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SYSTEMATIC REVIEW ARTICLE

The Patient-centered Medical Home as an Intervention Strategy for Diabetes Mellitus: A Systematic Review of the Literature

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Abstract: ***Background*:** Poorly managed diabetes mellitus increases health care expenditures and negatively impacts health outcomes. There are 34 million people living with diabetes in the United States with a direct annual medical cost of $237 billion. The patient-centered medical home (PCMH) was introduced to transform primary care by offering team-based care that is accessible, coordinated, and comprehensive. Although the PCMH is believed to address multiple gaps in delivering care to people living with chronic diseases, the research has not yet reported clear benefits for managing diabetes.

***Objective*:** The study reviews the scientific literature about diabetes mellitus outcomes reported by PCMHs, and understands the impact of team-based care, interdisciplinary communication, and care coordination strategies on the clinical, financial, and health-related outcomes.

***Methods*:** The systematic review was performed according to the Cochrane method and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses. Eight databases were systematically searched for articles. The Oxford Centre for Evidence-based Medicine Levels of evidence and the Critical Appraisal Skills Programme systematic review checklist were used to evaluate the studies.

***Results*:** The search resulted in 596 articles, of which 24 met all the inclusion criteria. Care management resulted in more screenings and better preventive care. Pharmacy-led interventions and technology were associated with positive clinical outcomes, decreased utilization, and cost savings. Most studies reported decreased emergency room visits and less inpatient admissions.

***Conclusion*:** The quality and strength of the outcomes were largely inconclusive about the overall effectiveness of the PCMH. Defining and comparing concepts across studies was difficult as universal definitions specific to the PCMH were not often applied. More research is needed to unpack the care model of the PCMH to further understand how the individual key components, such as care bundles, contribute to improved outcomes. Further evaluations are needed for team-based care, communication, and care coordination with comparisons to patient, clinical, health, and financial outcomes.

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1. INTRODUCTION

Throughout the world, chronic diseases are the leading cause of death, disability, and health care expense [1]. Impacting more than 460 million adults worldwide [2], diabetes is expected to rise to 578 million by 2030 and 700 million by 2045 [3]. Diabetes is responsible for two-thirds of deaths [4] and more than 10% of all health care expenses [5]. The majority of these expenses are related to complications associated with diabetes, including retinopathy, nephropathy, heart disease, and renal insufficiency [6]. However, nontraumatic limb amputations are the leading complica-

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tions associated with diabetes [7], as 60% worldwide are related to diabetes [8]. Finally, diabetic patients have a 15% greater risk for developing leg or foot ulcers due to diabetic neuropathy and infections [9, 10].

In the United States, 34.2 million people have diabetes, or 10.5% of the population, with 26.9 million diagnosed and 7.3 million undiagnosed [11]. As the seventh leading cause of death [11], diabetes has a direct medical cost of $237 billion annually [12], with more than $174 billion expended by Medicare [13]. About one-third of the people living with diabetes mellitus (PLDM), or 11 million, are 65 years of age or older [13]. As this number is anticipated to double by 2030 and triple by 2060 [6], the elderly segment of the population will require dramatically increased financial resources as they already currently consume more than 80% of all health spending [14]. As a result of this data, the government seeks to blunt the economic impact by shifting from fee-for-service to prospective reimbursement focused on paying for the quality not the quantity of care [15]. The current national strategies focus on advancing team-based care, interdisciplinary communication, care coordination, technology, and self-care to decrease utilization.

Originating from the Chronic Care Model [16], the patient-centered medical home (PCMH), also called the medical home, is anticipated to transform primary care [17] by providing accessible, comprehensive, coordinated, and technologically supported care [18]. With multidisciplinary teams, including dieticians, nurses, pharmacists, physicians (primary care and specialists). social workers, and therapists (physical and occupational), the PCMH is believed to increase care coordination resulting in improve clinical outcomes and decrease costs [19-22]. Historically, the PCMH model was intended to connect fragmented systems, align payment and providers, and engage patients in self-care to improve health outcomes and decrease costs [23]. Most recently, care managers have been added to the multidisciplinary team to guide patients through episodes and transitions with consistent care coordination and community resources [24]. As such, the PCMH can fill multiple gaps in care, clear access barriers, and address other problems.

Improving outcomes and controlling costs with the clinical management of people living with diabetes requires excellent care coordination and effective communication [25]. In this regard, health services are expected to be delivered by a multidisciplinary team, usually led by a primary care physician in collaboration with the care coordinator, usually a nurse, within a primary care setting. The goal is to minimize acute episodes requiring hospitalizations and reduce expensive complications. Despite the positive outlook for the model, there are few large studies and even less comprehensive evaluations of the PCMH to demonstrate the promised clinical efficacy and to quantify the true economic impact [26, 27]. As such, the purpose of this study was to systematically review the literature to understand the impact of the PCMH on the clinical, financial, and health outcomes associated with managing the care of PLDM.

1.1. PICO(T) Question

The research question for the study was developed using the PICO(T) process [28]. The acronym stands for population and problem, interventions, comparisons, outcome, and types of studies with time frames. The question makes the search strategy for a systematic review more precise to achieve a higher percentage of relevant citations in PubMed [29]. The PICO(T) question for this systematic review was: P – people diagnosed with diabetes clinically managed in a PCMH; I – care coordination and clinical management strategies (or programs, models, frameworks) including team-based care, coordination between providers, communication and referrals, and patient education; C – comparison of data from studies regarding the effectiveness of other types of care management on clinical and financial outcomes; O – clinical indicators, such as blood glucose levels, blood pressure (BP) including systolic, diastolic, and mean arterial, body mass index (BMI), hemoglobin A1c proteins (HbA1c), and low- and high-density lipoprotein (LDL, HDL), and utilization indicators such as hospital admissions, emergency visits, and costs; and T – a systematic literature review between January 2010 to May 2018; to analyze PCMC effectiveness for interventions and outcomes (clinical, financial, and health). The research question that guided the review was two parts, including 1) What are the clinical outcomes for PLDM resulting from the team-based care, care coordination, and/or communication strategies within the PCMH, including HbA1c, BP, and BMI?; and 2) What impact does care management in the coordinated care model of the PCMH have on diabetes related emergency department visits, hospital readmissions, and costs for care?

2. MATERIALS AND METHODS

This study was a systematic review following the Cochrane method [30] and adhering to the Preferred reporting items for systematic reviews and meta-analyses, or PRISMA [31]; the completed checklist is provided as a supplemental table. The systematic review requires a step-by-step process to search the scientific literature and to analyze the empirical evidence in order to answer a structured research question [32]. The process to complete this review is detailed in the next sections as well as an outline in the study protocol (Table **1**) approved by the university institutional review board.

2.1. Search Strategy

Eight electronic databases, including CINHAL, Cochrane Library, JBI Evidence-based Practice Database, ProQuest, PsycINFO, PubMed, Scopus, and Web of Science, were searched from January 2010 to May 2018. Articles resulting from a search of these databases, published, or partially published, including ahead of print or early online, were included in the title assessment (test search strategy for PubMed is included in Table **1**). The inclusion criteria were research studies with adult patients managed at a PCMH with a confirmed diagnosis of diabetes mellitus. Research methods included were experimental (randomized control,

repeated measures, independent measures, matched pairs), quasi-experimental (nonequivalent groups, pretest-posttest, and interrupted time-series), and observational (cohort, case-control, cross-sectional, and longitudinal studies). Other types of reviews (scoping, systematic, meta-analysis) were also considered, but none were identified specific to the review objective prior to initiating this study. Exclusion criteria were studies with a pediatric population or gestational diabetes, conducted outside the United States, interventions not related to the core PCMH model. The review focused on identifying the clinical, financial, and health outcomes related to diabetes management. These outcomes included but were not limited to BP, BMI, HbA1c, renal function, lipid profile, utilization of emergency department, inpatient admissions, and cost of care. Additional themes searched included lifestyle changes, such as smoking cessation, weight loss, dietary changes, and increasing physical activity.

2.2. Study Selection

The database search strategy was documented and trialed; a second reviewer validated replicability. Next, the database searches were completed, the duplicate articles removed, and the titles organized for screening. The initial tile list was screened by two reviewers to exclude articles clearly outside the scope of the evaluation criteria. To reduce the potential for bias through the accidental exclusion of relevant articles, exclusion discrepancies (defined as an article without two blinded affirmatives for exclusion) resulted in advancing the article to the next review for a more detailed screening.

Table 1. Outline of the Cochrane protocol for the systematic review.

1. Background
2. Objectives
3. Methods
    - 3.1. Criteria for selecting studies for this review:
        - 3.1.1. Types of studies
            - 3.1.1.1. Scoping and systematic reviews (and meta-analysis)
            - 3.1.1.2. Experimental, quasi experimental, nonexperimental
            - 3.1.1.3. Observational (cross-sectional and longitudinal)
            - 3.1.1.4. Mixed methods (but not only qualitative design)
        - 3.1.2. Types of participants
            - 3.1.2.1. Adults 18 years and older with diagnosis of diabetes mellitus
        - 3.1.3. Setting
            - 3.1.3.1. Patient-centered medical home (or medical home)
        - 3.1.4. Location
            - 3.1.4.1. United States
        - 3.1.5. Types of interventions
            - 3.1.5.1. Professional interventions (e.g. pharmacist lead interventions)
            - 3.1.5.2. Clinical management (e.g. collaborative, communication)
            - 3.1.5.3. Self-management and self-care
        - 3.1.6. Outcomes
            - 3.1.6.1. Laboratory (HbA1c, LDL)
            - 3.1.6.2. Clinical (assessments, blood pressure, BMI, weight)
            - 3.1.6.3. Utilization (appointments, emergency room visits, inpatient admissions)
            - 3.1.6.4. Economic (expenditures, costs, disease burden)
            - 3.1.6.5. Quality of life (ADL, QUALYS, satisfaction)
    - 3.2. Search strategy to identify studies
        - 3.2.1. Abbreviated list of keywords – Patient centered medical home, diabetes, outcomes, interventions, costs, expenditures, care coordination, teams, communication.
        - 3.2.2. Date for search – January 1, 2010 to May 30, 2018
        - 3.2.3. Data bases – CINHAL, Cochrane Library, JBI Evidence-based Practice Database, ProQuest, PsycINFO, PubMed, Scopus, and Web of Science.
    - 3.3. PubMed search strategy
        - 3.3.1. ((("patient centered medical home"[All Fields]) OR ("medical home"[All Fields])) OR ("pcmh"[All Fields])) AND ("diabetes"[All Fields])
    - 3.4. Appraisal assessments
        - 3.4.1. Critical Appraisal Skills Programme (CASP) Systematic Review Checklist.
        - 3.4.2. Oxford Centre for Evidence-based Medicine levels of evidence.
4. Analysis / Results
5. Discussion
6. Conclusion
7. References
8. Tables and figures
    - 8.1. Prisma figure
    - 8.2. Exclusion table
    - 8.3. Inclusion table
    - 8.4. Level of evidence table
    - 8.5. Prisma checklist

[30] Reference: Higgins & Green (2011)

Next, the abstracts for the included titles were screened by paired reviewers. Abstracts not meeting the inclusion criteria were eliminated, and the remaining articles advanced to the full-text screening for an assessment focused on the population, intervention, comparison, and outcome(s). A third researcher reviewed the final inclusion/exclusion work process to identify potential errors. The methods for the sample of included studies were evaluated with the Critical Appraisal Skills Programme (CASP) Systematic Review Checklist.

2.3. Data Collection and Analysis

Once the sample was completed, the data from each study were abstracted and organized into a literature matrix for analysis [33]. The quality of the evidence for the sample of studies was assessed with the Oxford Centre for Evidence-based Medicine Levels of evidence criteria [34, 35]. The sample was reviewed independently by the research team and then collectively reviewed, critiqued, and discussed. The data analysis focused on organizing the data in comparative themes, identifying the organizational strategies and clinical practices and evaluating the outcomes, including those related to the different interventions [36].

3. RESULTS

For this study, a total of 568 articles were assessed for inclusion as the review sample. Following the exclusion of title and abstract reviews, 73 articles were assessed in the full-text review. An additional 46 articles were excluded (Table **2**) for varied reasons, including diagnosis other than diabetes mellitus, ages less than 18 or no age range specified, type of practice, non-PCMH, and studies not performed in the United States. The final 24 articles, summarized in Table **3**, met the CASP minimum assessment to finalize the sample for the review. The PRISMA diagram(36), Fig. (**1**), provides an overview of the search, screening, and exclusion/inclusion processes.

The majority of the data extracted for this review resulted from evidence derived from level 2 studies, including 2c (outcomes research, n=12), 2b (individual cohort studies, n=9), and 2a (systematic review of cohort studies, n=1). There were two small randomized controlled trials. There were no level 3, 4, and 5 studies included in the sample (Table **4**). From the data, five major themes were identified to organize the review, including: 1) Clinical outcomes, 2) Utilization of health services, 3) Care and self-management, 4) Recognition and certification programs, and 5) Characteristics associated with care coordination. The last theme

Table 2. Excluded research studies during the abstract review.

First Author / Publication Year	Title of the Publication	Rationale for Exclusion
Dickinson *et al.* (2018).	A protocol for a cluster randomized trial comparing strategies for translating self-management support into primary care practices.	Study focused on the primary care and self-management; not a clear focus on diabetes.
Mahmud *et al.* (2018).	Examining differential performance of 3 medical home recognition programs.	Study focused on the certification programs for the PCMH, not the disease programs.
Rosland *et al.* (2018).	Engaging family supporters of adult patients with diabetes to improve clinical and patient-centered outcomes.	A study protocol, however, an important study to review in the future.
Tomoaia-Cotisel *et al.* (2018).	Implementation of care management: An analysis of recent AHRQ research.	Comprehensive review of research related to care management, but not specific to the research question.
Albanese *et al.* (2017).	Provider perception of pharmacy services in the patient-centered medical home.	Study was in a PCMH but focused on the perceptions of providers, not clinical or financial outcomes.
Hendricks *et al.* (2017).	The patient-centered medical home model and diabetes outcomes: An integrative literature review.	Integrated literature review but outcomes were not reported with specific data for each study.
Horny *et al.* (2017).	Patient navigation to improve diabetes outpatient care at a safety-net hospital: A retrospective cohort study.	Study focused on adding patient navigation in a safety-net hospital, not the impact of the PCMH model.
Smith *et al.* (2017).	Medical neighborhood model for the care of chronic kidney disease patients.	Study focused on PCMH but there was no focus on diabetes in this study, only kidney disease.
Breland *et al.*, (2016).	Key ingredients for implementing intensive outpatient programs within the patient-centered medical homes: A literature review and qualitative analysis	Study focused on implementing a program; there was not outcomes data reported.
Philpot *et al.* (2016).	Patient-centered medical home features and health care expenditures of Medicare beneficiaries with chronic disease dyads.	Study focused on chronic diseases; the diabetes outcomes were not presented in a useable manner.
Rivo *et al.* (2016).	The impact of comprehensive pre-visit preparation on patient engagement and quality of care in a population of underserved patients with diabetes: Evidence from the care management medical home center model.	Study focused on primary care practices and pre-visit preparation; the link to the PCMH elements were not established in the study.
Janiszewski *et al.*, (2015).	Patient experience diabetes self-management education in a patient centered medical home.	Focus group without the outcome measures in the inclusion criteria; also age was not provided.
Nuti *et al.* (2015).	The impact of interventions on appointment and clinical outcomes for individuals with diabetes: A systematic review.	Included studies outside the United States; focus was primarily on appointment keeping.

(Table 2) contd....

Wiley *et al.*, (2015).	Managing chronic illness: Physician practices increased the use of care management and medical home processes	Study focused on chronic diseases; age groups not defined and diabetes data within other chronic data.
Valentinjn *et al.* (2015).	Collaboration processes and perceived effectiveness of integrated care projects in primary care: A longitudinal mixed methods study	Studies from different primary care settings; diabetes data not separately described; not all United States sites.
Ackyrod *et al.*, (2014).	Effectiveness of diabetes interventions in the PCMH.	Descriptive and commentary article; not a study.
Aysola, *et al.* (2014).	Asking the patient about patient centered medical homes: A qualitative analysis.	Only 4 patients (8%) had diabetes; results not specific about how these patients answered PCMH questions.
Dickinson *et al.* (2014)	Practice Facilitation to improve diabetes care in primary care: A report from the EPIC randomized clinical trial.	Study about system capacity for supporting quality improvement; but no focus on inclusion outcomes.
Glueck *et al.* (2014)	Lessons learned from designing and leading a multidisciplinary diabetes educational group.	Study was a narrative about diabetes programs.
Hall *et al.* (2014).	Differences in patient ratings of medical home domains among adults with diabetes: Comparisons across primary care sites.	Mixed method study; focused on patient satisfaction not the outcomes in the 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.
Keeley *et al.* (2014).	A qualitative comparison of primary care clinicians' and their patients' perspectives on achieving depression care: Implications for improving outcomes	Study not focused on diabetes; primarily focused on depression outcomes.
Kern *et al.* (2014).	The patient centered medical home, electronic health records and quality of care.	Diabetes data was not discernable from other conditions; the age groups were not discernable.
Koopman *et al.* (2014).	Telemonitoring home blood glucose.	Study not conducted at a PCMH; also, the participant age ranges were not specified.
Simmonetti *et al.* (2014).	Racial comparisons in diabetes care and intermediate outcomes in a patient-centered medical home.	Study focused primarily on treatment and outcomes with racial characteristics; but not the inclusion criteria.
Stock *et al.* (2014).	Chronic care model strategies in the United States and Germany deliver patient-centered, high-quality diabetes care.	Part of the study included participants in Germany; but unable to discern portion in United States.
Wang *et al.* (2014).	PCMH impact on health plan members with diabetes.	Study included pediatric participants (27%); unable to discern the age groups and type of diabetes.
Baus *et al.* (2013).	Registry based diabetes risk detection schema for the systematic identification of patients at risk for DM in West Virginia PCC.	The participants were pre-diabetic.
Eisenstat *et al.* (2013).	Diabetes group visits: Integrated medical care and behavioral support to improve diabetes care and outcomes from primary care perspective.	Type of care model not discernible in the data; age groups not well described; not focused on outcomes.
Jackson *et al.* (2013).	The patient centered medical home.	Pediatric participants included in study; unable to discern the data for the participant groups.
Berkerlear *et al.* (2012).	Building a PCMH obtaining the patient's voice.	Study focused on one concept of the PCMH; but did not meet inclusion criteria for measured outcomes.
Burke *et al.* (2012)	Group visits hold great potential for improving diabetes care outcomes, but best practices must be developed.	Study included participants from Germany and the United States; focused on group visits not the PCMH.
Coburn *et al.*, (2012)	Effect of a community-based nursing interventions on mortality in chronically ill older adults: A randomized controlled trial.	Study not primarily focused on the PCMH; also, did not meet other inclusion criteria.
Green *et al.* (2012)	Lessons learned from implementing the patient centered medical home.	Study focused on implementation of PCMH versus measuring diabetes mellitus or outcomes.
Khanna *et al.* (2012)	Hemoglobin A1C improvements and better diabetes-specific quality of life among participants completing diabetes self-management programs: A nested cohort study.	Study focused on primary care, not the PCMH; the data could not be linked to the individual PCMH elements.
Kocarnik *et al.* (2012)	Does the presence of a pharmacist in primary care clinics improve diabetes medication adherence?	Study focused on primary care; the outcomes data could not be linked to the individual PCMH elements.
Parker *et al.* (2012)	Ethnic differences in appointment keeping and implications for the PCMH- findings from the diabetes study of Northern CA.	Study did not include interventions; focused on ethnic differences and appointment keeping.
Bojadzievski *et al.* (2011)	Patient centered medical homes and diabetes.	Article was not a research study; a descriptive paper.
Rittenhouse *et al.* (2011)	Small and medium sized physician practices use few patient-centered medical home processes.	Did not meet inclusion criteria. Focused on clinical practice than outcomes research.
Rustad *et al.* (2011)	The relationship of depression and diabetes pathophysiological and treatment implications.	Study focused on depression in relationship to diabetes; not focused on PCMH.
Friedberg *et al.* (2010)	Primary care: A critical review of the evidence on quality and cost of health care.	Study focused on primary care; not focused on diabetes; age requirements not clear; PCMH model not a focus.
Strange *et al.* (2010)	Defining and measuring patient-centered medical home.	Study focused on defining the PCMH; there was not participant data or outcomes data reported.

Table 3. Research studies included in the review.

First Author & (Year)	Research Design	Data Type for Analysis	Age Group	PCMH Intervention	Outcomes / Results	Level of Evidence
Meo *et al.* (2018).	Retrospective cohort study.	Electronic health record data	Adults	Eight domains of the PCMH model in primary care centers.	Adherence to oral hypoglycemic agents.	Level 2b
Gunter *et al.* (2017).	Observational cross-sectional study.	Chart audit and data from the Safety Net Medical Home Scale	Ages >18	PCMH characteristics and the quality of diabetes care using the Safety Net Medical Home Scale.	HbA1c control, LDL control, blood pressure control and a bundled measure of meeting all 3 individual outcome measures simultaneously.	Level 2c
Kinsell *et al.* (2017).	Observational longitudinal study.	Electronic health record data	Mean age 59	PCMH model and analysis for clinical outcomes for vulnerable patients with diabetes.	HbA1c control, blood pressure control and normal BMI.	Level 2b
Lauffenburger *et al.* (2017).	Retrospective cohort study.	Claims data from a large national health insurer	Adults	National Committee for Quality Assurance–recognized patient-centered medical home.	Medication adherence.	Level 2b
Miller *et al.* (2017).	Quasi-experimental single group design.	Educational cell-phone texts, pre/-post-test evaluation	Ages 27-73	PCMH, glucose control and self-care behaviors.	Glucose control, retinopathy screening rates, and self-care behaviors.	Level 2c
Shi *et al.* (2017).	Observational cross-sectional study.	Uniform Data System and PCMH recognition achievement	Adults	PCMH and recognition by certification.	HbA1c control, blood pressure control.	Level 2c
Timbie *et al.* (2017).	Observational cross-sectional study.	Medicare claims and NCQA PCMH data	Ages >18	PCMH capabilities and Medicare beneficiary outcomes.	Primary care, specialist, and emergency visits. Admissions for ambulatory care-sensitive conditions, and 30-day unplanned readmissions.	Level 2c
Carlin *et al.* (2016).	Observational cross-sectional study.	Chart audits and observation	Ages >18	PCMH transformation stage in 5 domains and health care utilization.	Utilization of health services, number of prescriptions, outpatient visits, probability of inpatient admissions and number of emergency visits.	Level 2c
Rosenthal *et al.* (2016).	Retrospective cohort.	Difference in difference analysis; with data from HEDIS	Ages >18	PCMH model and quality and cost of care mix.	Reductions in utilization, gradual and sustained, increased screenings, and improved clinical outcomes.	Level 2b
David *et al.* (2015).	Observational cross-sectional study	Difference in difference analysis; with Blue Cross claims data	Mean age 52	PCMH model concepts to decrease emergency room visits.	Reduction in potentially avoidable and avoidable ED visits.	Level 2c
Emerson *et al.* (2015).	Pilot randomized control trial.	Demographics and outcomes data	Ages 18-75	Communication tools; Health coach virtual visits, telephonic and cloud-based monitoring.	Improvements in HbA1c but not statistically significant when compared to control group.	Level 1b
Lamb *et al.* (2015).	Prospective quasi experimental	Medical record review data	Mean age 65	Pharmacist led interventions.	Improvements in HbA1c, LDL, blood pressure.	Level 2c
Ackroyd *et al.* (2014).	Meta-analysis of clustered & patient randomized trials	Other study data, primarily medical record, and office data	Ages >18	PCMH model and effectiveness in managing diabetes.	Team based care and improvements in clinical outcomes.	Level 1c
Depuccio *et al.* (2014).	Systematic review	Research studies in Medline focused on interventions.	Adults	Medical home interventions on diabetes including education, communication.	Improved HbA1c and self-management; improved relationships with providers.	Level 2a
Liss *et al.* (2014).	Interrupted time series design	Medical records review and outreach data	Ages 18-75	Electronic messaging and telephone encounters.	Increased utilization of alternate communication methods improved office visits.	Level 2c
Calman *et al.* (2013).	Retrospective cohort study	Medical records review data	Ages >18	Integration of PCMH concepts.	Reduction in HbA1c for those over 9%.	Level 2b
Gabbay *et al.* (2013).	Cross-sectional study from a pilot project	Practice reported diabetes data	Ages 18-75	PCMH model concepts regarding diabetes measures.	Higher performing PCMH with noted improvements in diabetes measures (HbA1c, BP, LDL).	Level 2b

(Table 3) contd....

Solberg *et al.* (2013).	Mixed method model	Survey data	Ages >18	PCMH and review of surveys and descriptive data.	Improvement in diabetes measures.	Level 2c
Berdine *et al.* (2012).	Case study with cross-sectional analysis	Pharmacy practice model located in a PCMH	Mean age 52.8	PCMH and a pharmacist practice in primary care.	Referrals for to pharmacists resulted in improvements in BMI, lipids and A1C at 1 and 2 years after baseline.	Level 2c
DeVries *et al.* (2012).	Observational cohort study	Claims data	Ages 18-75	PCMH concepts on diabetes outcomes.	Improvements in HbA1c, reduction in hospitalizations and ED visits.	Level 2b
Edwards *et al.* (2012).	Observational cohort study	Medical records review data	Ages 18-85	PCMH and pharmacist led interventions, and assessments.	Reductions in HbA1c, LDL, HDL, micro albumin. Improvement in retinal exams and vaccinations.	Level 2b
Flottemesch *et al.* (2012).	Retrospective cross sectional	Claims data (ICD9, CPT, E&M)	Ages 19-75	PCMH care model evaluated.	Avoidable costs, reduction in emergency care, and inpatient costs.	Level 2c
Seiber *et al.* (2012).	Observational cohort study	Medical record review data	Ages 40-60	Group medical visits.	No statistically significant improvements in diabetes measures.	Level 2b
Moran *et al.* (2011).	Observational pre- / post-test design	Medical record review data	Ages 18-80	RN-CDE integration and effect on diabetes outcomes.	Improvements noted on HbA1c, LDL, HDL, triglycerides.	Level 2c

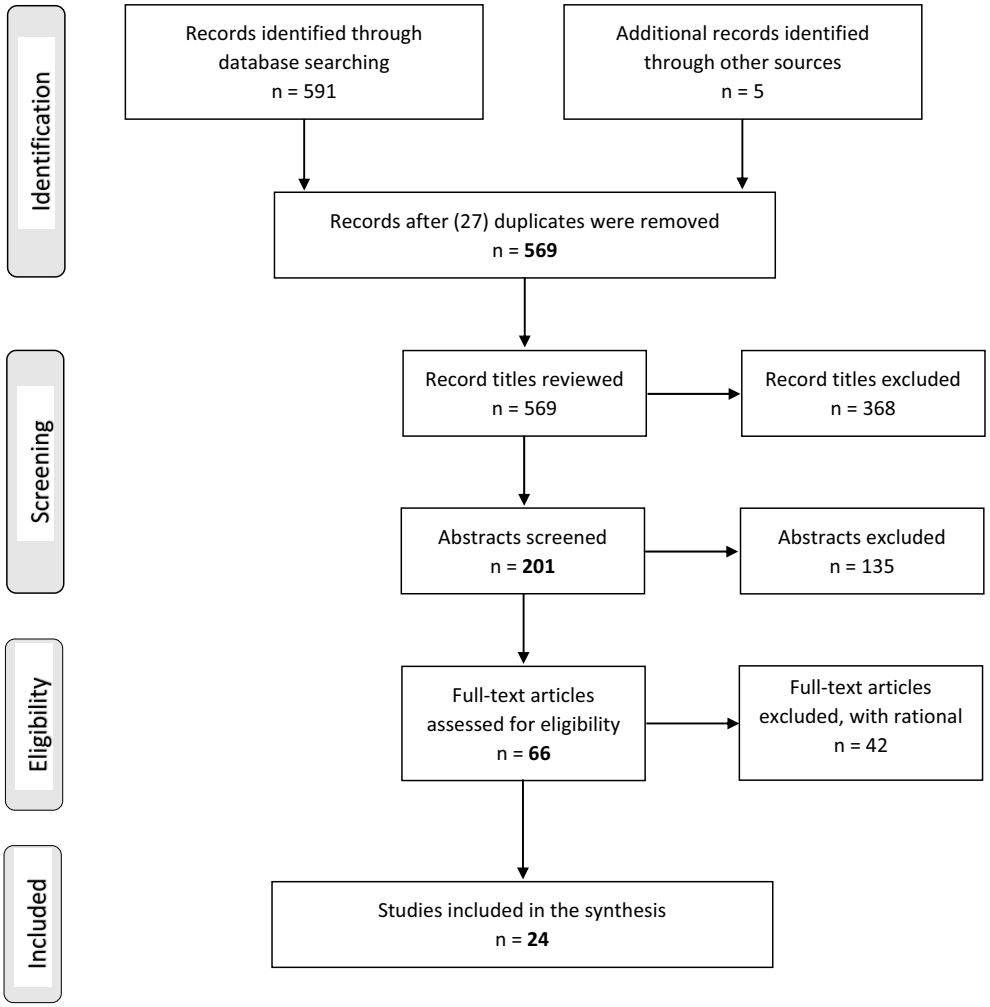


Fig. (1). PRISMA diagram.

was separated into two categories, professional roles and team-based approaches and the incorporation of technology. The next sections address the evidence from the review.

3.1. Clinical Outcomes

In the PCMH, practices considered higher performing can result in improvements in three outcomes. In this regard, communicating more effectively with diabetic patients regarding testing and appointments resulted in significant improvements in HbA1c<7% (8.8%) BP<130/80mg/Hg (19.5%) and LDL<100 mg/dl (14.9%) than lower performing practices [37]. When evaluating the effectiveness of group medical visits on clinical outcomes for patients with diabetes, there were also improvements in pre- and post-interventions from group medical visits (n=62), but not statistically significant when compared to the control group (n=137) [38]. Similarly, Solberg *et al.* [39] noted improvements ($p\leq0.001$) in diabetes measures were achieved in the context of a 'health care home' with an evaluation of the care model, clinical information, decision management, and self-management support. The health care homes are located in metropolitan (n=65) and non-urban areas (n=37). The clinic 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 diabetes care within these clinics consisted of control of HbA1c less than 7%, BP of 130/80 or lower and low-density lipoprotein (LDL) of 100mg/dl or less in addition to smoking cessation and daily aspirin use [39]. Optimal diabetes care was noted to be correlated to increased quality of care composite measures for diabetes in the nonurban clinics and midsized clinics. In this regard, there was a significant correlation (p=0.008) in the health care home composite scores and diabetes care.

Table 4. Levels of evidence summary for included studies.

Levels	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	9
2c	Outcomes research	12
3a	Systematic review of case-control studies	0
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

[35] Reference for table: https://www.cebm.net/2009/06/oxford-centre-evidence-based-medicine-levels-evidence-march-2009/

3.2. Utilization of Health Services

The costs associated with diabetes mellitus were estimated at $198 billion annually [40]. According DeVries *et al.* [41] PCMH demonstration projects have shown reductions in hospitalizations, ranging from 6% to 40%, and ER visit reductions, ranging from 7.3% to 29%. For example, the cost savings per patient were estimated from $71 to $640. The finding is similar to the $126 reduction reported from an evaluation of the total and potentially avoidable costs [42] resulting from practices engaged in quality improvement and performance improvement initiatives.

The PCMH model has reduced costs through improved clinical management and reduced unwarranted inpatient admissions and ED visits [41, 42]. In a large study of ED visits of PLDM (n=100,679), and those with chronic diseases (n=393,317), David *et al.* [43] reported four categories of interactions, including: 1) non-emergent care (n=100,679), 2) emergent care (n=50,015), 3) preventable emergent care (n=100,679), and 4) nonpreventable emergent care (n=50,015). The statistically significant differences (p<0.001) spanned all four categories of ED visits for PLDM managed by s PCMH. A smaller study evaluating the effect of the nurse CDE (certified diabetes educator), within the PCMH on ED visits and inpatient admissions reported no significant reductions in ED visits (p=0.65) or inpatient admissions (p=0.70) [40].

A meta-analysis of 142 studies (48 cluster-randomized and 94 patient level trials) revealed PCMH strategies decreased inpatient admissions by 18% (p<0.001) and readmissions by 36% (p<0.02) for diabetic patients [17]. The cost reduction associated with the interventions was estimated to be $338 per-patient-per-year. Furthermore, DeVries *et al.* [41] reported significant reductions for inpatient hospital admissions (p=0.003) and emergency room visits (p< 0.001) of PCMH patients ages 18 to 44 (n=642 and n=1,222 respectively) as compared to non-PCMH patients. 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). There was a small difference noted, however, for the unadjusted per-member-per-month in patients managed in the PCMH versus the non-PCMH (15.56% *versus* 17.62%).

At the end of a three-year study to evaluate the effects of a patient-centered medical home implementation in 15 small and medium-sized primary care groups, researchers reported changes in utilization, costs, and quality between patients attributed to pilot and non-pilot practices [44]. In this regard, the pilot practices had 1.6 fewer emergency department visits per 1,000 member months, or a 9.3% reduction from baseline (p=0.01). Emergency department costs were lower in the pilot practices after two (13.9% reduction, p<0.001) and three years (11.8% reduction, p=0.001). Also, primary care visits in the pilot practices decreased by 1.5% points (p=0.02) with improved HbA1c (0.7% reduction at three years, p=0.03).

In a cross-sectional study of Medicare claims data for fee-for-service beneficiaries (n=231,163), Timbie *et al.* [45] reported more advanced sites, or those with recognition of the National Committee for Quality Assurance (NCQA), were associated with 228 additional federally qualified health visits per 1,000 Medicare beneficiaries (95%CI:

176–278), compared with less advanced sites. In the advanced sites, there was a 0.02 point higher practice-level continuity of care (95% CI: 0.01–0.03); greater likelihood of administering two of four recommended diabetes tests; 181 additional visits to specialists per 1,000 beneficiaries (95% CI: 124–232). The lower sites had 64 additional visits to emergency departments (95% CI: 35–89). Rates of testing for LDL, cholesterol, and nephropathy were substantially higher in more advanced sites than in less advanced sites. These included LDL test rates 2.8 points higher (95% CI 0.4–5.1), nephropathy test rates 7.7 points higher; (95% CI 4.1–11.3). The more advanced sites also had an increased likelihood for completion of the four recommended diabetes tests (4.9 points, 95% CI 2.5–6.7). Overall, more advanced sites had higher Part B expenditures of $111 per beneficiary (95% CI: 61–158) and Medicare expenditures of $353 (95% CI: 65–614) [45].

3.3. Care and Self-Management

A retrospective cohort study used administrative claims data from a national health insurer to assess the association between medication adherence and PCMH recognition (NCQA) in a national patient and provider population. According to Lauffenburger *et al.* [46], from the 313,765 patients meeting the study criteria, 18,611 (5.9%) received care in a PCMH. In terms of medication adherence, 43.9% of the medical home patients were optimally adherent compared with 37.6% of the control patients. Among 4,660 matched control and medical home practices, medication adherence absolute rates were significantly higher in medical homes 2.2% (95% CI, 1.5–2.9). The authors attributed the results to the increased self-management resulting from NCQA PCMH recognition. The program requires standardized processes to support patient-provider relationships and patient engagement supported by technology and effective care coordination. Similarly, in a study using text messaging to improve glucose control, the majority of the participants (>70%) reported changes in self-care behaviors [47]. Finally, researchers reported access to routine care (standardized beta [Sβ] = .21, P = .004), and utilization of telephone encounters (Sβ = 0.23, P < .001) were significantly associated with increased adherence to oral hypoglycemic agents in a large cohort of veterans with diabetes [48]. Although the researchers used electronic health records to study the relationship between the organizational features related to the adoption of PCMH and the level of adherence to oral hypoglycemic agents, there were no clinical or financial variables reported.

3.4. Recognition and Certification

In an evaluation of PCMH characteristics and quality of diabetes care in 15 safety net clinics, Gunter *et al.* [49] reported a higher PCMH score was associated with increased odds of LDL control (OR=1.12, CI 1.02–1.23). In relationship to specific scales, higher access and communication scores were associated with decreased odds of HbA1c screening (OR=0.41, CI 0.19–0.90), and higher odds of HbA1c (OR=1.98, CI 1.14–3.47) and BP (OR=1.53, CI 1.18–1.99) control. A higher care management score was associated with increased odds of HbA1c control (OR=1.61, CI 1.03–2.50) and BP control (OR=1.21, CI 1.04–1.40). A higher-quality improvement score was associated with increased odds for two outcome measures: BP control (OR=1.62, CI 1.45–1.80) and achieving the bundled measure (OR=1.71, CI 1.18–2.47); however, it was also associated with decreased odds of HbA1c control (OR=0.78, CI=0.62–0.98). The two subscales were also negatively associated with outcome measures. In this regard, a higher patient registry/tracking score was associated with decreased odds of HbA1c control (OR=0.72, CI 0.60–0.87) and BP control (OR=0.65, CI 0.58–0.73) and a higher test/referral tracking score was associated with decreased odds of BP control (OR=0.86, CI 0.80–0.92).

In a cross-sectional study, researchers evaluated the relationship between PCMH recognition in medical homes and clinical performance [50] using data from the 2012 Uniform Data System and a survey of PCMH recognition. The centers receiving the PCMH recognition generally performed better on clinical measures than those without recognition. After controlling for the patient, provider, and practice characteristics, centers with PCMH recognition still reported significantly better performance on diabetes control evaluated through HBA1c levels (HbA1c<7%, SE=2.069 [0.7314], p<0.01); however, these results were not associated with provider and practice characteristics [50]. Similar outcomes were reported in a retrospective cohort that examined the transformation effects to an NCQA level three PCMH on clinical diabetes outcomes (odds for well-controlled glucose and BP and odds for normal BMI between 18.5 and 24.9 kg/m2) among 27 clinic sites in Florida. The transformation was associated with 19% greater odds of having well-controlled HbA1c (OR=1.19; 95% CI 1.05–1.34). Although the transformation had less effect on BP for African Americans and HbA1c control for Medicare insured, there was a greater effect on weight control for patients older than 35 years [51].

Through a cross-sectional study of 87 certified PCMHs in Minnesota, Carlin, Flottemesch, & Werner [52] examined the association between clinic transformation to a PCMH and health care defined by five domains: 1) health care organization, 2) delivery system redesign, 3) clinical information systems, 4) decision support, and 5) self-management support with each domain categorized as either early-stage, intermediate-stage, or late-stage. Overall, they reported a 12% to 18% decrease in the number of outpatient visits (p<0.05). The marginal effect of increasing maturity in the transformation of health care organization positively impacted total utilization, but increased utilization was observed for patients with two or more comorbidities (p<0.05). Also, there was a significant increase in the number of prescriptions written for patients when delivery system redesign was in the late-stage transformation and patient comorbidities were present (38% increase for the sickest cohort). In late-stage transformation, the clinical information system maturity was reported to drive a reduction in the number of outpatient visits (range of 25% to 35%), for patients with diabetes across all comorbidity status [52].

3.5. Characteristics of Care Coordination

3.5.1. Professionals Roles and Team-Based Approaches

Pharmacist integration into the PCMH team-based models has demonstrated improvements in patient care, medication adherence, completion of diabetes care standards, and self-management [53-55]. In smaller samples, PCMH demonstrated significant improvements in completion rates for screenings such as foot exams ($p \leq 0.0001$), referrals for specialty services such as eye exams ($p \leq 0.0001$), vaccinations for pneumococcal ($p \leq 0.0001$) and influenza ($p \leq 0.0001$), laboratory evaluations such as HbA1c ($p=0.0013$), lipids ($p \leq 0.0001$), and urine microalbumin ($p \leq 0.0001$) [55]. Specifically, the expanded role of the pharmacist in a diabetes assessment service contributed to higher completion rates of ADA standards for measuring and documenting HbA1c, lipid panel, foot exam, referral for eye exam, microalbumin, and pneumococcal and influenza vaccinations [55]. Furthermore, the addition of a pharmacist to the care team resulted in lasting improvements to clinical indicators. In this regard, an RCT with a pharmacist-led program focused on medication adherence and disease management services resulted in improvements in HbA1c, systolic BP, LDL and HDL, and total cholesterol outcomes at the two-years [54].

Generally, in smaller size studies, pharmacist integration has shown statistically significant improvements in multiple outcome measures over time. One study reported six months following a pharmacist-led intervention, several improvements were still noted from baseline, including HbA1c ($p=0.0122$), LDL ($p=0.0156$), systolic BP ($p=0.0302$), and diastolic BP ($p=0.0012$) [53]. Similarly, another study with measurements at the first year of intervention reported improvements in HbA1c ($p=0.000$), BMI ($p=0.000$), LDL ($p=0.000$), HDL ($p=0.000$), cholesterol ($p=0.000$), triglycerides ($p=0.000$), and systolic BP ($p=0.000$) [54]. Two years after pharmacist-led interventions, the same researchers reported patients continued significant improvements in HbA1c ($p=0.006$), LDL ($p=0.000$), total cholesterol ($p=0.000$), HDL ($p=0.000$), triglycerides ($p=0.002$), and BMI ($p=000$). Although the participants did not maintain the improvements in HbA1c ($p=0.132$), systolic BP ($p=0.777$), diastolic BP ($p=0.968$) three years after the intervention, some improvements were maintained from baseline, including LDL ($p=0.007$), total cholesterol ($p=0.000$), triglycerides ($p=0.008$), and HDL ($p=0.000$) [54].

Furthermore, some studies reported the registered nurse CDE integrated into PCMH with specific strategies in a similar manner as the pharmacist. The integration of the CDE demonstrated significant improvements in some clinical outcomes, patient satisfaction, and Healthcare Effectiveness Data Information Set measures for PLDM [40]. In a a pre- and post-test design, the integration of the nurse CDE with strategies focused on glucose control resulted in significant improvements in HbA1c ($p=0.000$), fasting blood glucose ($p=0.002$), and LDL ($p=0.04$). However, no statistically significant improvements were noted in microalbumin, BP, and BMI, primarily attributed by the researcher to the limited focus on glucose control [40]. In an intervention study evaluating integration of a nurse CDE into the PCMH, the post-test results revealed significant improvements in HbA1c from 9.6% to 8.0% ($p=0.0001$), LDL from 122.22mg/dl to 106.11mg/dl ($p=0.04$), and fasting blood glucose from 208.20 to 129.56 ($p=0.002$) [40]. Although not statistically significant, there were also slight improvements in BMI from 34.9 to 34.54 ($p=0.26$) and LDL decreases from 100 to 94.43mg/dl to 90.86 ($p=0.53$). There were no improvements noted in either BP or microalbumin. A retrospective study of PLDM ($n=4,595$) over a 9-year period revealed a 2% decrease in HbA1c (10.72% to 8.34%) for patients with a baseline HbA1c of 9% [56]. For all participants, however, the study reported a slight increase in the HbA1c (0.34%) from baseline.

3.5.2. Incorporation of Technology

The integration of alternate modalities for communication, such as electronic messaging and telephonic encounters, have improved some aspects of care in the PCMH. For example, in a small 'pilot' study, randomized and controlled PLDM ($n=10$), ages 18 to 44, engaged in telephonic encounters more frequently attended appointments and communicated with primary care provider [57]. Similarly, a systematic review reported PLDM benefited from targeted education incorporating technology, including improved self-management, increased medication adherence, and lower HbA1c values. Statistically significant decreases in hospitalizations, increased visits, and more interactions with the primary care providers were also reported [58]. Furthermore, an evaluation of multidisciplinary interventions and communication strategies on diabetic outcomes resulted in fewer office visits and more contacts (phone and vertical) in the intervention group than the control. The intervention group ($n=4$) had an initial HbA1c of 10.2 prior to the intervention and 8.1% post-intervention. The control group had similar decreases in HbA1c (11% to 8.4%) [59].

In a single-group design with a quasi-systematic random sample (n=20) study, Miller *et al.* [47] sent educational messages (three-time per week for three months) to the cellular phones of PLDM with uncontrolled type 2 diabetes managed by a PCMH recognized by NCQA. The intervention was intended to impact glucose control, retinopathy screening rates, and self-care behaviors. Although only 11 subjects complete the study, the researchers reported a mean HbA1c reduction from 9.46 to 8.63 mg/dL (p=0.033) and increased retinopathy screening. The 14 participants completing the exit survey agreed they would recommend the TMP as they were encouraged to take better care of their diabetes. During the study, other interventions were initiated, such as insulin initiation and intensification. However, there were no significant findings reported by the researchers.

4. DISCUSSION

The evidence suggests PLDM have better clinical outcomes (HbA1c, BMI, LDL, HDL, and triglycerides) when managed by clinicians within the care model of the PCMH.

Although the evidence did not show statistically significant improvements in systolic or diastolic BP; a contributing factor could be the comorbidities associated with the population. The literature suggests PCMH interventions have positively impacted quality-adjusted life years (QALY) and decreased expenditures for PLDM. Over a 20-year period, the cost savings per QALY per-member-per-month ranged from $7,898 to $16,649, using the Cardio-Metabolic Risk data set derived from the Archimedes model [60]. Notably silent in most reviewed studies was the financial impact on supporting the PCMH. The operating costs for PCMHs were reported to be $1.40 to $25 more per visit [61]. These costs might be difficult for small and medium-sized primary care practices to justify, especially with the financial burden associated with PCMH recognition [62].

PLDM managed by PCMHs were more likely to receive preventive services, experience improvements in clinical outcomes, and report reductions in emergency room visits [16]. One goal of the PCMH is to optimize care for chronically ill patients through improved access and effective coordination [56, 63]. Various interventions, such as group medical visits, nurse certified diabetes educators, self-management programs, and pharmacist-led interventions as part of the PCMH reported better care coordination that resulted in improved control of HbA1c, LDL, BMI, and BP. Similarly, the incorporation of technologies, such as electronic health records and texting applications, was reported to enhance care coordination. Further research is needed, however, to determine the long-term PCMH impact on outcomes such as lower extremity amputations, ulcerations, retinopathy, nephropathy, service utilization, and expenditures.

An important area discussed throughout the PCMH literature was team-based care [17, 54, 55, 64]. Although team-based care was considered central for managing the complexities and co-morbidities associated with chronic diseases, such as diabetes mellitus, there were surprisingly few studies focused on evaluating this specific dimension. In addition, effective communication and care coordination reported as critical strategies for team-based care within the PCMH [64] were also not widely reported in the quantitative studies. However, in the first qualitative study of care coordinators (n=25), Friedman *et al.* [63] reported coordinating factors, impeding or facilitating, including interoperable clinical information technology, access to resources for patients; level of care model integration, clinician and patient interactions, and self-care practices. Furthermore, Kraschnewski and Gabbay [65] reported technology, such as electronic health records, web-based patient portals, and telemedicine, supported clinician engagement in team-based care by facilitating communication and assisting with care coordination. Yet, the literature was not clear about the degree or level of technological integration for the typical PCMH.

The relationships between providers and patients that results in better patient engagement [66] have been strengthened by the PCMH. PLDM have reported positive experiences with access to care, care coordination, effective communication, knowledge development, health promotion, interpersonal relationships, and mutual trust [67]. There were appreciable differences noted between the PCMH and the normal primary care practices; however, statistically significant differences were not reported. In this regard, the integration of registered nurse certified diabetes educators (RN-CDE) and different strategies led by a pharmacist within the PCMH were supported by weak evidence but should be expanded and evaluated in larger studies. The relationship between PCMH recognition/certification and clinical performance have been established in at least three studies [50, 56, 67]. Similar to care bundles for clinical practice, where three to five evidence-informed practices can reliably improve the quality of care when collectively not separately implemented [68], the PCMH might need to be evaluated as a 'care model' bundle of target strategies rather than individual components or specific strategies. Overall, the current literature seems to suggest clinical outcomes, including screening and monitoring, are improved in environments with comprehensive multidisciplinary teams that have defined clinical roles, clear communication expectations, and active care coordination.

Finally, there were multiple expert opinions and consensus papers reviewed during the search process that advocated for further integration of specific clinical professionals into the PCMH. For example, clinical pharmacists were noted to be 'key members' for further integration into the PCMH because they are 'pioneering new and innovative ways to practice clinical pharmacy' to improve outcomes [69]. Yet, there is limited evidence to support this expanded role for clinical pharmacist focused that was noted to be focused on 'obtaining national provider status'. [69] This is only one of the multiple examples to justify the call for more research to focus on understanding the discipline-specific roles for physicians, nurses, pharmacists, dieticians, and others as they are integrated into a team-based care model, and the recognition that more evaluations are necessary to quantify the outcomes produced by specific innovations in care strategies and clinical practices.

4.1. Limitations

There are seven limitations for disclosure and discussion. First, there were inconsistencies in the methods selected to study PCMH variables across the studies. Second, when consistently applied across the studies, these variables were often poorly defined or applied differently with varied nomenclature [26]. Third, multiple interventions were reported by each study; hence identifying and reporting specific findings was challenging, which increased the opportunity for human error [70]. However, this limitation recognizes the need for researchers to incorporate standardized instruments, reliable and valid, and measurements for PCMH research [71]. Fourth, the smaller sample sizes observed with most studies [61] and the participant attrition was another limitation. Fifth, the largely positive but narrow results observed in most studies may be attributed to publication bias.

Sixth, the search strategy confined to a single chronic disease might not reflect the overall benefit of the PCMH strategies for other diseases. Finally, the systematic comparisons necessary for meta-synthesis were not possible due to methodological heterogeneity, including differences in study designs, operationalization of variables, prevalence and incidence reporting, and data collection methods. Despite these limitations, this study incorporated a rigorous method, implemented by experts in the areas of primary care, diabetes, care models, chronic disease management, and systematic reviews. Importantly, the limitations form this review can inform the development of future research as well as provide the foundation for future inquiry.

CONCLUSION

The primary goal for this systematic review was to provide an overview of the scientific evidence about the impact of the PCMH on clinical, financial, and health outcomes. Although the PCMH continues to be a promising solution to the longstanding challenges with managing diabetes, the quality and strength of the evidence spanned from partially conclusive to largely inconclusive about the overall effectiveness of the PCMH. However, this review observed evidence about the limited effectiveness of the PCMH in improving clinical, financial, and health outcomes. The sustainability of the positive outcomes was difficult to determine from the available evidence.

The PCMH seemed most effective at decreasing emergency room visits and lowering inpatient admission rates. There were also small but notable reductions in the costs associated with diabetes care, primarily related to excessive utilization. An important note of caution is the cost savings achieved by the PCMH need to be balanced with the additional expenses for implementation. These were largely missing from the studies or not reported in a manner for additional analysis. Researchers are recommended to report achieved cost savings in relation to the required investments to operate the care model, including considering the associated changes in payments and reimbursements.

In closing, multidisciplinary collaboration and teamwork were reported as central strategies to effectively managing diabetes mellitus. This review partially supports the effectiveness in terms of the observed improvements in clinical and economic outcomes. However, the opportunity to define and compare concepts across studies was limited due to the dissimilar terms and lack of universal definitions. In particular, the structure and function of the multidisciplinary team need to be evaluated with outcomes from different care models. For the benefit of future evaluations, researchers need to continue unpacking the PCMH '*black box*' by selecting outcome variables with standard terms and program variables with published definitions from recognition and/or certification frameworks to evaluate outcomes. Finally, qualitative research might provide value in further understanding the role of multidisciplinary collaboration and teamwork in the advancement of communication and care coordination from the perspective of the providers.

LIST OF ABBREVIATIONS

CASP	=	Critical Appraisal Skills Programme
CDE	=	Certified Diabetes Educator
BMI	=	Body Mass Index
BP	=	Blood Pressure
HbA1	=	Hemoglobin A1c Proteins
HDL	=	High-Density Lipoprotein
LDL	=	Low-Density Lipoprotein
NCQA	=	National Committee for Quality Assurance
PCMH	=	Patient-Centered Medical Home
PLDM	=	People Living with Diabetes Mellitus
PRISMA	=	Preferred Reporting Items for Systematic Reviews and Meta-analyses

AUTHORS' CONTRIBUTIONS

All authors participated in the manuscript submitted for journal review. The following authors were involved in the stated phases of the project: Study conception (LSM); study design (LSM, PAP); data collection (LSM, MKS, PAP); data analysis (KAD, JLM, LSM, MKS, ORL); data interpretation (KAD, LSM, PAP, JLM); drafting the manuscript (CEB, KAD, JLM, LSM, MKS, ORL, PAP); table development (KAD, LSM, PAP); substantial revisions to the manuscript (JLM, ORL, PAP), critical revisions to final manuscript (KAD, LSM, JLM, PAP); and senior scholar guidance (PAP).

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study protocol was approved by the university institutional review board (04-12-16-0147987). As the study utilized only publicly available databases and published literature, the consent to participate was not applicable. All the studies included in this systematic review, however, were approved by an institutional review board or ethics committee.

HUMAN AND ANIMAL RIGHTS

No animals were used in this research. All human research procedures were followed in accordance with the ethical standards of the committee responsible for human experimentation (institutional and national), and with the Helsinki Declaration of 1975, as revised in 2013.

CONSENT FOR PUBLICATION

Not applicable.

AVAILABILITY OF DATA AND MATERIALS

Not applicable.

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CONFLICT OF INTEREST

The authors have no conflicts of interest, financial or otherwise.

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SUPPLEMENTARY MATERIAL

The PRISMA (Preferred reporting items for systematic reviews and meta-analyses) checklist for this study is provided in Supplemental Table **1**.

REFERENCES

[1] Vos T, Abajobir AA, Abate KH, *et al.* GBD 2016 Disease and Injury Incidence and Prevalence Collaborators. Global, regional, and national incidence, prevalence, and years lived with disability for 328 diseases and injuries for 195 countries, 1990-2016: a systematic analysis for the Global Burden of Disease Study 2016. Lancet 2017; 390(10100): 1211-59. http://dx.doi.org/10.1016/S0140-6736(17)32154-2 PMID: 28919117

[2] Williams R, Colagiuri S, Eds. IDF diabetes atlas. Brussels, Belgium: International Diabetes Federation 2019.

[3] Saeedi P, Petersohn I, Salpea P, *et al.* Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045: Results from the International Diabetes Federation Diabetes Atlas, 9th edition. Diabetes Res Clin Pract 2019; 157. http://dx.doi.org/10.1016/j.diabres.2019.107843

[4] Bauer UE, Briss PA, Goodman RA, Bowman BA. Prevention of chronic disease in the 21st century: elimination of the leading preventable causes of premature death and disability in the USA. Lancet 2014; 384(9937): 45-52. http://dx.doi.org/10.1016/S0140-6736(14)60648-6 PMID: 24996589

[5] Zhang P, Zhang X, Brown J, *et al.* Global healthcare expenditure on diabetes for 2010 and 2030. Diabetes Res Clin Pract 2010; 87(3): 293-301. http://dx.doi.org/10.1016/j.diabres.2010.01.026 PMID: 20171754

[6] Li R, Bilik D, Brown MB, *et al.* Medical costs associated with type 2 diabetes complications and comorbidities. Am J Manag Care 2013; 19(5): 421-30. PMID: 23781894

[7] Hoffstad O, Mitra N, Walsh J, Margolis DJ. Diabetes, lower-extremity amputation, and death. Diabetes Care 2015; 38(10): 1852-7. http://dx.doi.org/10.2337/dc15-0536 PMID: 26203063

[8] Narres M, Kvitkina T, Claessen H, *et al.* Incidence of lower extremity amputations in the diabetic compared with the non-diabetic population: A systematic review. PLoS One 2017; 12(8): e0182081. http://dx.doi.org/10.1371/journal.pone.0182081 PMID: 28846690

[9] Markuson M, Hanson D, Anderson J, *et al.* The relationship between hemoglobin A(1c) values and healing time for lower extremity ulcers in individuals with diabetes. Adv Skin Wound Care 2009; 22(8): 365-72. http://dx.doi.org/10.1097/01.ASW.0000358639.45784.cd PMID: 19638800

[10] Margolis DJ, Jeffcoate W. Epidemiology of foot ulceration and amputation: can global variation be explained? Med Clin North Am 2013; 97(5): 791-805. http://dx.doi.org/10.1016/j.mcna.2013.03.008 PMID: 23992892

[11] Centers for Disease Control and Prevention. National diabetes statistics report: Estimates of diabetes and its burden in the United States. Atlanta, GA: United States Department of Health and Human Services 2020.

[12] American Diabetes Association. Economic costs of diabetes in the U.S. in 2017. Diabetes Care 2018; 41(5): 917-28. http://dx.doi.org/10.2337/dci18-0007 PMID: 29567642

[13] Caspersen CJ, Thomas GD, Boseman LA, Beckles GLA, Albright AL. Aging, diabetes, and the public health system in the United States. Am J Public Health 2012; 102(8): 1482-97. http://dx.doi.org/10.2105/AJPH.2011.300616 PMID: 22698044

[14] Thorpe KE, Ogden LL, Galactionova K. Chronic conditions account for rise in Medicare spending from 1987 to 2006. Health Aff (Millwood) 2010; 29(4): 718-24. http://dx.doi.org/10.1377/hlthaff.2009.0474 PMID: 20167626

[15] Aroh D, Colella J, Douglas C, Eddings A. An example of translating value-based purchasing into value-based care. Urol Nurs 2015; 35(2): 61-74. http://dx.doi.org/10.7257/1053-816X.2015.35.2.61 PMID: 26197624

[16] Coleman K, Austin BT, Brach C, Wagner EH. Evidence on the chronic care model in the new millennium. Health Aff (Millwood) 2009; 28(1): 75-85. http://dx.doi.org/10.1377/hlthaff.28.1.75 PMID: 19124857

[17] Ackroyd SA, Wexler DJ. Effectiveness of diabetes interventions in the patient-centered medical home. Curr Diab Rep 2014; 14(3): 471. http://dx.doi.org/10.1007/s11892-013-0471-z PMID: 24477830

[18] A Salzberg C, Bitton A, Lipsitz SR, *et al.* The impact of alternative payment in chronically ill and older patients in the patient-centered medical home. Med Care 2017; 55(5): 483-92. http://dx.doi.org/10.1097/MLR.0000000000000694 PMID: 28169976

[19] Bitton A, Martin C, Landon BE. A nationwide survey of patient centered medical home demonstration projects. J Gen Intern Med 2010; 25(6): 584-92. http://dx.doi.org/10.1007/s11606-010-1262-8 PMID: 20467907

[20] Hussey PS, Schneider EC, Rudin RS, Fox DS, Lai J, Pollack CE. Continuity and the costs of care for chronic disease. JAMA Intern Med 2014; 174(5): 742-8. http://dx.doi.org/10.1001/jamainternmed.2014.245 PMID: 24638880

[21] Ferrante JM, Balasubramanian BA, Hudson SV, Crabtree BF. Principles of the patient-centered medical home and preventive services delivery. Ann Fam Med 2010; 8(2): 108-16. http://dx.doi.org/10.1370/afm.1080 PMID: 20212297

[22] Kellerman R, Kirk L. Principles of the patient-centered medical home. Am Fam Physician 2007; 76(6): 774-5. PMID: 17910291

[23] Hughes JR, Grayson R, Stiles FC. Fragmentation of care and the medical home. Pediatrics 1977; 60(4): 559-9. PMID: 905034

[24] Daaleman TP, Hay S, Prentice A, Gwynne MD. Embedding care management in the medical home: a case study. J Prim Care Community Health 2014; 5(2): 97-100. http://dx.doi.org/10.1177/2150131913519128 PMID: 24414127

[25] Taliani CA, Bricker PL, Adelman AM, Cronholm PF, Gabbay RA. Implementing effective care management in the patient-centered medical home. Am J Manag Care 2013; 19(12): 957-64. PMID: 24512033

[26] Jackson GL, Powers BJ, Chatterjee R, *et al.* The patient centered medical home. A systematic review. Ann Intern Med 2013; 158(3): 169-78. http://dx.doi.org/10.7326/0003-4819-158-3-201302050-00579 PMID: 24779044

[27] Veet CA, Radomski TR, D'Avella C, *et al.* Impact of healthcare delivery system type on clinical, utilization, and cost outcomes of patient-centered medical homes: A systematic review. J Gen Intern Med 2020; 35(4): 1276-84.

http://dx.doi.org/10.1007/s11606-019-05594-3 PMID: 31907790
[28] Melnyk BM, Fineout-Overholt E, Stillwell SB, Williamson KM. Evidence-Based Practice: Step by Step: The Seven Steps of Evidence-Based Practice The Leading Voice of Nursing Since 1900 | AJN 2010; 110(1): 51-3.
[29] Schardt C, Adams MB, Owens T, Keitz S, Fontelo P. Utilization of the PICO framework to improve searching PubMed for clinical questions. BMC Med Inform Decis Mak 2007; 7(1): 16. http://dx.doi.org/10.1186/1472-6947-7-16 PMID: 17573961
[30] Higgins JPT, Green S, Eds. Cochrane handbook for systematic reviews of interventions. London, United Kingdom: The Cochrane Collaboration 2011.
[31] Moher D, Liberati A, Tetzlaff J, Altman DG. PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. BMJ 2009; 339: b2535. http://dx.doi.org/10.1136/bmj.b2535 PMID: 19622551
[32] Petticrew M, Roberts H. Systematic reviews in the social sciences: a practical guide. Malden, MA: Blackwell Publishing Co. 2006. http://dx.doi.org/10.1002/9780470754887
[33] Garrard J. Health sciences literature review made easy: The matrix method. (4th ed.), Burlington, MA: Jones & Bartlett Learning 2013.
[34] Howick J, Chalmers I, Glasziou P, *et al.* Explanation of the 2011 Oxford Centre for Evidence-Based Medicine (OCEBM) levels of evidence (background document) 2016.https://www.cebm.net/index.aspx?o=5653
[35] Oxford Centre for Evidence-based Medicine. Levels of evidence 2009.https://www.cebm.net/2009/06/
[36] Leyva-Moral JM, Palmieri PA, Feijoo-Cid M, *et al.* Reproductive decision-making in women living with human immunodeficiency virus: A systematic review. Int J Nurs Stud 2018; 77: 207-21. http://dx.doi.org/10.1016/j.ijnurstu.2017.10.012 PMID: 29112908
[37] Gabbay RA, Friedberg MW, Miller-Day M, Cronholm PF, Adelman A, Schneider EC. A positive deviance approach to understanding key features to improving diabetes care in the medical home. Ann Fam Med 2013; 11 (Suppl. 1): S99-S107. http://dx.doi.org/10.1370/afm.1473 PMID: 23690393
[38] Sieber WJ, Newsome A, Fiorella M, Mantila H. Translating patient self-management research into primary care: challenges and successes with group medical visits. Transl Behav Med 2012; 2(4): 535-42. http://dx.doi.org/10.1007/s13142-012-0150-7 PMID: 24073154
[39] Solberg LI, Crain AL, Tillema J, Scholle SH, Fontaine P, Whitebird R. Medical home transformation: a gradual process and a continuum of attainment. Ann Fam Med 2013; 11 (Suppl. 1): S108-14. http://dx.doi.org/10.1370/afm.1478 PMID: 23690379
[40] Moran K, Burson R, Critchett J, Olla P. Exploring the cost and clinical outcomes of integrating the registered nurse-certified diabetes educator into the patient-centered medical home. Diabetes Educ 2011; 37(6): 780-93. http://dx.doi.org/10.1177/0145721711423979 PMID: 22075501
[41] DeVries A, Li CH, Sridhar G, Hummel JR, Breidbart S, Barron JJ. Impact of medical homes on quality, healthcare utilization, and costs. Am J Manag Care 2012; 18(9): 534-44. PMID: 23009304
[42] Flottemesch TJ, Anderson LH, Solberg LI, Fontaine P, Asche SE. Patient-centered medical home cost reductions limited to complex patients. Am J Manag Care 2012; 18(11): 677-86. PMID: 23198711
[43] David G, Gunnarsson C, Saynisch PA, Chawla R, Nigam S. Do patient-centered medical homes reduce emergency department visits? Health Serv Res 2015; 50(2): 418-39. http://dx.doi.org/10.1111/1475-6773.12218 PMID: 25112834
[44] Rosenthal MB, Alidina S, Friedberg MW, *et al.* A difference-in-difference analysis of changes in quality, utilization and cost following the Colorado multi-payer patient-centered medical home pilot. J Gen Intern Med 2016; 31(3): 289-96. http://dx.doi.org/10.1007/s11606-015-3521-1 PMID: 26450279
[45] Timbie JW, Hussey PS, Setodji CM, *et al.* Association between patient-centered medical home capabilities and outcomes for Medicare beneficiaries seeking care from federally qualified health centers. J Gen Intern Med 2017; 32(9): 997-1004. http://dx.doi.org/10.1007/s11606-017-4078-y PMID: 28550610
[46] Lauffenburger JC, Shrank WH, Bitton A, *et al.* Association between patient-centered medical homes and adherence to chronic disease medications: A cohort study. Ann Intern Med 2017; 166(2): 81-8. http://dx.doi.org/10.7326/M15-2659 PMID: 27842386
[47] Miller JM, Phalen AG, Crawford A, Frisby A, Ziring BS. Text messaging in the patient-centered medical home to improve glucose control and retinopathy screening. Health Equity 2017; 1(1): 2-6. http://dx.doi.org/10.1089/heq.2016.0003 PMID: 30283829
[48] Meo N, Wong E, Sun H, *et al.* Elements of the Veterans Health Administration patient-centered medical home are associated with greater adherence to oral hypoglycemic agents in patients with diabetes. Popul Health Manag 2018; 21(2): 116-22. http://dx.doi.org/10.1089/pop.2017.0039 PMID: 28677990
[49] Gunter KE, Nocon RS, Gao Y, Casalino LP, Chin MH. Medical home characteristics and quality of diabetes care in safety net clinics. J Community Health 2017; 42(2): 303-11. http://dx.doi.org/10.1007/s10900-016-0256-9 PMID: 27659297
[50] Shi L, Lee D-C, Chung M, Liang H, Lock D, Sripipatana A. Patient-centered medical home recognition and clinical performance in U.S. community health centers. Health Serv Res 2017; 52(3): 984-1004. http://dx.doi.org/10.1111/1475-6773.12523 PMID: 27324440
[51] Kinsell HS, Hall AG, Harman JS, Tewary S, Brickman A. Impacts of initial transformation to a patient-centered medical home on diabetes outcomes in federally qualified health centers in Florida. J Prim Care Community Health 2017; 8(4): 192-7. http://dx.doi.org/10.1177/2150131917742300 PMID: 29161972
[52] Carlin CS, Flottemesch TJ, Solberg LI, Werner AM. System transformation in patient-centered medical home (PCMH): Variable impact on chronically ill patients' utilization. J Am Board Fam Med 2016; 29(4): 482-95. http://dx.doi.org/10.3122/jabfm.2016.04.150360 PMID: 27390380
[53] Lamb KD, Baker JW, McFarland MS. Implementation of a pharmacotherapy clinic into the patient centered medical home model by a second year pharmacy resident American Journal of Health-System Pharmacy 2015; 72 (17_Supplement_2): 83 -9 . http://dx.doi.org/10.2146/sp150015
[54] Berdine HJ, Skomo ML. Development and integration of pharmacist clinical services into the patient-centered medical home. J Am Pharm Assoc (2003) 2012; 52(5): 661-7. http://dx.doi.org/10.1331/JAPhA.2012.10206 PMID: 23023848
[55] Edwards HD, Webb RD, Scheid DC, Britton ML, Armor BL. A pharmacist visit improves diabetes standards in a patient-centered medical home (PCMH). Am J Med Qual 2012; 27(6): 529-34. http://dx.doi.org/10.1177/1062860612444304 PMID: 22679128
[56] Calman NS, Hauser D, Weiss L, *et al.* Becoming a patient-centered medical home: a 9-year transition for a network of Federally Qualified Health Centers. Ann Fam Med 2013; 11 (Suppl. 1): S68-73. http://dx.doi.org/10.1370/afm.1547 PMID: 23690389
[57] Liss DT, Reid RJ, Grembowski D, Rutter CM, Ross TR, Fishman PA. Changes in office visit use associated with electronic messaging and telephone encounters among patients with diabetes in the PCMH. Ann Fam Med 2014; 12(4): 338-43. http://dx.doi.org/10.1370/afm.1642 PMID: 25024242
[58] DePuccio MJ, Hoff TJ. Medical home interventions and quality outcomes for older adults: a systematic review. Qual Manag Health Care 2013; 22(4): 327-40. http://dx.doi.org/10.1097/QMH.0000000000000000 PMID: 24088881
[59] Emerson JF, Welch M, Rossman WE, *et al.* A multidisciplinary intervention utilizing virtual communication tools to reduce health disparities: A pilot randomized controlled trial. Int J Environ Res Public Health 2015; 13(1): h13010031. http://dx.doi.org/10.3390/ijerph13010031 PMID: 26703661
[60] Pagán JA, Carlson EK. Assessing long-term health and cost outcomes of patient-centered medical homes serving adults with poor diabetes control. J Prim Care Community Health 2013; 4(4): 281-5. http://dx.doi.org/10.1177/2150131913489885 PMID: 23799676

[61] Martsolf GR, Kandrack R, Friedberg MW, Briscombe B, Hussey PS, LaBonte C. Estimating the Costs of Implementing Comprehensive Primary Care: A Narrative Review. Health Serv Res Manag Epidemiol 2019; 6: 2333392819842484. http://dx.doi.org/10.1177/2333392819842484 PMID: 31069248

[62] Magill MK, Ehrenberger D, Scammon DL, *et al.* The cost of sustaining a patient-centered medical home: experience from 2 states. Ann Fam Med 2015; 13(5): 429-35. http://dx.doi.org/10.1370/afm.1851 PMID: 26371263

[63] Friedman A, Howard J, Shaw EK, Cohen DJ, Shahidi L, Ferrante JM. Facilitators and barriers to care coordination in patient-centered medical homes (PCMHs) from coordinators' perspectives. J Am Board Fam Med 2016; 29(1): 90-101. http://dx.doi.org/10.3122/jabfm.2016.01.150175 PMID: 26769881

[64] Bojadzievski T, Gabbay RA. Patient-centered medical home and diabetes. Diabetes Care 2011; 34(4): 1047-53. http://dx.doi.org/10.2337/dc10-1671 PMID: 21447667

[65] Kraschnewski JL, Gabbay RA. Role of health information technologies in the Patient-centered Medical Home. J Diabetes Sci Technol 2013; 7(5): 1376-85. http://dx.doi.org/10.1177/193229681300700530 PMID: 24124967

[66] Schottenfeld L, Petersen D, Peikes D, *et al.* Creating patient-centered team-based primary care. Rockville, MD: Agency for Healthcare Research and Quality 2016.

[67] Hall AG, Webb FJ, Scuderi CB, Tamayo-Friedel C, Harman JS. Differences in patient ratings of medical home domains among adults with diabetes: comparisons across primary care sites. J Prim Care Community Health 2014; 5(4): 247-52. http://dx.doi.org/10.1177/2150131914538455 PMID: 24928567

[68] Lavallée JF, Gray TA, Dumville J, Russell W, Cullum N. The effects of care bundles on patient outcomes: a systematic review and meta-analysis. Implement Sci 2017; 12(1): 142. http://dx.doi.org/10.1186/s13012-017-0670-0 PMID: 29187217

[69] Nigro SC, Garwood CL, Berlie H, *et al.* Clinical pharmacists as key members of the patient-centered medical home: an opinion statement of the Ambulatory Care Practice and Research Network of the American College of Clinical Pharmacy. Pharmacotherapy 2014; 34(1): 96-108. http://dx.doi.org/10.1002/phar.1357 PMID: 24122857

[70] John JR, Ghassempour S, Girosi F, Atlantis E. The effectiveness of patient-centred medical home model versus standard primary care in chronic disease management: protocol for a systematic review and meta-analysis of randomised and non-randomised controlled trials. Syst Rev 2018; 7(1): 215. http://dx.doi.org/10.1186/s13643-018-0887-2 PMID: 30497523

[71] Alexander JA, Paustian M, Wise CG, *et al.* Assessment and measurement of patient-centered medical home implementation: the BCBSM experience. Ann Fam Med 2013; 11 (Suppl. 1): S74-81. http://dx.doi.org/10.1370/afm.1472 PMID: 23690390