 44 ($n = 642$; $n = 1222$ respectively) as compared to non-PCMH patients (DeVries et al., 2012). Statistically significant reductions were also noted for inpatient hospitalizations ($p < 0.001$) in patients ages 45-64 ($n = 571$); however, there was no statistical significance for emergency room visits ($p =0.056$) in patients 45-64 ($n = 782$; DeVries et al., 2012). Furthermore, a 15.56% to 17.62% difference was noted for the unadjusted per member per month (PMPM) PCMH patient versus non-PCMH patients. This study provides additional information on the impact the PCMH has on healthcare

utilization and costs. The limitations of the study included the potential for errors within the data from the managed care population and potential miscoding.

Self-Management

One of the recurring themes noted in the systematic review was self-management. Three of the sixteen articles were included in this section. Self-management is a key factor in improving diabetes outcomes; however, there has to be commitment and readiness for lifestyle changes. These changes can be as simple as medication adherence, physical activity, weight and dietary control.

A retrospective review by Solberg et al. (2013) revealed patients from 102 clinics (n = 102) demonstrated optimal improvement in diabetes measure (p = < 0.001). The majority of the clinics were located in metropolitan areas (n = 65) and the remaining in non-urban areas (n = 37; Solberg et al., 2013). The clinic patients weekly visits ranged from less than 350, 350-549, 550-999 and over 1,000 visits per week (n = 21, 27, 27, 27 respectively). Optimal care of diabetes within these clinics consisted of control of HgA1c less than 7%, blood pressure of 130/80 or lower and low density lipoprotein (LDL) of 100mg/dl or less in addition to smoking cessation and daily aspirin use (Solberg et al., 2013). Optimal diabetes care was noted more in the nonurban clinics and midsized clinics had more increases in the quality of care composite measures for diabetes in this study focused on health care organization, delivery system, clinical information, decision management and self-management support (Solberg et al., 2013). There was a noted correlation in the health care home (HCH) performance scores and diabetes care (p =

0.008). There were notable limitations to this study including inconsistency in measurement and issues with validation of responses prior to the study.

Liss et al. (2014) discuss the effect of integrating alternate communication modalities, such as electronic messaging and telephonic encounters on patients with diabetes mellitus (Liss et al., 2014). The population consisted of adults with diabetes (n = 18,486). The study indicated improved access and communication can facilitate the patient's self-management. The study revealed patients ages 18-44 (n = 10) utilizing telephonic encounters appeared to take the initiative for more frequent office visits and encounters with the primary care provider. The information increased office visits were a positive aspect of the enhanced assess component of the PCMH. The study limitations included the singular focus on diabetes, the lack of information on the content of these alternate contacts with the patients. There was no way to identify if the contacts were for educational purposes or questions initiated by the patient.

Depuccio and Hoff (2014) performed a systematic review resulting in 13 research studies (n = 13) focusing on medical home interventions for the older adult. The systematic review revealed patients receiving targeted diabetes education with clinicians showed improvements in self- management, medication adherence and HgA1c results. In addition, there were decrease in hospitalizations and an increase in visits and interactions with the primary care provider (Depuccio & Hoff, 2014). The limitations of the study include the small data group focused on the older population within the PCMH and the associated outcomes. The authors recommended additional studies to improve quality and safety for the older adults treated within the PCMH (Depuccio & Hoff, 2014).

Implications

The implications of this systematic review provides supporting evidence the PCMH model is effective in managing and improving diabetic outcomes. Team based multidisciplinary care within the PCMH was key in effectively managing diabetes mellitus. As previously discussed, PCMHs have shown statistically significant improvements in HgA1c, LDL, total cholesterol, HDL, BMI for diabetic patients. In addition, there notable reductions in health costs associated with diabetes and ED visits. The extrapolation of the data from the research study supports the effectiveness of PCMHs in managing diabetes mellitus.

Project Strengths and Weaknesses

The strengths of the project include the use of Cochrane protocol to guide the systematic review of critically appraised research studies, cohort studies, randomized control trials and systematic reviews. The first limitation of this systematic review includes the levels of evidence utilized meeting the inclusion criteria. The second limitation are the various interventions within the studies meeting the inclusion criteria. The third limitation was the smaller sample sizes within the studies and the attrition of during the lifetime of the studies. Another limitation of the study to consider was the limitations of the inclusion criteria and the researcher's narrow focus on one disease process within the patient center medical home. The goal is for this study to provide a platform for future studies on the effectiveness of the PCMH with a much broader focus to include all disease processes.

Declaration of Conflict of Interest

There were no conflicts of interest declared by the author(s) regarding the research and publication of this article. The primary purpose was to increase understanding of the effectiveness PCMHs have on diabetes outcomes.

Funding

This systematic review was performed as partial fulfillment of a doctorate of nursing practice degree from Walden University in Minneapolis, MN. There was no funding or financial support for this systematic review. The author(s) primary goal was to provide information on PCMH and the impact they have on diabetes mellitus and note the various interventions utilized to improve clinical and financial outcomes.

Summary and Conclusions

In conclusion, the evidence suggests diabetic patients demonstrated better clinical outcomes of HgA1c, BMI, LDL, HDL and triglycerides when they were managed by a PCMH. The evidence did not show statistically significant improvements in systolic or diastolic blood pressure; however, one contributing factor could include the comorbidities associated with this population. The PCMH continues to show promise in managing chronic illnesses such as diabetes mellitus. The literature suggests PCMH interventions have positive impact on quality-adjusted life years (QALY) and cost effective (Pagán & Carlson, 2013). The cost savings per QALY over a 20-year period, per various PMPM, ranged from $7897.72 to $16,648.94 (Pagan & Carlson, 2013). diabetes. Further research is needed to determine the effectiveness of the PCMH on long-

term outcomes on poorly controlled diabetes mellitus, such as lower extremity amputations, multiple chronic diseases and associated costs.

Section 5: Dissemination Plan

Dissemination Plan

The systematic review protocol was submitted for PROSPERO registration. A focal area abstract was submitted in October 2016 for presentation at the International Congress of Nursing (May 2017, Barcelona, Spain), recorded under the identifier ICN17-EN-ABS-2174. The full review abstract was submitted in January 2016, for presentation at the Sigma Theta Tau International 44th Biennial Convention (October 2017) Indianapolis, Indiana, USA. There is a potential opportunity to present the work at a PCMH conference/workshop in the future but the date has not been scheduled at this time. Finally, the final systematic review will be developed into a publishable manuscript for publication in a Scopus indexed journal. The future plan includes continued collaboration with my mentor and an PCMH expert to expand this review to other chronic conditions managed by the PCMH and the outcomes.

Analysis of Self

Performance of the literature review and systematic review provided me with an opportunity to apply the methods learned throughout my tenure at Walden. This was a very labor-intensive process that required hours of reading, writing, organization, appraisal, and synthesis of the data. The ability to perform the systematic review made me appreciate the rigor involved in research studies, especially systematic reviews. The lessons learned from the exposure will assist in the future with performing research studies and systematic reviews as a doctorate of nursing scholar.

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Appendix A: The Cochrane Protocol

Background

Objectives

Methods

Criteria for selecting studies for this review:

Types of studies

- Systematic Reviews
- Randomized control trials
- Retrospective Cohort Studies
- Focus groups
- Qualitative study

Types of participants

- Adults 18 years and older
- Diagnosis of Diabetes Mellitus
- Patient-Centered Medical Homes (PCMH)
- United States

Types of interventions

- Pharmacist lead interventions
- Group visits
- Self-Management

Types of outcome measures

- Self-management
- HgA1C
- LDL
- Blood pressure
- Emergency Room visits
- Inpatient admissions

Search methods for identification of studies

- Keywords: Patient Centered Medical Home, PCMH, Diabetes Mellitus, DM, Randomized control trials, RCT, Cohort studies, Quantitative and qualitative studies.

Data collection and analysis

Acknowledgements

References

- Other published versions of this review
- Protocol being submitted to Prospero

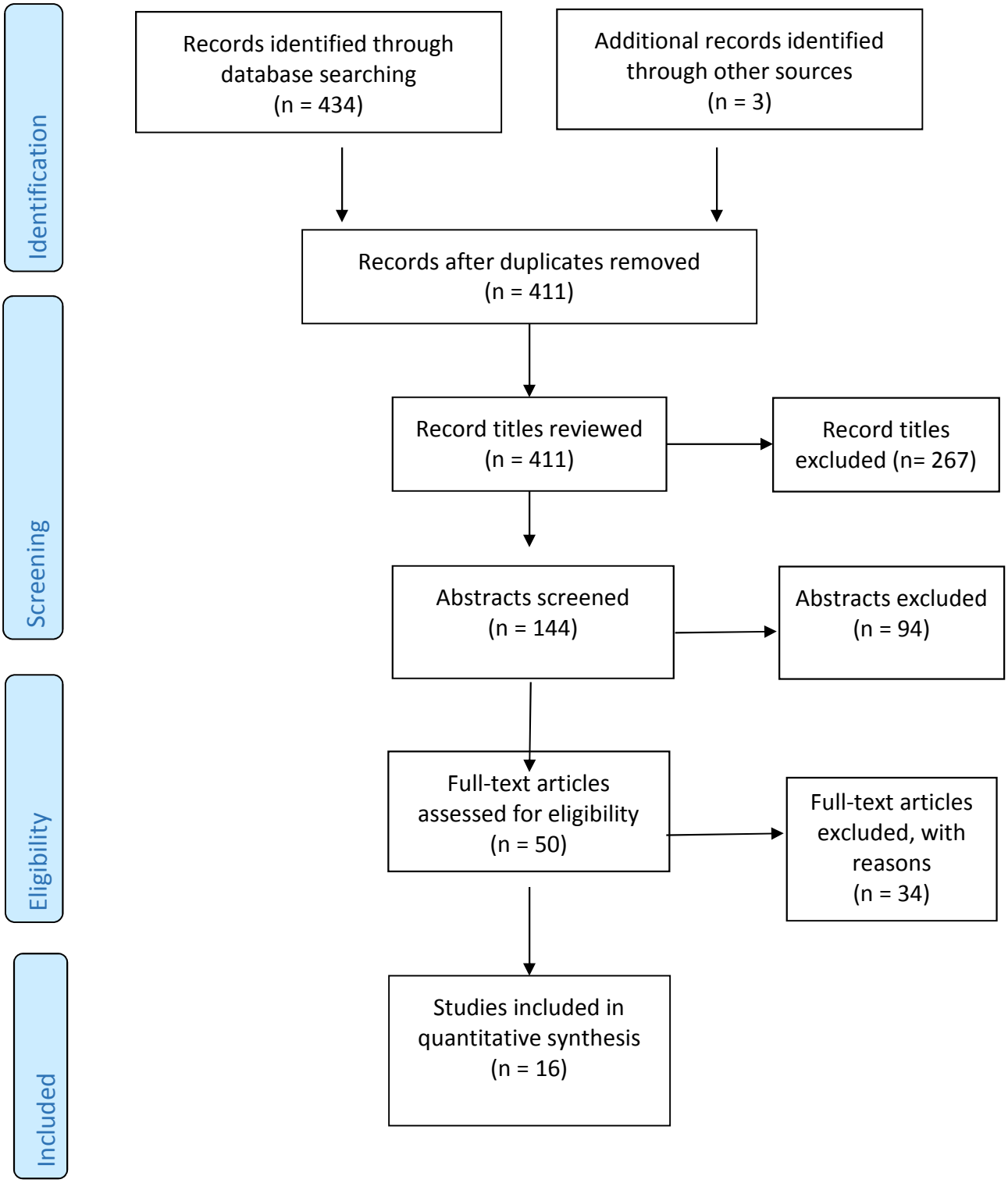
Tables and figures:

- Chronic care Model
- Patient-Centered Medical Home Model
- Timeline
- Evidence Based Pyramid
- Prisma Table
- Inclusion table
- Exclusion table

Additional tables
Figures

(Higgins & Green, 2011).

Appendix B: PRISMA Table



Appendix C: Excluded Research Studies

Excluded Research Studies with Rationale		
Author, Year reference	**Title**	**Rationale for Exclusion**
Jackson et al., (2013)	The Patient Centered Medical Home	Pediatric patients included
Janiszewski, O'Brian, & Lipman, (2015)	Patient experience diabetes Self-management education in PCMH	Age not provided
Koopman, et al., (2014)	Telemonitoring Home Blood Glucose	Was not a PCMH and age not specified
Simmonetti, et al., (2014)	Racial Comparisons in Diabetes Care and Intermediate Outcomes in a Patient-Centered Medical Home	Focus was more on treatment and outcomes based on racial characteristics
Bojadzievski & Gabbay (2011)	Patient Centered Medical Homes and Diabetes	Age not specific
Dickinson et al., (2014)	Practice Facilitation to improve diabetes care in primary care: A report from the EPIC randomized clinical trial.	Focus on systems capacity for supporting continuous quality improvement which is a key component of PCMH; however, it does no focus on evaluating impact of PCMH feature on improving care
Ackyrod & Wexler (2014)	Effectiveness of Diabetes Interventions in the PCMH	Age range not given
Baus et al., (2013)	Registry based diabetes risk detection schema for the systematic identification of patients at risk for DM in West Virginia PCC	Patients were pre-diabetes.
Wang et al., (2014)	PCMH impact on Health Plan members with Diabetes	Did not meet age requirements. 27% of patient population pediatrics.
Rustad, Musselman, & Nemerroff (2011)	The Relationship of depression and diabetes pathophysiological and treatment implications	Did not meet inclusion criteria- focus on depression and relationship with diabetes
Kocarnik et al., (2012)	Does the presence of a pharmacist in primary care	Study done prior to implementation of PCMH

	clinics improve diabetes medication adherence?.	
Parker et al., (n.d.)	Ethnic Differences in appointment keeping and implications for the PCMH-findings from the diabetes study of Northern CA	No interventions noted. Does not meet criteria. Focus on ethnic differences and appointment keeping
Aysola et al., (2014)	Asking the patient about patient centered medical homes: A qualitative analysis	Only 4 patients (8%) had diabetes and the results were not specific as to how those patients answered questions about PCMH
Berkerlear et al., (2012)	Building a PCMH obtaining the patient's voice	Only focused on one concept of the PCMH and did not meet inclusion criteria
Coburn et al., (2012)	Effect of a community-based nursing interventions on mortality in chronically ill older adults: A randomized controlled trial.	Not a PCMH and did not meet inclusion criteria
Herbert et al., (2014)	Patient-centered medical home initiative produced modest economic results for Veterans	Does not meet inclusion criteria. Unable to discern diabetic outcomes from other outcomes within the study
Wiley et al., (2015)	Managing chronic illness: Physician practices increased the use of care management and medical home processes	Does not meet. Unable to discern age or diabetes from other chronic conditions
Glueck & Foreman (2014)	Lessons learned from designing and leading a multidisciplinary diabetes educational group	Age not specific
Burke & O'Grady (2012)	Group visits hold great potential for improving diabetes care outcomes, but best practices must be developed	Did not meet inclusion criteria Population from Germany and U.S.
Friedberg, Hussey, & Schneider (2010)	Primary care: A critical review of the evidence on quality and cost of health care	Did not meet age requirements
Breland et al., (2016)	Key ingredients for implementing intensive outpatient programs within the	Unable to discern if all inclusion criteria were met.

	patient-centered medical homes: A literature review and qualitative analysis	Focus appeared to be on implementing the programs.
Kern, Edwards, & Kaushal (2014)	The patient centered medical home, electronic health records and quality of care	Did not meet age requirements.
Nuti et al. (2015)	The impact of interventions on appointment and clinical outcomes for individuals with diabetes: A systematic review.	Did not meet inclusion criteria. Utilized studies outside of the U.S. Focus was on appointment keeping.
Green et al. (2012)	Lessons learned from implementing the patient centered medical home	Focused more on implementation of PCMH versus diabetes mellitus or outcomes.
Strange et al. (2010)	Defining and measuring patient-centered medical home	Did not meet inclusion criteria. Focused on defining the PCMH
Rittenhouse et al. (2011)	Small and medium sized physician practices use few patient centered medical home processes	Did not meet inclusion criteria. Focus more on practice
Clarke et al. (2012)	Tool used to assess how well community health centers function as medical homes may be flawed	Did not meet inclusion criteria- focus on process and NCQA
Keeley et al. (2014)	A qualitative comparison of primary care clinicians' and their patients' perspectives on achieving depression care: Implications for improving outcomes	Excluded focus more on depression
Stock et al. (2014)	Chronic care model strategies in the United States and Germany deliver patient-centered, high-quality diabetes care	Portion of study performed in Germany. Unable to discern portion in U.S.
Khanna et al. (2012)	HgA1c improvements and better diabetes-specific quality of life among participants completing diabetes self-management programs: A nested cohort study.	Does not meet all of inclusion criteria and only focuses on one concept of PCMH

Eisenstat et al. (2013)	Diabetes group visits: Integrated medical care and behavioral support to improve diabetes care and outcomes from primary care perspective	Did not meet inclusion criteria for age and focus
Valentinjn et al. (2015)	Collaboration processes and perceived effectiveness of integrated care projects in primary care: A longitudinal mixed methods study	Does not meet inclusion criteria age and within the U.S.

Appendix D: Included Studies

Authors	Research Design	Methods	Age Group	PCMH Intervention	Outcomes/Results	Level of Evidence
Edwards et al., (2012)	Cohort Study	Quantitative-medical charts	Age 18-85	Pharmacist led interventions- Diabetes Assessment	Statistically significant reductions in HgA1c, LDL, HDL, micro albumin. Improvement in Retinal exams and pneumococcal and influenza vaccinations.	Level 2b
Flottemesch et al, (2012)	Retrospective cross sectional	Quantitative-Claims data using ICD9, CPT and Evaluation and Management (E&M) codes	Age 19-75	Retrospective review of claims data of patients managed within a medical home	Potentially avoidable costs. Reduction in Emergency care and inpatient costs.	Level 2c
Solberg et al., (2013)	Mixed model	Quantitative-Questionnaires-Physician Practice Connection-Research Survey (PPC- RS)	Age-18 years and older – Adult clinics	Review of surveys and descriptive data. Data from TrasforMN.	Improvement in diabetes measures	Level 2c
Gabbay et al., (2013)	Cross sectional study from a pilot project	Quantitative-using practice-reported diabetes data. Qualitative for questionnaire	Age 18-75	PCMH model concepts regarding diabetes measures	Higher performing PCMH with noted improvements in diabetes measures (HgA1c, BP, LDL)	Level 2b
David et al., (2015)	Difference in difference approach	Data from Independent Blue Cross Claims	Age 52.11 (mean)	PCMH model concepts to decrease emergency room visits	Reduction in potentially avoidable and avoidable ED visits	Level 2c
Seiber et al., (2012)	Cohort study-intervention / control; Original research	Quantitative-medical record	Age: 40-60	Group Medical Visits (GMV)	No statistically significant improvements in diabetes measures	Level 2b

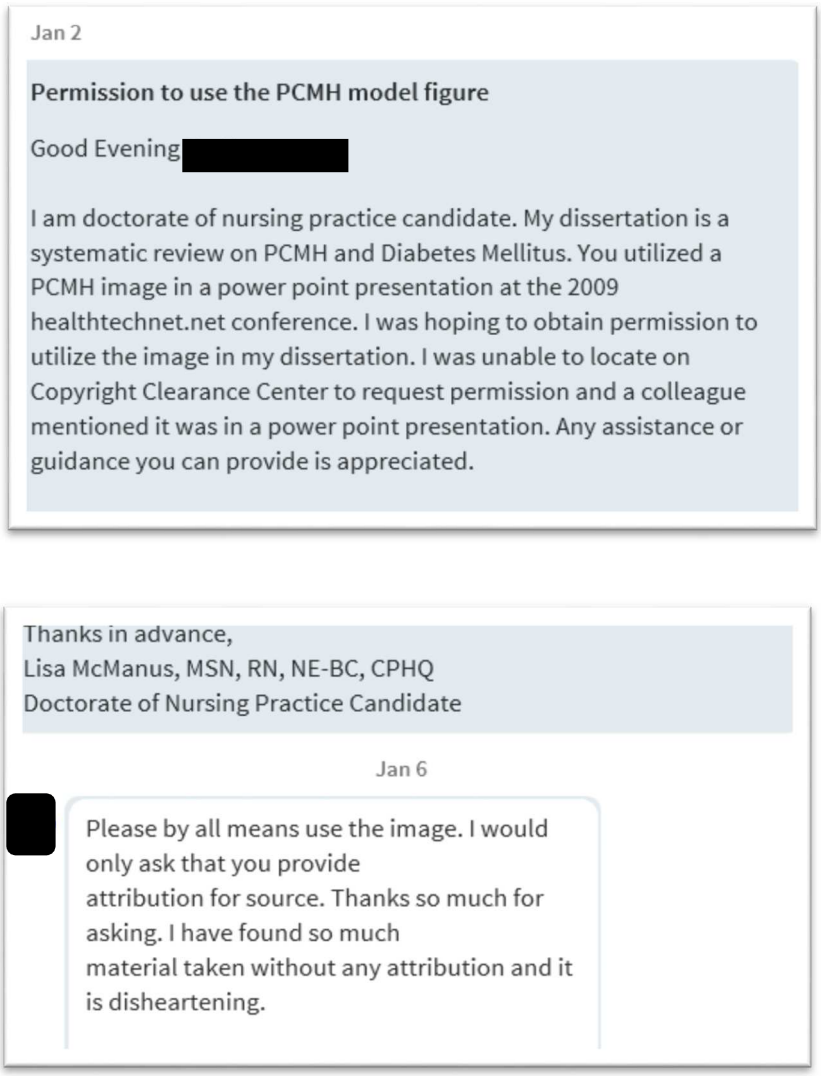
Emerson et al., (2015)	Pilot randomized control trial	Descriptive statistics of data-demographics, outcomes	Age 18-75	Use of alternate communication tools. Health coach facilitated virtual visits, telephonic and cloud based glucose monitoring	Improvements in HgA1c but not statistically significant when compared to control group	1b
Liss et al., (2014)	Interrupted time series design	Quantitative-data from record and outreach	Age 18-75	Electronic messaging and telephone encounters	Increased utilization of alternate communication methods improved office visits	Level 2c
Moran et al., (2011)	Pre-test / Post Test design	Quantitative-data from medical record	Age 18-80	RN-CDE integration and effect on diabetes outcomes	Improvements noted on HgA1c, LDL, HDL, Triglycerides	Level 2c
Coleman et al., (2013)	Retrospective cohort study	Quantitative data from medical records	Age 18 and over	Integration of PCMH concepts	Reduction in HgA1c for those over 9%	Level 2b
Ackroyd et al., (2014)	Meta-analysis of clustered randomized trials & patient randomized trials	Quantitative data from medical records/office practices	Age 18 and over	PCMH model and the effectiveness in managing diabetes	Team based care showed improvement in clinical outcomes	Level 1c
DeVries et al., (2012)	Observational Cohort Study	Quantitative – data from claims	Age 18-75	PCMH concepts on diabetes outcomes	Improvements in HgA1c, reduction in hospitalizations and ED visits	Level 2b
Depuccio et al., (2014)	Systematic Review	Quantitative data from medical charts	Age 65 and older	Medical Home interventions on diabetes-education, communication	Improved HgA1c and self-management. Improved relationships with provider	Level 2a
Hall et al., (2014)	Mixed method approach	Quantitative and qualitative data	Age 18 and older	PCMH model and	Variations in PCMH model concepts affect	Level 2c

				variations of delivery	the patient's outcomes/perceptions	
Lamb et al., (2015)	Prospective quasi experimental design	Data from medical records	Age 65 (mean)	Pharmacist led interventions	Improvements in HgA1c, LDL, blood pressure.	Level 2c
Hildegarde et al., (2012)	Non-randomized Cohort study	Data from medical records	Age 52.8 (mean)	Pharmacist led interventions	Improvements in HgA1c, LDL, HDL, triglycerides and BMI	Level 2b

Appendix E: Description and Levels of Evidence

Hierarchy of Evidence		
Levels of Evidence	Definition or Description	Numbers
1a	Systematic review of randomized, controlled clinical trials	0
1b	Individual randomized controlled clinical trial	1
1c	All or none	1
2a	Systematic review of cohort studies	1
2b	Individual cohort studies	6
2c	Outcomes research	7
3a	Systematic review of case-control studies	
3b	Individual case control	0
4	Case series, poor quality cohort and case-control studies and reviews	0
5	Expert opinion without explicit critical appraisal	0

Appendix F: Permission to Use PCMH Model Image



Jan 2

Permission to use the PCMH model figure

Good Evening [redacted]

I am doctorate of nursing practice candidate. My dissertation is a systematic review on PCMH and Diabetes Mellitus. You utilized a PCMH image in a power point presentation at the 2009 healthtechnet.net conference. I was hoping to obtain permission to utilize the image in my dissertation. I was unable to locate on Copyright Clearance Center to request permission and a colleague mentioned it was in a power point presentation. Any assistance or guidance you can provide is appreciated.

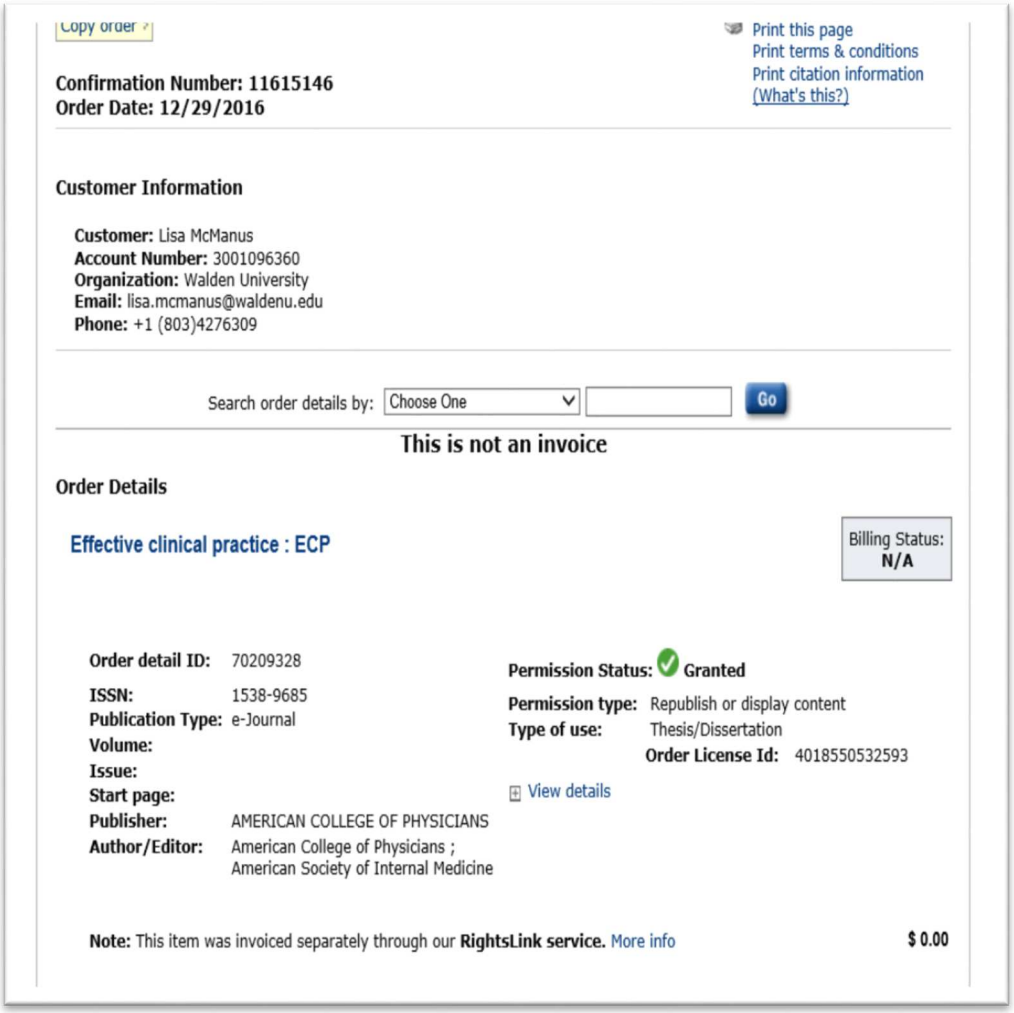
Thanks in advance,
Lisa McManus, MSN, RN, NE-BC, CPHQ
Doctorate of Nursing Practice Candidate

Jan 6

[redacted]

Please by all means use the image. I would only ask that you provide attribution for source. Thanks so much for asking. I have found so much material taken without any attribution and it is disheartening.

Appendix G: Permission to Use CCM Model Image



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