



2. The Patient-Centered Medical Home

Closing the Quality Gap: Revisiting the State of the Science



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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions, and new health care technologies and strategies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

In 2004, AHRQ launched a collection of evidence reports, *Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies*, to bring data to bear on quality improvement opportunities. These reports summarized the evidence on quality improvement strategies related to chronic conditions, practice areas, and cross-cutting priorities.

This evidence report is part of a new series, *Closing the Quality Gap: Revisiting the State of the Science*. This series broadens the scope of settings, interventions, and clinical conditions, while continuing the focus on improving the quality of health care through critical assessment of relevant evidence. Targeting multiple audiences and uses, this series assembles evidence about strategies aimed at closing the “quality gap,” the difference between what is expected to work well for patients based on known evidence and what actually happens in day-to-day clinical practice across populations of patients. All readers of these reports may expect a deeper understanding of the nature and extent of selected high-priority quality gaps, as well as the systemic changes and scientific advances necessary to close them.

AHRQ expects that the EPC evidence reports will inform consumers, health plans, other purchasers, providers, and policymakers, as well as the health care system as a whole, by providing important information to help improve health care quality.

We welcome comments on this evidence report or the series as a whole. Comments may be sent by mail to the Task Order Officer named in this report to: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

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The Patient-Centered Medical Home

Closing the Quality Gap: Revisiting the State of the Science

Structured Abstract

Objectives. As part of the Closing the Quality Gap: Revisiting the State of the Science series of the Agency for Healthcare Research and Quality (AHRQ), this systematic review sought to identify completed and ongoing evaluations of the comprehensive patient-centered medical home (PCMH), summarize current evidence for this model, and identify evidence gaps.

Data Sources. We searched PubMed[®], CINAHL[®], and the Cochrane Database of Systematic Reviews for published English-language studies, and a wide variety of databases and Web resources to identify ongoing or recently completed studies.

Review Methods. Two investigators per study screened abstracts and full-text articles for inclusion, abstracted data, and performed quality ratings and evidence grading. Our functional definition of PCMH was based on the definition used by AHRQ. We included studies that explicitly claimed to be evaluating PCMH and those that did not but which met our functional definition.

Results. Seventeen studies with comparison groups evaluated the effects of PCMH (Key Question [KQ] 1). Older adults in the United States were the most commonly studied population (8 of 17 studies). PCMH interventions had a small positive impact on patient experiences (including patient-perceived care coordination) and small to moderate positive effects on preventive care services (moderate strength of evidence [SOE]). Staff experiences were also improved by a small to moderate degree (low SOE). There were too few studies to estimate effects on clinical or most economic outcomes.

Twenty-one of 27 studies reported approaches that addressed all 7 major PCMH components (KQ 2), including team-based care, sustained partnership, reorganized care or structural changes to care, enhanced access, coordinated care, comprehensive care, and a systems-based approach to quality. A total of 51 strategies were used to address the 7 major PCMH components.

Twenty-two of 27 studies reported information on financial systems used to implement PCMH, implementation strategies, and/or organizational learning strategies for implementing PCMH (KQ 3).

The 31 studies identified in the horizon scan of ongoing PCMH studies (KQ 4) were broadly representative of the U.S. health care system, both in geography and in the complexity of private and public health care payers and delivery networks.

Conclusions. Published studies of PCMH interventions often have similar broad elements, but precise components of care varied widely. The PCMH holds promise for improving the experiences of patients and staff, and potentially for improving care processes. However, current evidence is insufficient to determine effects on clinical and most economic outcomes. Ongoing studies identified through the horizon scan have potential to greatly expand the evidence base relating to PCMH.

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Executive Summary

Background

The United States spends a greater proportion of its gross domestic product on health care than any other country in the world (17.6 percent in 2009),¹ yet often fails to provide high-quality and efficient health care.²⁻⁶ U.S. health care has traditionally been based on a solid foundation of primary care to meet the majority of preventive, acute, and chronic health care needs of its population; however, the recent challenges facing health care in the United States have been particularly magnified within the primary care setting. Access to primary care is limited in many areas, particularly rural communities. Fewer U.S. physicians are choosing primary care as a profession, and satisfaction among primary care physicians has waned amid the growing demands of office-based practice.⁷ There has been growing concern that current models of primary care will not be sustainable for meeting the broad health care needs of the American population.

The patient-centered medical home (PCMH) is a model of primary care transformation that seeks to meet the variety of health care needs of patients and to improve patient and staff experiences, outcomes, safety, and system efficiency.⁸⁻¹¹ The term “medical home” was first used by the American Academy of Pediatrics in 1967 to describe the concept of a single centralized source of care and medical record for children with special health care needs.¹² The current concept of PCMH has been greatly expanded and is based on 40 years of previous efforts to redesign primary care to provide the highest quality of care possible.^{13,14} The chronic care model,^{15,16} a conceptual model for organizing chronic illness care that is associated with improved health outcomes, is the cornerstone of PCMH.¹⁷ Interventions based on the chronic care model (CCM) and focused on single conditions such as diabetes mellitus, asthma, chronic obstructive pulmonary disease, or depression have been shown to improve patient outcomes and/or quality of care.¹⁸⁻²¹ PCMH builds on this model and is intended to address the full range of patient-focused health care needs.⁸ As defined by physician and consumer groups, the core principles of the PCMH are wide-ranging team-based care, patient-centered orientation toward the whole person, care that is coordinated across all elements of the health care system and the patient’s community, enhanced access to care that uses alternative methods of communication, and a systems-based approach to quality and safety.⁹ While these principles are frequently cited in relation to PCMH, it should be recognized that specific PCMH definitions vary widely, reflecting the rapid expansion of the use of PCMH concepts in the last decade.²² As described below, we based the operational definition of PCMH for this review on the definition outlined by the Agency for Healthcare Research and Quality (AHRQ).⁸

It has been hypothesized that comprehensive PCMH interventions hold promise as a pathway to improved primary health care quality, safety, efficiency, and effectiveness. The PCMH has also been described as a “lifeline for primary care” that has the potential to transform and increase the appeal and viability of primary care practice.²³ Given the conceptual promise of PCMH, professional societies have endorsed the model,²⁴ and payers (e.g., Medicare) and large health systems have begun to implement PCMH-based programs. These include health maintenance organizations (HMOs), networks of Medicaid providers, community health centers, private integrated delivery systems, private practices, the U.S. Department of Veterans Affairs (VA) health care system, and components of the Department of Defense military health care system.²⁵⁻²⁸ The goal is to improve the care of patients across the continuum of prevention and

treatment of chronic and acute illness, while potentially improving both patient and provider experiences with the health care system. Further, it has been hypothesized that PCMH may introduce efficiencies in care that help contain rising health care costs.²⁵

Although PCMH is built on a solid foundation, the evidence for benefit of comprehensive PCMH interventions is uncertain. Therefore, AHRQ commissioned a systematic review to evaluate the current state of the evidence for a range of outcomes and to identify ongoing studies that could address current gaps in evidence. Medical homes can be established in specialty settings, but for the purposes of this review we chose to focus on evaluations of the model in the primary care–based setting, the setting of broadest applicability and with the most extant research. Further, we developed an operational definition of a comprehensive PCMH intervention that is based on the AHRQ definition of PCMH, which does not require an enhanced payment model.⁸ Using the AHRQ definition made our review more inclusive of studies that tested the critical principles that embody the Institute of Medicine (IOM) concept of patient-centered care.²⁹

Objectives

As part of the Closing the Quality Gap: Revisiting the State of the Science series of reviews by Evidence-based Practice Centers (EPCs), this systematic review was commissioned to identify completed and ongoing efforts to evaluate the comprehensive PCMH model, summarize current evidence for this model, and identify gaps in the evidence. Because the PCMH model is being implemented widely but the number of completed studies was expected to be small, the identification of ongoing studies was an important goal of this review. This “horizon scan” component of the review helped to identify forthcoming studies that may address gaps in the currently available evidence.

The Key Questions (KQs) for the review are listed below. For clarification, KQs 1–3 concern published studies, while KQ 4 is a horizon scan question that relates to unpublished comparative studies now in progress.

KQ 1. In published, primary care–based evaluations of comprehensive PCMH interventions, what are the effects of the PCMH on patient and staff experiences, process of care, clinical outcomes, and economic outcomes?

- a. Are specific PCMH components associated with greater effects on patient and staff experiences, process of care, clinical outcomes, and economic outcomes?
- b. Is implementation of comprehensive PCMH associated with unintended consequences (e.g., decrease in levels of indicated care for nonpriority conditions) or other harms?

KQ 2. In published, primary care–based evaluations of comprehensive PCMH interventions, what individual PCMH components have been implemented?

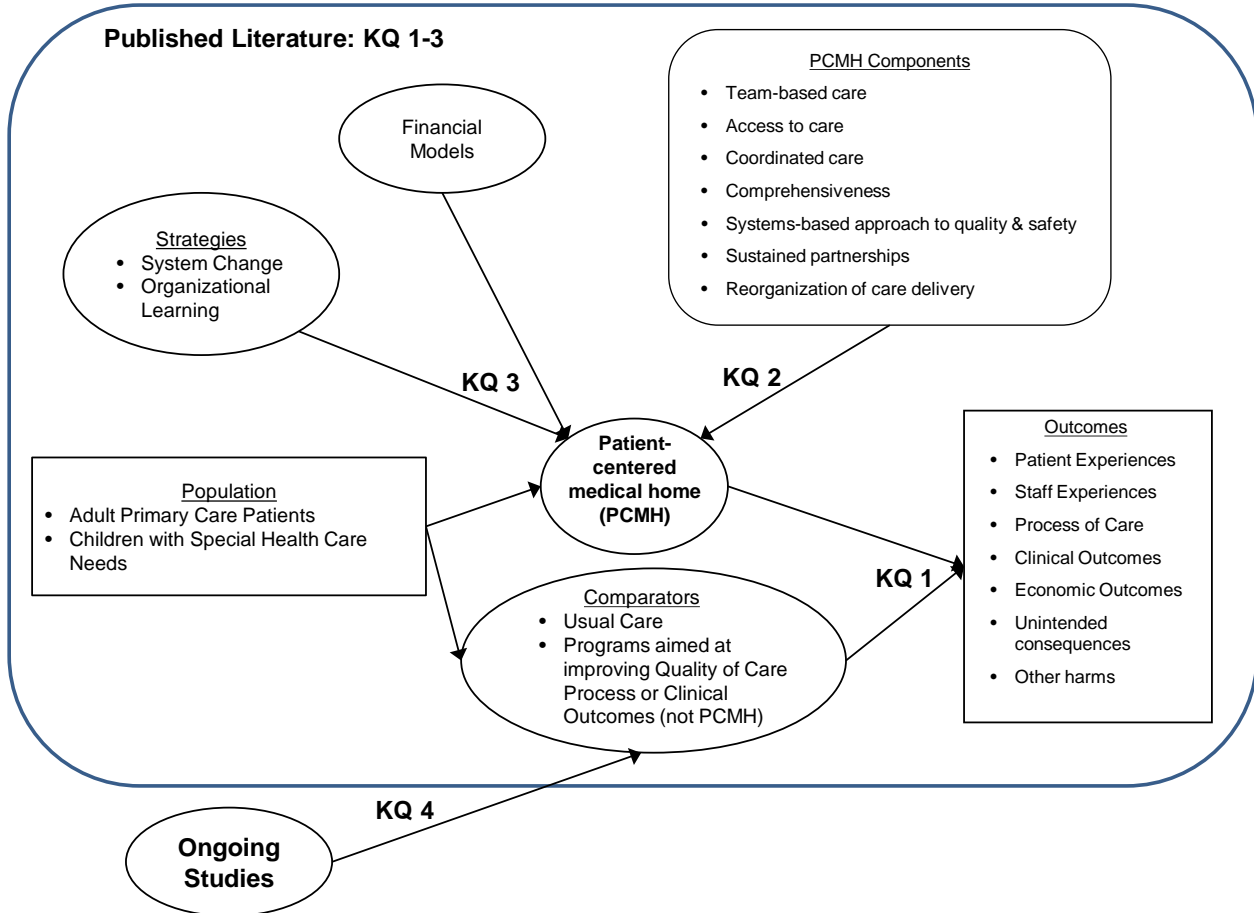
KQ 3. In published, primary care–based evaluations of comprehensive PCMH interventions, what financial models and implementation strategies have been used to support uptake?

KQ 4. What primary care–based studies evaluating the effects of comprehensive PCMH interventions on patient and staff experiences, process of care, clinical outcomes, or economic outcomes are currently underway? In these ongoing studies, what are the study designs, PCMH components, comparators, settings, financial models, and outcomes to be evaluated?

Analytic Framework

Figure A shows the analytic framework for the review.

Figure A. Analytic framework



Notes: KQ = Key Question; PCMH = patient-centered medical home

The figure illustrates how we hypothesized the potential mechanism by which comprehensive PCMH interventions (the combination of PCMH elements taken as a group, not just the individual components) and their comparators may impact outcomes of interest (KQ 1), including patient and staff experiences, process of care, clinical outcomes, and economic outcomes. This hypothesis motivated the search for potentially relevant published literature. In addition, we searched the literature to determine if there have been any reports of an association between PCMH and unintended consequences or other harms. The individual components of PCMH and their incorporation and/or implementation in PCMH evaluations were examined (KQ 2), as well as the financial models and strategies for system change or organizational learning used to support uptake (KQ 3). Finally, the figure illustrates the way in which these outcomes and moderators were identified in ongoing studies (KQ 4).

Methods

- 1. Input From Stakeholders.** Topics for the Closing the Quality Gap: Revisiting the State of the Science series were solicited from the leads of AHRQ portfolios (areas of research). Nominations included a brief background and context, the importance of and/or rationale for the topic, the focus or population of interest, relevant outcomes, and references to recent or ongoing work. The EPC performing the review refined the KQs via discussions with the EPC coordinating the Closing the Quality Gap: Revisiting the State of the Science series and with AHRQ. A Technical Expert Panel with experts knowledgeable in PCMH as a primary care model provided input during the protocol development process.
- 2. Data Sources and Selection.** For KQs 1–3, we searched PubMed[®], the Cumulative Index to Nursing & Allied Health Literature (CINAHL[®]), and the Cochrane Database of Systematic Reviews (CDSR). Our search strategy used the National Library of Medicine’s medical subject heading (MeSH) keyword nomenclature and text words for the medical home and related concepts, and for eligible study designs. We included studies published in English and indexed from database inception through December 6, 2011 (PubMed), or March 30, 2011 (CINAHL and CDSR). All searches were designed and conducted in collaboration with an experienced search librarian. We supplemented these electronic searches with a manual search of citations from a set of key primary and review articles.^{30,31}

For KQ 4, we used the term “medical home” to search for ongoing or recently completed studies in the following databases: ClinicalTrials.gov, Commonwealth Fund, Robert Wood Johnson Foundation, and databases of federally funded studies—AHRQ, Centers for Disease Control and Prevention, Health Services Research Projects in Progress, National Institutes of Health (NIH) Reporter (NIH Research Portfolio Online), Health Resources and Services Administration, VA, and Department of Defense. All databases were searched using the enGrant Scientific interface. In addition, we conducted manual searches of Web-based resources that did not have searchable databases, exploring all Web links that showed promise for relevant information, including the Patient-Centered Primary Care Collaborative, American College of Physicians, National Academy for State Health Policy, and Centers for Medicare & Medicaid Services (CMS). To supplement electronic sources, we sent letters to 10 contacts involved in State-level projects funded by CMS and a letter to the VA Director of PCMH (designated Patient Aligned Care Teams within the VA environment) demonstration labs, requesting information about any ongoing or recently completed studies. Finally, we identified a published horizon scan that included interviews with key informants designed to collect detailed information about the participants, design, and implementation of ongoing PCMH programs.³¹ We used information from this horizon scan to verify and augment data obtained from the above-mentioned databases/study registries.

Using the criteria described in Table A, two investigators independently reviewed each title and abstract for potential relevance to the KQs; articles included by either investigator underwent full-text screening. At the full-text screening stage, two investigators independently reviewed the full text of each article and indicated a decision

to include or exclude the article for data abstraction. When the paired reviewers arrived at different decisions about whether to include or exclude an article, or about the reason for exclusion, we reached a final agreement through review and discussion among investigators. Articles meeting eligibility criteria were included for data abstraction. For KQ 4, these procedures were modified such that a single screener initially reviewed all citations; final eligibility for data abstraction was determined by duplicate review.

Table A. Inclusion/exclusion criteria

Study Characteristic	Inclusion Criteria	Exclusion Criteria
Population	<ul style="list-style-type: none"> • Adult primary care patients, selected to represent the practice rather than on the basis of a particular chronic illness. • Children with special health care needs according to the HRSA definition. 	Studies where PCMH transformation was focused on a small proportion of patients being cared for in the practice; for example, studies restricted to patients with diabetes or asthma.
Interventions	<p>KQs 1–3: A comprehensive PCMH intervention that includes items 1, 3, and 4, below, along with at least two components of item 2:</p> <ol style="list-style-type: none"> 1. <u>Team-based</u> care (team may be <i>virtual</i>). 2. At least 2 of the following 4 components: <ol style="list-style-type: none"> a. Enhanced <u>access</u> to care b. <u>Coordinated</u> care across settings c. <u>Comprehensiveness</u> d. <u>A systems-based approach to improving quality and safety</u> 3. A sustained partnership and personal relationship over time oriented toward the whole person. 4. Structural changes to the traditional practice, reorganizing care delivery. <p>KQ 4: PCMH intervention should meet the above definition; however, because descriptions of ongoing studies were often sparse, we accepted the designation of “medical home” as meeting our intervention criteria without explicit documentation that the study truly met our functional definition.</p>	KQs 1–3: Studies that were self-identified as pertaining to “medical home” but did not describe the intervention sufficiently to meet the AHRQ definition.
Comparators	<p>KQs 1–4:</p> <ul style="list-style-type: none"> • Usual care. • Programs aimed at improving the quality of care, process outcomes, or clinical outcomes that do not meet the operational definition of a comprehensive PCMH intervention (above). <p>KQ 4: For this question, we also accepted comparisons across different levels of PCMH implementation (high vs. low adopters).</p>	KQs 1 and 4: No comparator. Analyses for KQs 2–3 include studies without comparators, while KQ 1 and KQ 4 analyses include only studies with comparison groups).

Table A. Inclusion/exclusion criteria (continued)

Study Characteristic	Inclusion Criteria	Exclusion Criteria
Outcomes	<p>KQ1: PCMH interventions may lead to a variety of effects on the health care system and patient health status. We prioritized and abstracted a specific subset of these outcomes that had face validity and were reported across studies, and/or were collected using validated instruments or methods. These included:</p> <ol style="list-style-type: none"> 1. Patient experiences: <ol style="list-style-type: none"> a. Global/overall patient experiences b. Coordination of care (as perceived by patients) c. Patient-provider interaction 2. Staff experiences: <ol style="list-style-type: none"> a. Global/overall staff experiences b. Staff retention rates c. Staff burnout 3. Process of care: <ol style="list-style-type: none"> a. Preventive services b. Chronic illness care services 4. Clinical outcomes: <ol style="list-style-type: none"> a. Health status b. Laboratory tests c. Mortality 5. Economic outcomes: <ol style="list-style-type: none"> a. Inpatient use b. Emergency department use c. Overall costs 6. Unintended consequences or other harms <p>KQ 2: PCMH components as listed in the Interventions section.</p> <p>KQ 3:</p> <ol style="list-style-type: none"> 1. Financial models. 2. System change, along with any theoretical basis provided. 3. Organizational learning strategies and any theoretical basis provided for these strategies. <p>KQ 4 (horizon scan of ongoing studies):</p> <ol style="list-style-type: none"> 1. Study design 2. PCMH components 3. Settings (e.g., practice size, geographic location) 4. Financial models 5. Outcomes assessed (if reported): <ol style="list-style-type: none"> a. Patient experiences b. Staff experiences c. Process of care d. Clinical outcomes e. Economic outcomes 	No outcomes of interest reported.
Timing	Studies had to have at least 6 months longitudinal followup.	Less than 6 months longitudinal followup.

Table A. Inclusion/exclusion criteria (continued)

Study Characteristic	Inclusion Criteria	Exclusion Criteria
Setting	Primary care settings, e.g., family medicine, general internal medicine, primary care pediatrics, general medical clinics such as Federally Qualified Health Centers, general medical clinics primarily staffed by midlevel providers, general practices/practitioners, geriatric practices providing longitudinal care rather than consultative services. KQ 1–3: Studies conducted in a high-income economy ^a as defined by the World Bank. KQ 4: Studies underway in the United States. ^b	<ul style="list-style-type: none"> • Geriatric practices providing consultative services. • Medical subspecialties.
Study design	KQ 1, KQ 4: Patient or cluster RCT, nonrandomized clustered controlled trial, controlled before-and-after study. KQ 2, KQ 3: Patient or cluster RCT, nonrandomized clustered controlled trial, controlled before-and-after study, uncontrolled pre- and postintervention study.	Not a clinical study (e.g., editorial, nonsystematic review, letter to the editor, case series).
Publications	KQs 1–4: English-language only. ^c KQs 1–3: <ul style="list-style-type: none"> • Publication date from database inception to present. • Peer-reviewed article. KQ 4: Studies had to be ongoing or scheduled to be completed on or after April 2010. ^d	<ul style="list-style-type: none"> • Non-English-language publication.^c • Not peer reviewed (e.g., letter to editor).

^aWe restricted studies for KQs 1–3 to high-income economies—i.e., to countries that have greater cultural and health care system similarities to the United States—to improve applicability of the study results to the United States.

^bKQ 4 studies were restricted to those conducted in the United States to maximize applicability to our target audience and because our knowledge of gray literature sources is good within the United States but poor outside it.

^cWe excluded non-English-language publications for two reasons: (a) we are most interested in health care systems that are similar to U.S. health care, and reports from these countries are likely to be published in English; and (b) it is the opinion of the investigators that the resources required for translation of non-English articles would not be justified by the low potential likelihood of identifying relevant data unavailable from English-language sources.

^dOur rationale was that studies completed prior to April 2010 should already have been published.

Notes: AHRQ = Agency for Healthcare Research and Quality; HRSA = Health Resources and Services Administration; KQ = Key Question; PCMH = patient-centered medical home; RCT = randomized controlled trial

3. Data Extraction and Quality Assessment. The investigative team created forms for abstracting the data elements for the KQs. Based on clinical and methodological expertise, a pair of researchers was assigned to abstract data from the eligible articles. One researcher abstracted the data, and the second reviewed the completed abstraction form alongside the original article to check for accuracy and completeness. Disagreements were resolved by consensus or by obtaining a third reviewer’s opinion if the first two investigators could not reach consensus.

To aid in both reproducibility and standardization of data collection, researchers received data abstraction instructions directly on each form. Forms were created specifically for this project using the DistillerSR data synthesis software program (Evidence Partners Inc., Manotick, ON, Canada). The abstraction form templates were pilot tested with a sample of included articles to ensure that all relevant data elements were captured and that there were consistency and reproducibility across abstractors. Data abstraction forms for KQs 1–3 included descriptions of the study design, study population, interventions and comparators, financial models, implementation methods, study outcomes, and study quality. Outcomes of interest included patient experiences, staff experiences, process of

care, clinical outcomes, and economic outcomes. For KQ 4, we developed a less detailed data abstraction form that included basic study design; geographic location; study setting, including health care system; number of practices/physicians; payment reform/financial model; major components of the intervention/PCMH model; comparator; types of outcomes being assessed; study dates; and source of funding.

We assessed the quality/risk of bias of studies included for KQ 1 based on their reporting of relevant data. We evaluated the quality of individual studies using the approach described in AHRQ's Methods Guide for Effectiveness and Comparative Effectiveness Reviews.³² To assess quality, we (1) classified the study design, (2) applied predefined criteria for quality and critical appraisal, and (3) arrived at a summary judgment of the study's quality. To evaluate methodological quality, we applied criteria for each study type derived from core elements described in the Methods Guide. To indicate the summary judgment of the quality of the individual studies, we used the summary ratings of good, fair, and poor, based on the studies' adherence to well-accepted standard methodologies and the adequacy of the reporting. For each study, one investigator assigned a summary quality rating, which was then reviewed by a second investigator; disagreements were resolved by consensus or by a third investigator if agreement could not be reached.

The strength of evidence for the highest priority outcomes in KQ 1 was assessed using the approach described in AHRQ's Methods Guide.^{32,33} In brief, the Methods Guide recommends assessment of four domains: risk of bias, consistency, directness, and precision. Additional domains, to be used when appropriate, are coherence, dose-response association, impact of plausible residual confounders, strength of association (magnitude of effect), and publication bias. These domains were considered qualitatively, and a summary rating was assigned, after discussion by two reviewers, as "high," "moderate," or "low" strength of evidence. In some cases, high, moderate, or low ratings were impossible or imprudent to make—for example, when no evidence was available or when evidence on the outcome was too weak, sparse, or inconsistent to permit any conclusion to be drawn. In these situations, a grade of "insufficient" was assigned. This four-level rating scale consists of the following definitions:

- *High*: High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.
- *Moderate*: Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
- *Low*: Low confidence that the evidence reflects the true effect. Further research is likely to change the confidence in the estimate of effect and is likely to change the estimate.
- *Insufficient*: Evidence either is unavailable or does not permit estimation of an effect.

We did not rate the strength of evidence for KQs 2–4 because these questions were purely descriptive.

4. Data Synthesis and Analysis. We summarized key features of the included studies by KQ. For published studies, we created an overview table of basic study characteristics, an intervention table giving details of the intervention, and a summary table of implementation strategies. Studies were categorized into those that explicitly tested the PCMH model and those that met our functional definition for PCMH but did not use the terms “PCMH” or “medical home.” (The latter are referred to as “functional PCMH” studies in the report.) Studies were evaluated initially in aggregate, and then by PCMH versus functional PCMH studies and adult versus pediatric studies. For KQ 1, we used a random-effects model to compute summary estimates of effect for hospitalizations and emergency department visits for the subset of studies using randomized controlled trial (RCT) designs. Summary estimates were calculated using Comprehensive Meta-Analysis software and are reported as summary risk ratios.³⁴ For other outcomes, the study populations, designs, and outcomes were too variable for quantitative analysis, and results were accordingly synthesized qualitatively. Because the continuous measures used for most outcomes reported varied greatly across studies, we computed effect sizes, represented as the standardized mean difference (SMD), to aid interpretation. The SMD is useful when studies assess the same outcome with different measures or scales. In this circumstance, it is necessary to standardize the results for the studies to a uniform scale to facilitate comparisons. We calculated the SMD for each study, using Hedges’ *g*, by subtracting (at post-test) the average score of the control group from the average score of the experimental group and dividing the result by the pooled standard deviations (SDs) of the experimental and control groups. To aid interpretation, we standardized presentation such that beneficial effects for the medical home are presented as positive effect sizes. We planned to use cross-case analyses to evaluate the association between independent variables (e.g., specific components of comprehensive PCMH) and study effect, using methods based on Miles and Huberman.³⁵ However, there were too few studies and too little variability to complete this exploratory analysis.

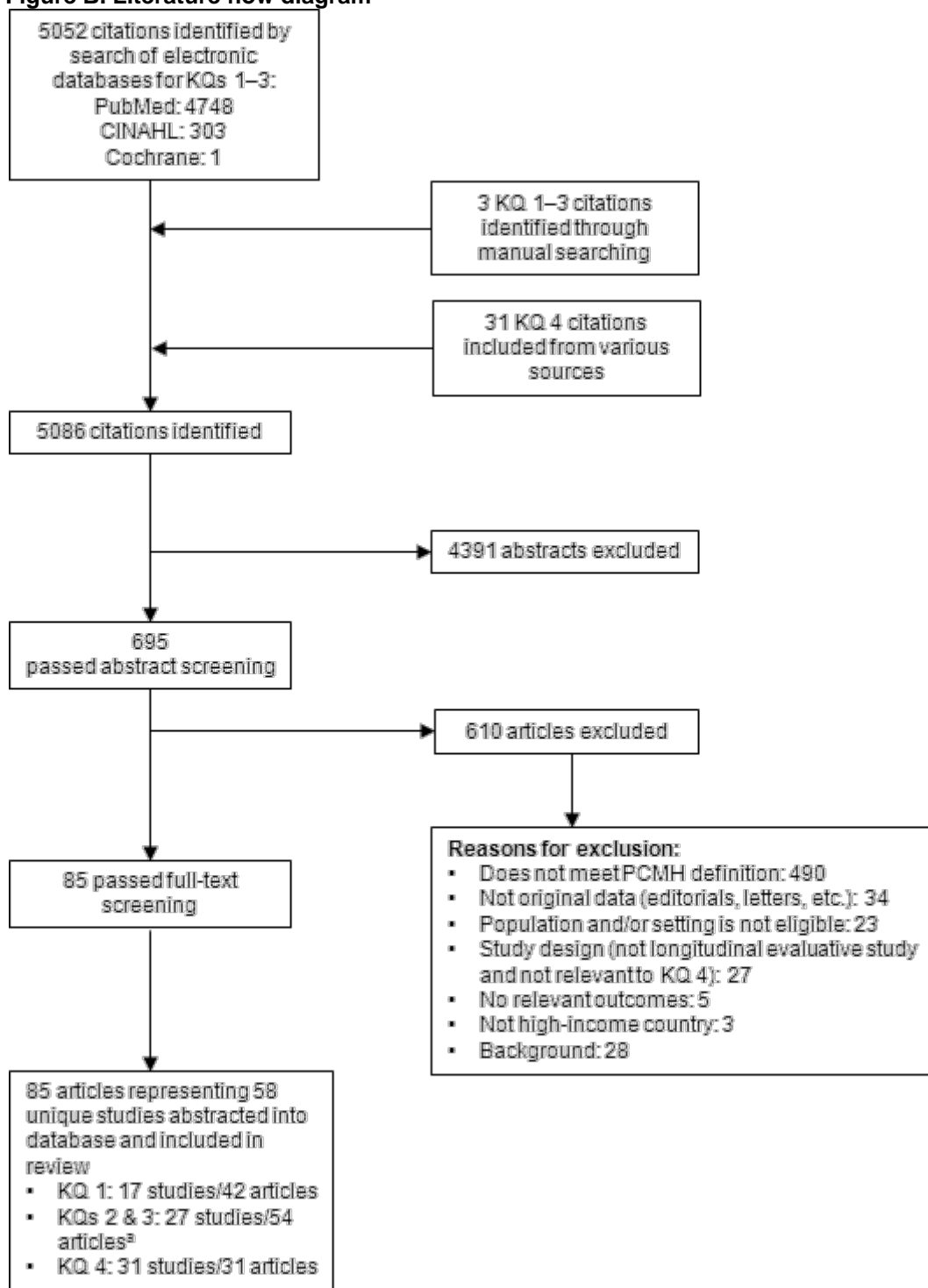
Results

Results of Literature Searches

Figure B depicts the flow of articles through the literature search and screening process.

We identified 5,086 citations. After inclusion/exclusion criteria were applied at the title and abstract level, 695 full-text articles were retrieved and screened. Of these, 610 were excluded at the full-text screening stage, leaving 85 articles (representing 58 unique studies) for data abstraction. We included 27 studies from the published peer-reviewed literature (17 were comparative and 10 descriptive) and 31 ongoing studies identified from the horizon scan.

Figure B. Literature flow diagram



^aAll studies/articles included for KQ 1 were also included for KQs 2 and 3.

Notes: KQ = Key Question; PCMH = patient-centered medical home

KQ 1. Effects of PCMH Interventions

Only 6 studies explicitly evaluated PCMH; an additional 11 studies evaluated functional PCMH interventions. Studies included both observational designs (n = 9) and RCTs (n = 8). Older adults in the United States with multiple chronic conditions were the most commonly studied population (8 of the 17 studies). Most studies were conducted in integrated health care systems (10 of 17 studies). Studies varied widely in the range of outcomes reported and the specific measures used. With the exception of one study, which examined facilitated versus nonfacilitated PCMH implementation, all studies compared interventions meeting the definition of PCMH to usual care.

Table B summarizes the findings and strength of evidence (SOE) for each major outcome. The SOE is a summary rating of the confidence in the estimate of effect for each outcome that incorporates evidence across all relevant studies. Rating the SOE for this body of evidence was challenging because the range of study designs, populations, and outcomes precluded quantitative summaries for most outcomes. We thus did not have the usual quantitative tools that are part of meta-analyses for assessing consistency and precision. In brief, there was moderately strong evidence that the medical home has a small positive impact on patient experiences and small to moderate positive effects on preventive care services. Staff experiences were also improved by a small to moderate degree (low SOE), but no study reported effects on staff retention. Current evidence is insufficient to determine effects on clinical and most economic outcomes. Given the relatively small number of studies directly evaluating the medical home and the evolving approaches to designing and implementing the medical home model, these findings should be considered preliminary.

Table B. Summary of the strength of evidence for KQ 1

Outcome [SOE & Magnitude of Effect ^{a,b,c,j}]	Number of Studies (Subjects)	SOE Domain–Risk of Bias: Study Design/Quality	SOE Domain–Consistency	SOE Domain–Directness	SOE Domain–Precision	Effect Estimate (Range or 95% CI)
Patient Experiences [Moderate SOE: small positive effects]	5 (6,884)	RCT/Fair	Consistent	Direct	Precise	ES median (range): 0.27 (-0.36 to 0.42)
	2 (3,513)	Observational/Fair	Inconsistent	Direct	Precise	ES: ^d +0.13
Staff Experiences [Low SOE: small to moderate positive effects]	2 (NR)	RCT/Fair	Inconsistent	Some indirectness	Imprecise	ES median (range): 0.18 (0.14 to 0.87)
	1 (82)	Observational/Fair	Unknown	Direct	Imprecise	ES median (range): 0.49 (0.32 to 0.61)

Table B. Summary of the strength of evidence for KQ 1 (continued)

Outcome [SOE & Magnitude of Effect^{a,b,c}]	Number of Studies (Subjects)	SOE Domain– Risk of Bias: Study Design/ Quality	SOE Domain– Consistency	SOE Domain– Directness	SOE Domain– Precision	Effect Estimate (Range or 95% CI)
Process of Care for Preventive Services [Moderate SOE: small to moderate positive effects]	3 (8,377)	RCT/Fair	Consistent	Direct	Precise	RD median (range): 1.3% (-0.4% to +7.7%)
	2 (57,832)	Observational/ Fair	Consistent	Direct	Precise	RD median (range): 14.2% (5.6% to 20.6%)
Process of Care for Chronic Illness Care Services [Insufficient]	2 (4,640)	RCT/Fair	Inconsistent	Some indirectness	Precise	RD median (range): 6.6% (0.2% to 20.8%)
	3 (455,832)	Observational/ Fair	Seriously inconsistent	Some indirectness	Precise	RD median (range): 7.1% (7.1% to 21.4%)
Clinical Outcomes: Biophysical Markers, Health Status, Mortality [Insufficient]	3 (2,586)	RCT/Good	Consistent	Some indirectness	Imprecise	Not reliably estimated
	3 (58,393)	Observational/ Poor	Consistent	Some indirectness	Imprecise	Not reliably estimated
Economic Outcomes: Hospital Inpatient Admissions, ED Visits, Total Costs^e [Low SOE for lower ED visits in older adults and no reduction in admissions; insufficient for total costs in adults; insufficient for all economic outcomes in children]	5 (8,001)	RCT/Fair	Consistent	Some indirectness	Imprecision	Admissions: RR 0.96 (95% CI, 0.84 to 1.10) in adults; ED visits: RR 0.81 (95% CI, 0.67 to 0.98) in adults; total costs: no summary estimate
	6 (229,883)	Observational/ Fair	Consistent	Direct	Precise	Admissions: RD median (range): -0.2% (1.4% to -8.9%); ED visits: RD median (range): -1.2% (3.1% to -8.3%); total costs: no summary estimate

Table B. Summary of the strength of evidence for KQ 1 (continued)

Outcome [SOE & Magnitude of Effect ^{a,b,c}]	Number of Studies (Subjects)	SOE Domain–Risk of Bias: Study Design/Quality	SOE Domain–Consistency	SOE Domain–Directness	SOE Domain–Precision	Effect Estimate (Range or 95% CI)
Unintended Consequences or Other Harms [Insufficient]	0	NA	NA	NA	NA	No estimate

^aSOE ratings are provided for outcomes overall (incorporating evidence from all studies), while magnitude-of-effect estimates are provided for RCTs vs. observational studies. The effect size for economic outcomes represents a summary estimate of effect from meta-analysis. Other effect sizes are presented as the range across individual studies.

^bIn one study, a program of facilitated PCMH (intervention) was compared with providing practices with information on PCMH but not facilitating the implementation (control). This study generally showed no differences on the key outcomes addressed. Both arms implemented components of the PCMH model, and this may be why there were no significant differences between them.

^cThe small number of studies conducted among children precluded formal comparison with studies conducted in adults. However, results in these two populations were generally congruent.

^dThe effect size for one of the two available observational studies could not be calculated with available information. As a result, an effect size median and range could not be calculated.

^eTwo of the 13 studies that reported economic outcomes—1 RCT and 1 observational study—reported only total costs and so did not inform the summary effect estimates reported in this table.

Notes: CI = confidence interval; ED = emergency department; ES = effect size; KQ = Key Question; NA = not applicable; NR = not reported; RCT = randomized controlled trial; RD = risk difference; RR = risk ratio; SMD = standardized mean difference; SOE = strength of evidence

For KQ 1a, there were too few studies in each outcome domain that also had appropriate variation in PCMH elements to conduct a planned qualitative analysis. As a result, we concluded that there is insufficient evidence to evaluate whether specific PCMH components are associated with greater effects on patient and staff experiences, process of care, clinical outcomes, and economic outcomes. For KQ 1b, no study reported unintended consequences; therefore, we concluded that the effects of PCMH on unintended consequences or other harms are uncertain.

KQs 2–4

We included 27 studies of PCMH or functional PCMH that described the intervention components and the financial models and implementation strategies used to support uptake. These studies included comparative and descriptive designs. Most studies were conducted in older adults or children with special health care needs. In addition, we identified 31 ongoing studies that are evaluating the medical home. These studies are being carried out in all major regions of the United States, and the majority are being fielded with participation by a commercial insurer. Only two of these studies are RCTs. Compared with the published literature, more of these studies plan comparisons across different levels of PCMH implementation. Because we limited inclusion to comparative studies and study descriptions were often incomplete, we believe the number of studies reporting the impact of PCMH in the next few years will exceed the list cataloged in this horizon scan. Table C summarizes these findings.

Table C. Summary of findings for KQs 2–4

KQ 2—PCMH Components Implemented
Variability in components: Although most studies reported implementing most of the 7 major medical home domains, studies varied considerably in their approach to implementing major components (e.g., variable approaches to enhancing access to care).
Evaluation of specialty care: Few medical home studies directly address medical specialty care (n = 6) or mental health specialty care (n = 3).
KQ 3—Financial Models and Implementation Strategies
Financial models: Few medical home studies (n = 11) provided detailed information about the financial models used to support the medical home. Financial models described included enhanced fee-for-service, additional per-member per-month payments, stipends to support aspects of the intervention, and payments linked to quality and efficiency targets.
Organizational implementation strategies: Audit and feedback were the most commonly used specific strategies to implement the medical home, described in 13 studies.
Organizational learning strategies: Learning collaboratives and collaborative program planning were the most commonly used organizational learning strategies, described in 19 studies.
KQ 4—Horizon Scan of Ongoing PCMH Studies
Ongoing studies: A relatively large number of studies evaluating the medical home are scheduled to conclude within the next 2 years. However, only 2 of the 31 studies are RCTs. Most studies report planned outcomes of patient or staff experiences, process-of-care outcomes, and economic outcomes. These studies appear to have the potential for improving our understanding and the strength of evidence for a range of important outcomes.

Notes: KQ = Key Question; PCMH = patient-centered medical home; RCT = randomized controlled trial

Discussion

Summary of Findings

In summary, our review found moderately strong evidence that PCMH improves patient experiences and preventive care services. For staff experience, the evidence was less robust but suggests benefit. We judged the SOE as low for an association between PCMH and lower health care use (combination of inpatient and primarily emergency department use), but estimated effects were imprecise. Further, we did not find evidence of an effect of PCMH on total costs. These findings do not exclude an economic benefit of PCMH, and in fact, current studies are likely underpowered for this outcome.³⁶ Overall, these findings are encouraging and build on prior reviews showing that CCM-based interventions that focus on single conditions have improved health outcomes across a range of chronic conditions, including congestive heart failure, diabetes mellitus, asthma, and major depression.^{17,37,38}

Our review identified important gaps in currently available evidence on the effects of PCMH. Most studies evaluated effects in older adults with multiple chronic illnesses; few studies were conducted in pediatric or general adult primary care populations. Effects on quality indicators for chronic illness care and on clinical outcomes are uncertain. These are among the most important outcomes to patients, clinicians, and policymakers. Individuals with chronic medical illness consume the most health care resources, and this is a particularly important set of outcomes for this group. Other gaps in evidence include the absence of data on staff retention and unintended consequences. If the improvements in staff experiences translate into improved staff retention and greater attractiveness of primary care practice, then PCMH will have met one of its goals. The potential for unanticipated consequences has not received much attention in the literature and was not evaluated in any of our included studies. Because PCMH requires substantial change for primary care practices, unanticipated consequences, such as increased provider burden (e.g., enhanced access through 24/7 coverage and email) and potential patient safety risks (e.g., patients using email for emergent medical issues), are possible and should be examined.

Given inclusion criteria that allowed for a relatively broad set of interventions, it is not surprising that there was wide variability in the approaches to implementing the various components of PCMH. Interventions explicitly developed from the PCMH model used more approaches than those simply meeting our operational definition of “functional PCMH.” More robust implementation of the model and/or specific strategies to address a particular model component may be associated with greater benefit, but there were too few studies to conduct even an exploratory analysis to test this hypothesis. As the evidence base expands, these analyses will be important to clarify the key approaches and could provide information for efficient implementation and certifying agencies’ criteria for medical home practices. In addition to the need to identify the key approaches, practices and policymakers need better information on the financial context and implementation strategies needed for successful spread and sustainability of the PCMH model. Fewer than half of the studies included in this report described any new payment model, such as enhanced fee-for-service or additional per-member per-month payments to PCMH practices. Further, there was an absence of data on direct financial consequences to the practice of implementing PCMH. This information, possibly gained through the mechanism of detailed case studies, could inform implementation efforts and the design of enhanced payment mechanisms for medical home practices.

Finally, our horizon scan identified ongoing studies with specified comparator groups that, when published, should more than double the size of the published literature. In contrast to the majority of studies included in our review, all of these studies describe explicit plans to test the medical home, and most are being conducted with the participation of a commercial insurer. These studies have the potential to add substantially to our knowledge about the medical home, particularly if some of the evaluations can be tailored to address the gaps in evidence identified by our report.

Limitations of the Review Process

The PCMH is a model of care with considerable flexibility, not a narrowly defined intervention or manualized protocol. Further, multiple definitions of the PCMH model have been proposed by various professional and patient organizations.²² We developed an operational definition—derived from the AHRQ definition of the medical home,⁸ which does not require an enhanced payment model—to identify eligible interventions. Because we used the AHRQ definition, our review was more inclusive of studies that tested the critical principles that embody the IOM concept of patient-centered care.²⁹ However, greater inclusivity came with the trade-off of greater variability in study interventions. Heterogeneity in study designs, populations, and outcomes meant that standard quantitative summary methods were generally not possible. The general nature of the intervention also complicated our literature search, given the potential for relevant studies that did not use the term “medical home” and the lack of MeSH terms for this topic. Finally, no standard nomenclature or measures exist for many of the concepts that form part of the definition. The lack of a standard nomenclature and the often sparse reporting of interventions made uniform data abstraction and classification of intervention components particularly challenging.

Implications for Future Research

The horizon scan conducted for this review identified 31 ongoing PCMH studies that are broadly representative of the U.S. health care system, both in geography and in the complexity of private and public health care payers and delivery networks. Many of these studies are being

done in cooperation with payer organizations, and most are expected to be completed in the next 2 years. As a result, the evidence base related to PCMH will soon be greatly expanded. We encourage investigators to report the interventions in detail, adjust for clustering when appropriate, report meaningful quality indicators for chronic illness (both processes and clinical outcomes), and provide data related to the impact of PCMH on staff. If researchers clearly link intervention components to the core components of PCMH, this could greatly improve our understanding of the conceptual basis for interventions tested and, ultimately, the key features of successful models. Finally, we encourage long-term followup of results. Outcomes examined in this report rarely had followup periods longer than 2 years. In addition to addressing the impact of PCMH on specific outcomes, we encourage the expanded use of both quantitative and qualitative methods to address the processes used to implement the PCMH model.

Although ongoing studies have the potential to fill important gaps, the lack of detail contained in published research plans generates uncertainty about how well these studies will address these gaps. We therefore describe a series of research priorities in this report.

Missing Outcomes

The strength of evidence was judged to be low or insufficient for most outcomes. Studies that address quality indicators for chronic illness care and clinical outcomes (e.g., symptom status or functional status) are urgently needed. Because PCMH is oriented toward broad populations of patients and not focused on specific illnesses, the impact on chronic illness could be attenuated. Studies assessing staff retention and the impact of PCMH on practice costs or patient out-of-pocket costs would provide an important new perspective on economic outcomes. Evaluators should also carefully consider the outcomes most relevant to the population studied, particularly considering differences in the emphasis of the medical home and relevant outcomes for pediatric versus adult populations.³⁹

Most Important PCMH Components

We were unable to determine the PCMH components most associated with benefit. Understanding the “active ingredients” of PCMH is important to help practices with limited resources realize the greatest return on investment and to assist organizations developing certifying standards for medical home practices. Observational studies from natural experiments comparing differing levels of PCMH and different approaches to PCMH could address this gap. In addition, as the evidence base grows, an updated systematic review could be valuable. For this latter approach to succeed, studies will need to report the details of the PCMH intervention and, ideally, use a more consistent set of outcome measures and nomenclature for PCMH components and measures of PCMH components.

Most Effective Implementation Approaches

PCMH is a complex intervention that requires substantial changes to most practices. Understanding the level of support needed to implement and sustain the model, including the necessary financial context, is critical to any long-term success. Our horizon scan identified a number of studies that planned formative evaluations to identify factors associated with successful implementation. Additional studies that examine long-term sustainability are needed.

Effects of PCMH in More Representative Populations

Most PCMH studies were conducted in older adults with multiple chronic health conditions or in children with special health care needs. Studies that examine the effects in more broadly representative primary care samples are needed to fully understand the impact of this care model. Because PCMH has the potential to reduce health disparities, evaluating effects in important subgroups (e.g., the socioeconomically disadvantaged) is important.

Conclusions

The PCMH model is a conceptually sound approach to organizing patient care and appears to hold promise, especially for improving the experiences of patients and staff involved in the health care system. Evidence points to the possibility of improved care processes. If ongoing and future studies indicate that these improvements translate into improved clinical outcomes or economic benefit, the health care value would be increased.

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Introduction

Background

The United States spends a greater proportion of its gross domestic product on health care than any other country in the world (17.6 percent in 2009),¹ yet often fails to provide high-quality and efficient health care.²⁻⁶ U.S. health care has traditionally been based on a solid foundation of primary care to meet the majority of preventive, acute, and chronic health care needs of its population; however, the recent challenges facing health care in the United States have been particularly magnified within the primary care setting. Access to primary care is limited in many areas, particularly rural communities. Fewer U.S. physicians are choosing primary care as a profession, and satisfaction among primary care physicians has waned amid the growing demands of office-based practice.⁷ There has been growing concern that current models of primary care will not be sustainable for meeting the broad health care needs of the American population.

The patient-centered medical home (PCMH) is a model of primary care transformation that seeks to meet the variety of health care needs of patients and to improve patient and staff experiences, outcomes, safety, and system efficiency.⁸⁻¹¹ The term “medical home” was first used by the American Academy of Pediatrics in 1967 to describe the concept of a single centralized source of care and medical record for children with special health care needs.¹² The current concept of PCMH has been greatly expanded and is based on 40 years of previous efforts to redesign primary care to provide the highest quality of care possible.^{13,14} The chronic care model (CCM),^{15,16} a conceptual model for organizing chronic illness care that is associated with improved health outcomes, is the cornerstone of PCMH.¹⁷ Interventions based on CCM and focused on single conditions such as diabetes mellitus, asthma, chronic obstructive pulmonary disease, or depression have been shown to improve patient outcomes and/or quality of care.¹⁸⁻²¹ PCMH builds on this model and is intended to address the full range of patient-focused health care needs.⁸

As defined by physician and consumer groups, the core principles of the PCMH are: wide-ranging team-based care; patient-centered orientation toward the whole person; care that is coordinated across all elements of the health care system and the patient’s community; enhanced access to care that utilizes alternative methods of communication; and a systems-based approach to quality and safety.⁹ While these principles are frequently cited in relation to PCMH, it should be recognized that specific PCMH definitions vary widely, reflecting the rapid expansion of the utilization of PCMH concepts in the last decade.²² As described in detail below, we based the operational definition of PCMH for this review on the definition outlined by the Agency for Healthcare Research and Quality (AHRQ).⁸

It has been hypothesized that comprehensive PCMH interventions hold promise as a pathway to improved primary health care quality, safety, efficiency, and effectiveness. The PCMH has also been described as a “lifeline for primary care” that has the potential to transform and increase the appeal and viability of primary care practice.²³ Given the conceptual promise of PCMH, professional societies have endorsed the model,²⁴ and payers (e.g., Medicare) and large health systems have begun to implement PCMH-based programs. These include health maintenance organizations (HMOs), networks of Medicaid providers, community health centers, private integrated delivery systems, private practices, the United States Department of Veterans Affairs (VA) health care system, and components of the Department of Defense military health

care system.²⁵⁻²⁸ The goal is to improve the care of patients across the continuum of prevention and treatment of chronic and acute illness, while potentially improving both patient and provider experiences with the health care system. Further, it has been hypothesized that PCMH may introduce efficiencies in care that help contain rising health care costs.²⁵

Scope and Key Questions

Scope of the Review

Individual elements of the PCMH are associated with improvements in selected outcomes for individual conditions.²⁹⁻³³ However, it is uncertain if primary care reorganization according to a comprehensive PCMH model (i.e., combining the use of PCMH components for multiple conditions) improves overall care processes and clinical outcomes. For this review, we examined the results of studies focusing on changing care for all or most patients served by a health care organization, not just a specific group of patients such as those with a given illness or set of illnesses.

As part of the Closing the Quality Gap: Revisiting the State of the Science series of Evidence-based Practice Center (EPC) reviews,^{34,35} the purpose of the systematic review is to identify completed and ongoing efforts to evaluate the comprehensive PCMH model, summarize current evidence for this model, and identify gaps in the evidence. Because the PCMH model is being implemented widely but the number of completed and published studies is expected to be small, the identification of ongoing studies is an important goal of this review. This “horizon scan” component of the review will help to identify forthcoming studies that may address gaps in the currently available evidence.

The PCMH is a cross-cutting topic, relevant to broad areas of health care and patient populations and we therefore anticipated important challenges for this review:

- Multiple definitions of the PCMH model have been proposed by various professional and patient organizations.²² Further, the agreed upon elements of the PCMH are expressed in general terms and are subject to different interpretations and operational definitions, particularly when applied to each unique delivery system.³⁶⁻³⁸ As a result, we have identified components of comprehensive PCMH interventions that must be present for studies to be included in this review. These components are based on the PCMH definition proposed by the Agency for Healthcare Research and Quality (AHRQ).⁸
- Based on a preliminary review of the literature, we anticipated few randomized controlled trials (RCTs) and a diverse range of study designs. Because RCTs, quasiexperimental designs, and observational designs vary in their risk of bias, we prioritized RCTs. However, we included other study designs when necessary.

For the purpose of this report, we created an operational definition for a PCMH intervention that is based on the AHRQ definition of PCMH.⁸ The operational definition requires a combination of components as follows: (1) team-based care; (2) having ≥ 2 of 4 elements focused on how to improve the entire organization of care (enhanced access, coordinated care, comprehensiveness, systems-based approach to improving quality and safety); (3) a sustained partnership; and (4) having an intervention that involves structural changes to the traditional practice. Specifics on these elements can be found in the PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings) section, below. This definition was applied for Key Questions (KQs) 1–3, below, for inclusion in the review. Intervention programs did not have to

specifically identify themselves as a PCMH if they otherwise described the components required for inclusion. Because reports of ongoing studies for KQ 4 (horizon scan) often provided very limited detail on the intervention, we applied a more liberal definition, including any intervention that claimed to be testing a PCMH, regardless of the detail provided on the intervention.

Key Questions

KQs 1–3 include published studies describing completed PCMH interventions, while KQ 4 is a “horizon scan” that addresses unpublished comparative studies now in progress.

- **KQ 1:** In published, primary care–based evaluations of comprehensive PCMH interventions, what are the effects of the PCMH on patient and staff experiences, process of care, clinical outcomes, and economic outcomes?
 - a. Are specific PCMH components associated with greater effects on patient and staff experiences, process of care, clinical outcomes, and economic outcomes?
 - b. Is implementation of comprehensive PCMH associated with unintended consequences (e.g., decrease in levels of indicated care for nonpriority conditions) or other harms?
- **KQ 2:** In published, primary care–based evaluations of comprehensive PCMH interventions, what individual PCMH components have been implemented?
- **KQ 3:** In published, primary care–based evaluations of comprehensive PCMH interventions, what financial models and implementation strategies have been used to support uptake?
- **KQ 4:** What primary care–based studies evaluating the effects of comprehensive PCMH interventions on patient and staff experiences, process of care, clinical outcomes, or economic outcomes are currently under way? In these ongoing studies, what are the study designs, PCMH components, comparators, settings, financial models, and outcomes to be evaluated?

PICOTS Framework for the Key Questions

Populations

Populations included were:

1. Adult, primary care patients, selected to represent the practice rather than on the basis of a particular chronic illness
2. Children with special health care needs according to the Health Resources and Services Administration (HRSA) definition.³⁹ The broad definition of children with special health care needs includes those who have or are at increased risk for chronic physical, developmental, behavioral, or emotional conditions that require health and related services of a type or amount beyond those required by children generally.

Interventions

The PCMH is a broad-based strategy aimed at improving chronic illness care or provision of preventive services. Using the AHRQ definition of the PCMH (items marked with an asterisk [*] below),⁸ we operationalized the concept of a PCMH intervention as a comprehensive intervention that includes items 1, 3, and 4, along with at least two elements of item 2. The comprehensive PCMH intervention is the combination of the components described below, not the individual components themselves.

The components are:

1. Team*-based care, defined as a team-based structure in which two or more clinicians work together to provide care. The team may be *virtual*.
2. The intervention includes ≥ 2 of the following 4 elements:
 - a. Enhanced access* to care (e.g., advanced electronic communications such as Internet or telephone visits, open access scheduling, group visits, 24/7 coverage).
 - b. Coordinated* care (care coordinated across settings such as inpatient and outpatient, or across specialty and nonspecialty care [such as mental health], or subspecialty medicine and primary care; care management; or referral tracking).
 - c. Comprehensiveness,* i.e., care that is accountable for addressing a large majority of personal health needs; (e.g., preventive care, acute care, chronic disease care, and mental health).
 - d. A systems-based approach to improving quality and safety* (e.g., care planning process, evidence-based medicine/clinical guidelines, point-of-care resources, electronic prescribing, test-tracking, performance measurement, self-management support, accountability, and shared decisionmaking).
3. A sustained partnership* and personal relationship over time oriented towards the whole person* (e.g., designating a primary point of contact who coordinates care, a personal physician, and shared decisionmaking).
4. The intervention involves structural changes to the traditional practice, reorganizing care delivery (e.g., new personnel, new role definitions, functional linkages with community organizations and/or other health care entities such as hospitals, specialists or other service providers, and disease registries).

Comparators

1. Usual care.
2. Programs aimed at improving the quality of care, process outcomes, or clinical outcomes that do not meet the operational definition of a comprehensive PCMH intervention given above. These comparator programs may include some components of the PCMH model, but not enough to qualify as a comprehensive PCMH intervention.

Outcomes

KQ 1: PCMH interventions may lead to a variety of effects on the health care system and patient health status. We prioritized and abstracted a specific subset of these outcomes that had face validity and were reported across studies, and/or were collected using validated instruments or methods. These included:

1. Patient experiences:
 - a. Global/overall patient experiences
 - b. Coordination of care
 - c. Patient-provider interaction
2. Staff experiences:
 - a. Global/overall staff experiences
 - b. Staff retention rates
 - c. Staff burnout
3. Process of care:
 - a. Preventive services

- b. Chronic illness care services
- 4. Clinical outcomes:
 - a. Health status
 - b. Laboratory tests
 - c. Mortality
- 5. Economic outcomes:
 - a. Inpatient utilization
 - b. Emergency department utilization
 - c. Overall costs
- 6. Unintended consequences or other harms

KQ 2: PCMH components as listed under “Interventions,” above. We describe the use of specific PCMH components and related activities reported in the reviewed studies, as follows:

- 1. Team-based care (description, including disciplines represented)
- 2. Enhanced access (description of components)
- 3. Coordinated care (description of components)
- 4. Comprehensiveness (yes/no)
- 5. A systems-based approach to improving quality and safety (description of components)
- 6. Sustained partnership (yes/no)
- 7. Reorganizing care delivery (description of components)

KQ 3:

- 1. Financial models (e.g., bundled payments, fee-for-service, performance-based incentives)
- 2. System-change (e.g., Plan-Do-Study-Act cycles,⁴⁰ academic detailing⁴¹), along with any theoretical basis provided
- 3. Organizational learning strategies (e.g., quality improvement collaboratives⁴⁰), and any theoretical basis provided for these strategies

KQ 4: Because KQ 4 is a horizon scan of ongoing studies, we anticipated that many study details would not be available, but we examined data sources for the following information:

- 1. Study designs, including patient or cluster RCTs, nonrandomized clustered controlled trials, and controlled before-and-after studies
- 2. PCMH components (as defined in intervention PICOTS) and comparators
- 3. Settings (e.g., practice size, geographic location)
- 4. Financial models (e.g., bundled payments, fee-for-service, performance-based incentives)
- 5. Types of outcomes assessed:
 - a. Patient experiences
 - b. Staff experiences
 - c. Process of care
 - d. Clinical outcomes
 - e. Economic outcomes

Timing

1. Studies had to have at least 6 months' longitudinal followup.

Settings

1. Primary care (i.e., we did not consider studies in specialty care settings such as infectious disease for patients with HIV/AIDS). Primary care includes:
 - a. General internal medicine
 - b. Family medicine
 - c. Primary care pediatrics
 - d. Primary care clinics directed by mid-level providers
 - e. Terms commonly used for primary care outside the United States (e.g., general practice/practitioner)
2. KQ 4 was further restricted specifically to studies underway in the United States. We imposed this restriction on the horizon scan to identify ongoing studies that are most relevant to the U.S health care system and because we believed we would more reliably be able to identify studies conducted in the United States.

Type of Studies

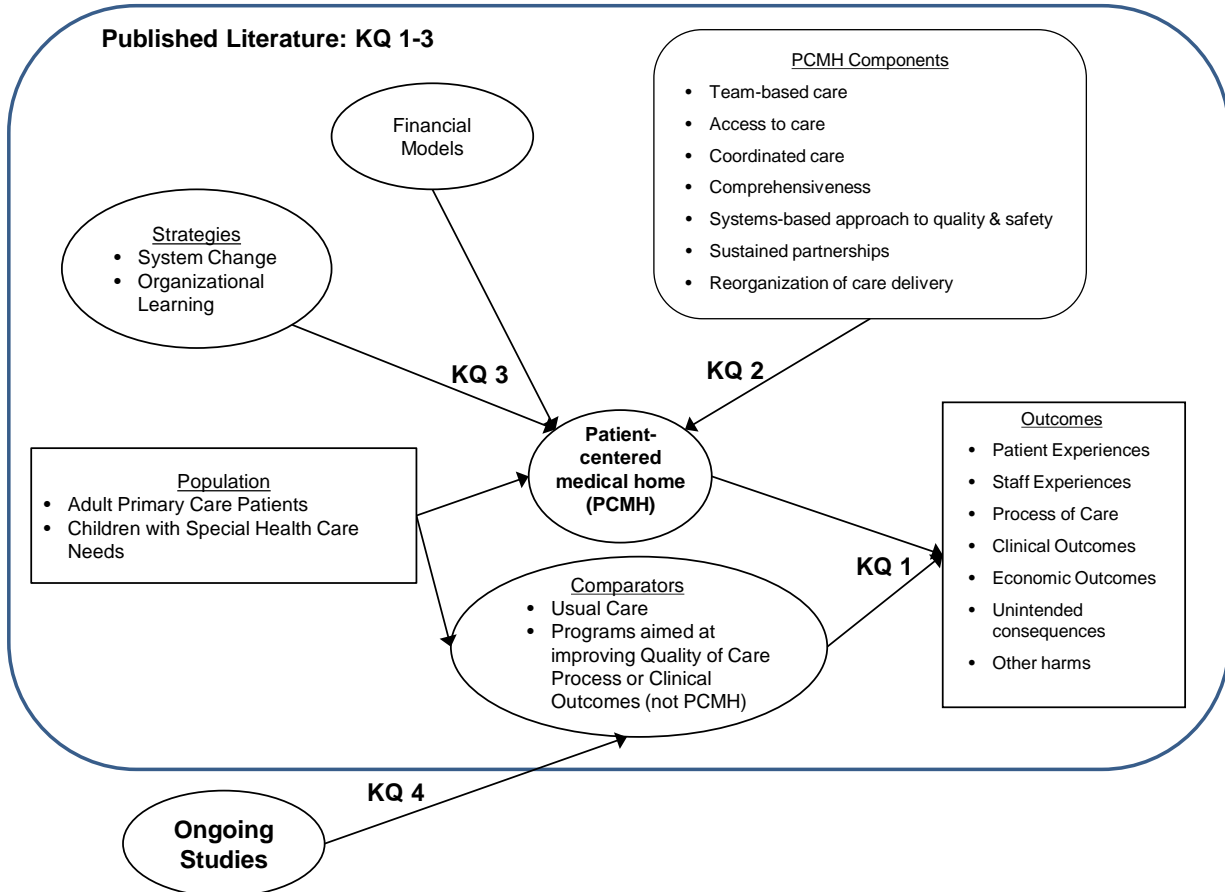
The description below represents the types of studies that were eligible for inclusion in the report. Not all types were found as a result of the literature search.

1. **KQ 1:** We focused on studies of comprehensive PCMH interventions with a comparison group. Specific study designs are based on guidance from the Cochrane Effective Practice and Organisation of Care Review Group (EPOC) and include:⁴²
 - a. Patient or cluster RCTs
 - b. Nonrandomized clustered controlled trials: an experimental study in which practices or clinicians are allocated to different interventions using methods that are not random
 - c. Controlled before-and-after studies: A study in which observations are made before and after the implementation of an intervention, both in a group that receives the intervention and in a comparison group that does not. These studies include observational studies of “natural experiments.”
2. **KQ 2–3:** All of the designs listed above plus uncontrolled studies that include a pre- and postintervention assessment. We included uncontrolled studies for these questions because the aims of the questions are descriptive. By including uncontrolled studies, we were able to give a more comprehensive description of the PCMH components, financial models, and implementation strategies examined to date.
3. **KQ 4:** Same as KQ1. Because this question represents a “horizon scan” of ongoing and/or yet-to-be-published literature, we sought ongoing longitudinal studies, including pilot and demonstration projects, with a comparison group. Given the large number of organizations conducting ongoing evaluations of PCMH, we prioritized studies from major Federal funders (e.g. Centers for Medicare & Medicaid Services [CMS], AHRQ, VA) and large studies from non-Federal funders that are most likely to yield high quality data and address gaps in existing evidence.

Analytic Framework

Figure 1 shows the analytic framework for this review.

Figure 1. Analytic framework



Notes: KQ = Key Question; PCMH = patient-centered medical home

The figure illustrates how we hypothesized the potential mechanism by which comprehensive PCMH interventions (the combination of PCMH elements taken as a group, not just the individual components) and their comparators may impact outcomes of interest (KQ 1), including patient and staff experiences, process of care, clinical outcomes, and economic outcomes. This hypothesis motivated the search for potentially relevant published literature. In addition, we searched the literature to determine if there have been any reports of an association between PCMH and unintended consequences or other harms. The individual components of PCMH and their incorporation and/or implementation in PCMH evaluations were examined (KQ 2), as well as the financial models and system change or organizational learning strategies used to support uptake (KQ 3). Finally, the figure illustrates the way in which the above-mentioned outcomes and moderators were identified in ongoing studies (KQ 4).

Methods

Our overall methodological approach, as described in this chapter, was guided by the Agency for Healthcare Research and Quality's (AHRQ's) Methods Guide for Effectiveness and Comparative Effectiveness Reviews (hereafter referred to as the Methods Guide).⁴³ and by the methods used in the original Closing the Quality Gap series, drawing particularly on Volume 1, Series Overview and Methodology,³⁴ and Volume 7, Care Coordination.¹⁷ Consistent with these earlier works, we adopted the framework developed by the Cochrane Effective Practice and Organisation of Care Review Group (EPOC) for relevant study designs, as follows: patient or cluster randomized controlled trials (RCTs; Key Questions [KQs] 1–4), nonrandomized cluster controlled trials (KQs 1–4), controlled before-and-after studies (KQs 1–4), and uncontrolled studies that include a pre- and post-intervention assessment (KQs 2–3 only). These designs can yield valid evidence about quality improvement interventions. Other key methodological decisions from this series include a focus on outpatient care and the inclusion of studies where the intervention seeks to improve outcomes for a broad and relatively unselected group of patients.

The main sections in this chapter reflect the elements of the protocol established for this evidence report, and certain methods map to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist.⁴⁴

Topic Refinement and Review Protocol

Topics for the Closing the Quality Gap: Revisiting the State of the Science series were solicited from the portfolio leads at AHRQ. Nominations included a brief background and context; the importance and/or rationale for the topic; the focus or population of interest; relevant outcomes; and references to recent or ongoing work. The following factors were considered in making final decisions about which of the nominated topics would be included in the series: the ability to focus and clarify the topic area appropriately; relevance to quality improvement and a systems approach; applicability to the Evidence-based Practice Center (EPC) program/amenability to systematic review; potential for duplication and/or overlap with other known or ongoing work; relevance and potential impact in improving care; and fit of the topics as a whole in reflecting the AHRQ portfolios.

The EPC refined the KQs via discussions with the EPC coordinating the Closing the Quality Gap: Revisiting the State of the Science series and with AHRQ. A Technical Expert Panel (TEP), with experts knowledgeable in the PCMH as primary care model, provided input during the protocol development process.

Literature Search Strategy

Search Strategy

KQs 1–3

For KQs 1-3, we searched PubMed[®], the Cumulative Index to Nursing & Allied Health Literature (CINAHL[®]), and the Cochrane Database of Systematic Reviews (CDSR). Our search strategy used the National Library of Medicine's medical subject headings (MeSH) keyword nomenclature and text words for the medical home and related concepts, and for eligible study

designs. Where possible, we used validated search filters (such as the Clinical Queries Filters in PubMed) and drew on other groups' experience in searching for quality improvement studies (e.g., EPOC). We included studies published in English and indexed from database inception through December 6, 2011 (PubMed), or March 30, 2011 (CINAHL and CDSR). The exact search strings used are given in Appendix A. All searches were designed and conducted in collaboration with an experienced search librarian.

We supplemented these electronic searches with a manual search of citations from a set of key primary and review articles.⁴⁵⁻⁵²

All citations were imported into an electronic bibliographic database (EndNote[®] Version X4; Thomson Reuters, Philadelphia, PA).

KQ 4

For KQ 4, we sought to identify ongoing or recently completed studies by searching the following databases using the search term "medical home":

- Clinical trials databases (e.g., ClinicalTrials.gov, 5/10/11)
- Web sites of non-Federal PCMH funders (e.g., Commonwealth Fund, 7/20/11; Robert Wood Johnson Foundation, 6/6/11);
- Databases of Federally funded studies; searched using the enGrant Scientific interface (www.engrant.com): AHRQ, Centers for Disease Control and Prevention [CDC], Health Services Research Projects in Progress [HSRProj], National Institutes of Health [NIH] Reporter (NIH Research Portfolio Online), Health Resources and Services Administration [HRSA], United States Department of Veterans Affairs [VA], and the Department of Defense; search dates 4/5 to 4/11/11. This search was updated on 1/18/12 for the final report.

Several Web-based sources (American College of Physicians [ACP], Centers for Medicare and Medicaid Services [CMS], National Academy for State Health Policy [NASHP], Patient-Centered Primary Care Collaborative [PCPCC]) did not have searchable databases. For these sites, we conducted manual searches, exploring all Web links that showed promise for relevant information:

- Databases of PCMH demonstration programs (e.g., the Patient-Centered Primary Care Collaborative [www.pcpcc.net]); 4/11/11
- Primary care professional societies sponsoring PCMH demonstration projects (e.g., ACP, at www.acponline.org/running_practice/pcmh/); 4/11/11
- Databases of state-sponsored PCMH studies (e.g., NASHP); 4/11/11
- CMS; 4/11/11

In addition, we sent letters to 10 contacts involved in state-level projects funded by CMS (contacts identified from documents available on the CMS Web site), and a letter to the VA Director of PCMH (designated Patient Aligned Care Teams [PACT] within the VA environment) demonstration labs, requesting information about any ongoing or recently completed studies.

Finally, we identified a published horizon scan that included interviews with key informants designed to collect detailed information about the participants, design, and implementation of ongoing PCMH programs.⁴⁶ We used information from this horizon scan to verify and augment data obtained from the above-mentioned databases/study registries.

Inclusion and Exclusion Criteria

The criteria used to screen articles for inclusion/exclusion at both the title-and-abstract and full-text screening stages are detailed in Table 1 (see PICOTS section of Introduction for further details).

Table 1. Inclusion/exclusion criteria

Study Characteristic	Inclusion Criteria	Exclusion Criteria
Population	<ul style="list-style-type: none"> • Adult, primary care patients, selected to represent the practice rather than on the basis of a particular chronic illness. • Children with special health care needs according to the Health Resources and Services Administration (HRSA) definition. 	Studies where PCMH transformation was focused on a small proportion of patients being cared for in the practice; for example, studies restricted to patients with diabetes or asthma.
Interventions	<p>KQs 1–3: A comprehensive PCMH intervention that includes items 1, 3, and 4, below, along with at least two components of item 2:</p> <ol style="list-style-type: none"> 1. <u>Team-based</u> care (team may be <i>virtual</i>). 2. At least 2 of the following 4 components: <ol style="list-style-type: none"> a. Enhanced <u>access</u> to care b. <u>Coordinated</u> care across settings c. <u>Comprehensiveness</u> d. <u>A systems-based approach to improving quality and safety</u> 3. A sustained partnership and personal relationship over time oriented towards the whole person 4. Structural changes to the traditional practice, reorganizing care delivery <p>KQs 4: PCMH intervention should meet the above definition; however, because descriptions of ongoing studies were often sparse, we accepted the designation of “medical home” as meeting our intervention criteria without explicit documentation that the study truly met our functional definition.</p>	KQs 1–3: Studies self-identified as “medical home” but did not describe the intervention sufficiently to meet the AHRQ definition.
Comparators	<p>KQs 1–4:</p> <ul style="list-style-type: none"> • Usual care. • Programs aimed at improving the quality of care, process outcomes, or clinical outcomes that do not meet the operational definition of a comprehensive PCMH intervention given immediately above. <p>KQ4: For this question, we also accepted comparisons across different levels of PCMH implementation (high vs. low adopters).</p>	KQs 1 and 4: No comparator (i.e., analyses for KQs 2–3 include studies without comparators, while KQ 1 and KQ 4 analyses include only studies with comparison groups).

Table 1. Inclusion/exclusion criteria (continued)

Study Characteristic	Inclusion Criteria	Exclusion Criteria
Outcomes	<p>KQ1: PCMH interventions may lead to a variety of effects on the health care system and patient health status. We prioritized and abstracted a specific subset of these outcomes that had face validity and were reported across studies, and/or were collected using validated instruments or methods. These included:</p> <ol style="list-style-type: none"> 1. Patient experiences: <ol style="list-style-type: none"> a. Global/overall patient experiences b. Coordination of care (as perceived by patients) c. Patient-provider interaction 2. Staff experiences: <ol style="list-style-type: none"> a. Global/overall staff experiences b. Staff retention rates c. Staff burnout 3. Process of care: <ol style="list-style-type: none"> a. Preventive services b. Chronic illness care services 4. Clinical outcomes: <ol style="list-style-type: none"> a. Health status b. Laboratory tests c. Mortality 5. Economic outcomes: <ol style="list-style-type: none"> a. Inpatient utilization b. Emergency department utilization c. Overall costs 6. Unintended consequences or other harms <p>KQ 2: PCMH components as listed in the Intervention section, above (described).</p> <p>KQ 3:</p> <ol style="list-style-type: none"> 1. Financial models. 2. System-change, along with any theoretical basis provided. 3. Organizational learning strategies and any theoretical basis provided for these strategies. <p>KQ 4 (horizon scan of ongoing studies):</p> <ol style="list-style-type: none"> 1. Study design 2. PCMH components 3. Settings (e.g., practice size, geographic location) 4. Financial models 5. Outcomes assessed (if reported): <ol style="list-style-type: none"> a. Patient experiences b. Staff experiences c. Process of care d. Clinical outcomes e. Economic outcomes 	No outcomes of interest reported.

Table 1. Inclusion/exclusion criteria (continued)

Study Characteristic	Inclusion Criteria	Exclusion Criteria
Timing	Studies had to have at least 6 months' longitudinal followup.	< 6 months' longitudinal followup.
Setting	Primary care settings, e.g., family medicine, general internal medicine, primary care pediatrics, general medical clinics such as Federally Qualified Health Centers, general medical clinics primarily staffed by mid-level providers, general practice/practitioner, geriatric practices providing longitudinal care rather than consultative services. KQ 1–3: Studies conducted in a high-income economy ^a as defined by the World Bank. ⁵³ KQ 4: Studies underway in the United States. ^b	<ul style="list-style-type: none"> • Geriatric practices providing consultative services. • Medical subspecialties.
Study design	KQ1, KQ4: Patient or cluster RCT; nonrandomized clustered controlled trial; controlled before-and-after study. KQ2, KQ3: Patient or cluster RCT; nonrandomized clustered controlled trial; controlled before-and-after study; uncontrolled pre- and postintervention study.	Not a clinical study (e.g., editorial, non-systematic review, letter to the editor, case series).
Publications	KQs 1–4: English-language only. ^c KQs 1–3: <ul style="list-style-type: none"> • Published date database inception to present. • Peer-reviewed article. KQ 4: Studies had to be ongoing or scheduled to complete on or after April 2010. ^d	<ul style="list-style-type: none"> • Non-English language publication.^c • Not peer-reviewed (e.g., letter to editor).

^aWe restricted studies for KQs 1–3 to high-income economies—i.e., to countries that have greater cultural and health care system similarities to the United States—to improve applicability of the study results to the United States.

^bKQ 4 studies were restricted to those conducted in the United States to maximize applicability to our target audience, and because our knowledge of gray literature sources is good within the U.S., but poor outside the U.S.

^cWe excluded non-English-language publications for two reasons: (a) we are most interested in health care systems that are similar to U.S. health care, and reports from these countries are likely to be published in English; and (b) it is the opinion of the investigators that the resources required for translation of non-English articles would not be justified by the low potential likelihood of identifying relevant data unavailable from English-language sources.

^dThe rationale for this was that studies completed prior to April 2010 should already have been published.

Notes: HRSA = Health Resources and Services Administration; KQ = Key Question; PCMH = patient-centered medical home; RCT = randomized controlled trial

Study Selection

Using the criteria described in Table 1, two investigators independently reviewed each title and abstract for potential relevance to the KQs; articles included by either investigator underwent full-text screening. At the full-text screening stage, two investigators independently reviewed the full text of each article and indicated a decision to “include” or “exclude” the article for data abstraction. When the paired reviewers arrived at different decisions about whether to include or exclude an article, or about the reason for exclusion, we reached a final agreement through review and discussion among investigators. Articles meeting eligibility criteria were included for data abstraction. For KQ4, these procedures were modified such that a single screener initially reviewed all citations; final eligibility for data abstraction was determined by duplicate review. All screening decisions were made and tracked in a Distiller SR database (Evidence Partners Inc., Manotick, ON, Canada).

Data Extraction

The investigative team created forms for abstracting the data elements for the KQs. Based on their clinical and methodological expertise, a pair of researchers was assigned to abstract data from the eligible articles. One researcher abstracted the data, and the second over-read the article and the accompanying abstraction form to check for accuracy and completeness. Disagreements were resolved by consensus or by obtaining a third reviewer's opinion if consensus could not be reached by the first two investigators.

To aid in both reproducibility and standardization of data collection, researchers received data abstraction instructions directly on each form created specifically for this project within the DistillerSR data synthesis software program (Evidence Partners Inc., Manotick, ON, Canada). The abstraction form templates were pilot-tested with a sample of included articles to ensure that all relevant data elements were captured and that there was consistency and reproducibility across abstractors. Data abstraction forms for KQs 1–3 included: descriptions of the study design, study population, interventions and comparators, financial models, implementation methods, study outcomes, and study quality. Outcomes of interest included patient experiences, staff experiences, process of care, clinical outcomes, and economic outcomes. Appendix B provides a detailed listing of the data elements abstracted for KQs 1–3.

For KQ 4, we developed a less detailed data abstraction form, based on the expectation (which turned out to be correct) that descriptions of ongoing studies would not provide the necessary information for more detailed abstraction. Abstracted data were: basic study design; geographic location; study setting, including health care system; number of practices/physicians; payment reform/financial model; major components of the intervention/PCMH model; the comparator; types of outcomes being assessed; study dates; and source of funding. Appendix C provides a detailed listing of the data elements abstracted for KQ 4.

Quality (Risk of Bias) Assessment of Individual Studies

We assessed the quality/risk of bias of studies included for KQ 1 based on their reporting of relevant data. We evaluated the quality of individual studies using the approach described in AHRQ's General Methods Guide.⁴³ To assess quality, we (1) classified the study design, (2) applied predefined criteria for quality and critical appraisal, and (3) arrived at a summary judgment of the study's quality (see Appendix D for details). To evaluate methodological quality, we applied criteria for each study type derived from core elements described in the Methods Guide. To indicate the summary judgment of the quality of the individual studies, we used the summary ratings of good, fair, and poor, based on the studies' adherence to well-accepted standard methodologies and the adequacy of the reporting (Table 2). For each study, one investigator assigned quality ratings, which were then over-read by a second investigator; disagreements were resolved by consensus or by a third investigator if agreement could not be reached.

Table 2. Definitions of overall quality ratings

Quality Rating	Description
Good	A study with the least bias; results are considered valid. A good study has a clear description of the population, setting, interventions, and comparison groups; uses a valid approach to allocate patients to alternative treatments; has a low dropout rate; and uses appropriate means to prevent bias, measure outcomes, and analyze and report results.
Fair	A study that is susceptible to some bias but probably not enough to invalidate the results. The study may be missing information, making it difficult to assess limitations and potential problems. As the fair-quality category is broad, studies with this rating vary in their strengths and weaknesses. The results of some fair-quality studies are possibly valid, while others are probably valid.
Poor	A study with significant bias that may invalidate the results. These studies have serious errors in design, analysis, or reporting; have large amounts of missing information; or have discrepancies in reporting. The results of a poor-quality study are at least as likely to reflect flaws in the study design as to indicate true differences between the compared interventions.

For RCTs, we used the key criteria described in AHRQ’s Methods Guide,⁴³ adapted for this specific topic. These criteria include adequacy of randomization and allocation concealment; the comparability of groups at baseline; blinding; the completeness of followup and differential loss to followup; whether incomplete data were addressed appropriately; the validity of outcome measures; and conflict of interest. After considering each individual quality element, we assigned the study a global quality rating of good, fair, or poor, using definitions from the Methods Guide.

We anticipated that this review would identify and include nonrandomized clinical trials (*see* Table 1 for eligible study designs). Because of the complexity of PCMH-based interventions, studies may have included an observational control group that was not randomized. Per the AHRQ Methods Guide,^{43,54} threats to internal validity of systematic review conclusions based on observational studies were identified through assessment of the body of observational literature as a whole, with an examination of characteristics of individual studies. Study-specific issues that were considered include: potential for selection bias (i.e., degree of similarity between intervention and control patients); performance bias (i.e., differences in care provided to intervention and control patients not related to the study intervention); attribution and detection bias (i.e., whether outcomes were differentially detected between intervention and control groups); and magnitude of reported intervention effects (see the section on “Selecting Observational Studies for Comparing Medical Interventions” in AHRQ’s Methods Guide.)⁴³

Data Synthesis

We summarized key features of the included studies by KQ. For published studies, we created the following summary tables: overview table of basic study characteristics, intervention table giving details of the intervention, and a summary table of implementation strategies. Studies were categorized into those that explicitly tested the PCMH model and those that met our functional definition for PCMH but did not use the terms “PCMH” or “medical home”; the latter are referred to as “functional PCMH” studies in this report. Studies were evaluated initially in aggregate, and then by PCMH versus functional PCMH studies and adult versus pediatric studies. For KQ 1, we used a random-effects model to compute summary estimates of effect for hospitalizations and emergency department visits for the subset of studies using RCT designs. Summary estimates were calculated using Comprehensive Meta-analysis and are reported as summary risk ratios.⁵⁵ For other outcomes, the study populations, designs, and outcomes were too variable for quantitative analysis, and results were accordingly synthesized qualitatively. Because the continuous measures used for most outcomes reported varied greatly across studies,

we computed effect sizes, represented as the standardized mean difference (SMD), to aid interpretation. The SMD is useful when studies assess the same outcome but with different measures or scales. In this circumstance, it is necessary to standardize the results for the studies to a uniform scale to facilitate comparisons. We calculated the SMD for each study, using Hedges' *g*, by subtracting (at post-test) the average score of the control group from the average score of the experimental group and dividing the result by the pooled standard deviations (SDs) of the experimental and control groups. To aid interpretation, we standardized presentation such that beneficial effects for the medical home are presented as positive effect sizes.

We planned to use cross-case analyses to evaluate the association between independent variables (e.g., specific components of comprehensive PCMH) and study effect, using methods based on Miles and Huberman.⁵⁶ However, there were too few studies and too little variability in outcomes to complete this exploratory analysis.

Strength of the Body of Evidence

We assessed the strength of evidence for the highest priority outcomes in KQ 1 using the approach described in AHRQ's Methods Guide.^{43,57} In brief, the Methods Guide recommends assessment of four domains: risk of bias, consistency, directness, and precision. Additional domains are to be used when appropriate: coherence, dose-response association, impact of plausible residual confounders, strength of association (magnitude of effect), and publication bias. These domains were considered qualitatively, and a summary rating assigned, after discussion by two reviewers, as "high," "moderate," or "low" strength of evidence. In some cases, high, moderate, or low ratings were impossible or imprudent to make; for example, when no evidence was available or when evidence on the outcome is too weak, sparse, or inconsistent to permit any conclusion to be drawn. In these situations, a grade of "insufficient" was assigned. This four-level rating scale consists of the following definitions:

- *High*: High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.
- *Moderate*: Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
- *Low*: Low confidence that the evidence reflects the true effect. Further research is likely to change the confidence in the estimate of effect and is likely to change the estimate.
- *Insufficient*: Evidence either is unavailable or does not permit estimation of an effect.

We did not rate the strength of evidence for KQs 2–4 because these questions were purely descriptive.

Applicability

Systematic evidence reviews are conducted to summarize knowledge and to support clinicians, patients, and policymakers in making informed decisions. "Does this information apply?" is the core question for decisionmakers weighing the usefulness and value of a specific intervention or choosing among interventions. Interventions that work well in one context may not in another. The primary aim of assessing applicability is to determine whether the results obtained under research conditions are likely to reflect the results that would be expected in

broader populations under “real-world” conditions. In this particular instance, we focused on application to primary care populations.

We assessed applicability using methods described in the Methods Guide.⁵⁸ In brief, this method uses the PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings) framework as a way to organize information relevant to applicability. We evaluated the applicability to clinical practice, paying special attention to study eligibility criteria, demographic features of the enrolled population (such as age, ethnicity, and sex), organizational context, and clinical relevance and timing of the outcome measures. We summarized issues of applicability qualitatively.

Peer Review and Public Commentary

The peer review process is our principal external quality-monitoring device. Nominations for peer reviewers were solicited from several sources, including the TEP and interested Federal agencies. Experts in PCMH as a primary care model and individuals representing stakeholder and user communities were invited to provide external peer review of the draft report; AHRQ and an associate editor also provided comments. The draft report was posted on AHRQ’s Web site for public comment for 4 weeks, from December 6, 2011, to January 3, 2012. We have addressed all reviewer comments, revising the text as appropriate, and have documented everything in a disposition of comments report that will be made available 3 months after the Agency posts the final report on AHRQ’s Web site. A list of peer reviewers submitting comments on the draft report is provided in the front matter of this report.

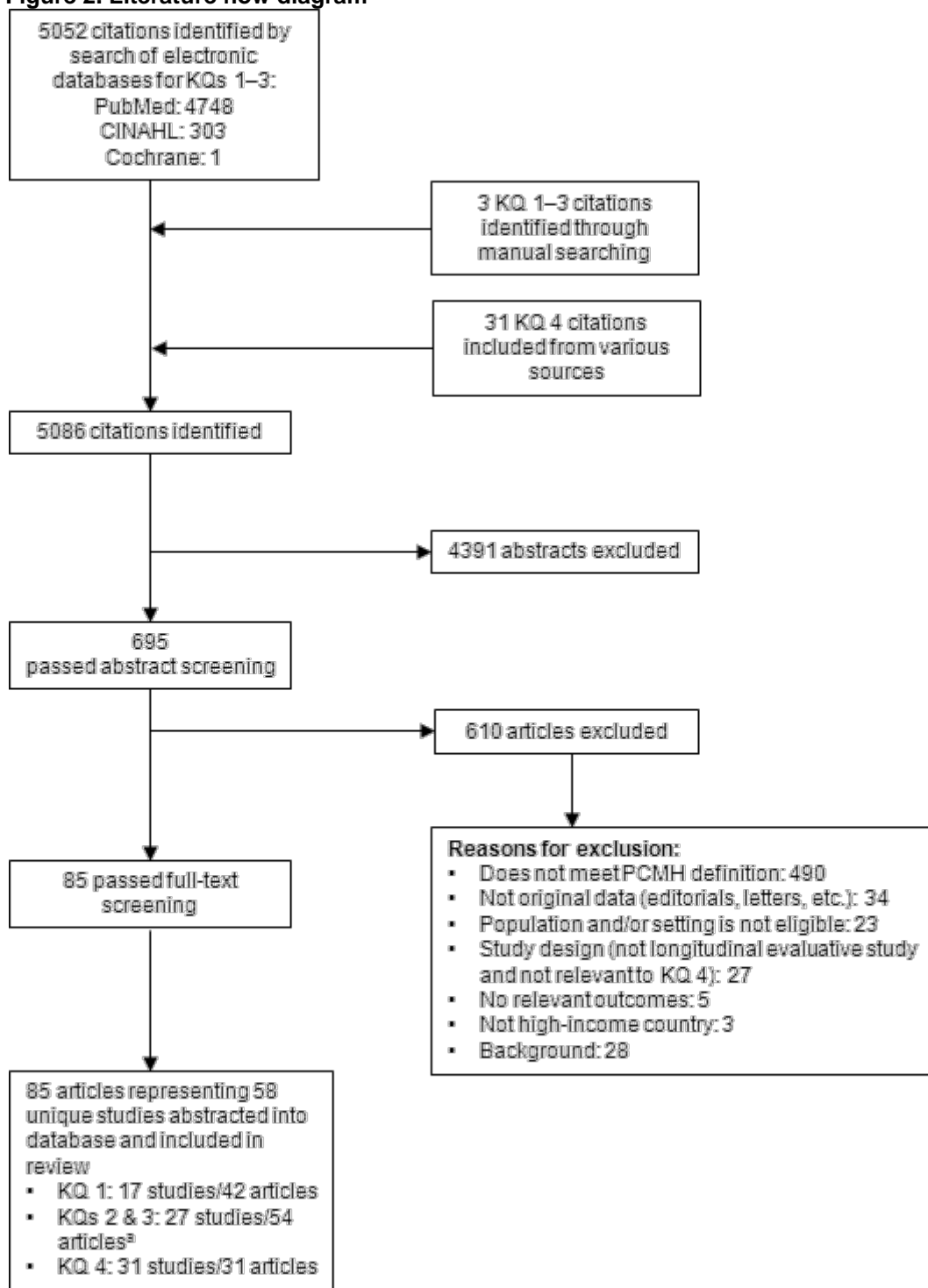
Results

Results of Literature Searches

Figure 2 depicts the flow of articles through the literature search and screening process. Searches of electronic databases for Key Questions (KQs) 1–3 yielded 5,052 citations. Manual searching identified an additional 3 citations, and searches of all sources relevant to KQ 4 yielded 31 relevant citations, for a total of 5,086 citations. After applying inclusion/exclusion criteria at the title-and-abstract level, 695 full-text articles were retrieved and screened. Of these, 610 were excluded at the full-text screening stage, leaving 85 articles (representing 58 unique studies) for data abstraction.

As indicated here, many studies included for KQs 1–3 were described in more than one publication. Appendix E provides a detailed listing of the included primary and secondary publications for these questions. Appendix F provides a complete list of published articles excluded at the full-text screening stage, with reasons for exclusion.

Figure 2. Literature flow diagram



^aAll studies/articles included for KQ 1 were also included for KQs 2 & 3.

Notes: KQ = Key Question; PCMH = patient-centered medical home

Description of Included Studies

For KQs 1–3, we identified 27 peer-reviewed studies; 17 were comparative and 10 descriptive. Studies were conducted in the United States (n = 23), Canada (n = 2), Israel (n = 1), and France (n = 1). Studies most commonly recruited older adults (n = 13) or children with special health care needs (n = 8). Among the comparative studies, there were 8 trials (3 good- and 5 fair-quality) involving 10,084 subjects and 9 observational studies (2 good-, 5 fair-, and 1 poor-quality).

For the KQ 4 horizon scan, we identified 31 ongoing studies, of which 2 were RCTs. These studies are described in detail under KQ 4.

Further details are provided in the relevant KQ sections, below. The following Appendixes provide details of the characteristics of included studies:

- Appendix G. Characteristics of Included Studies (KQs 1–3, RCTs)
- Appendix H. Characteristics of Included Studies (KQs 1–3, Observational Studies)
- Appendix I. Characteristics of Included Studies (KQs 2–3 Only)
- Appendix J. Characteristics of Included Studies (KQ 4)

Key Question 1. Effects of PCMH Interventions

KQ 1: In published, primary care–based evaluations of comprehensive PCMH interventions, what are the effects of the PCMH on patient and staff experiences, process of care, clinical outcomes, and economic outcomes?

- a. Are specific PCMH components associated with greater effects on patient and staff experiences, process of care, clinical outcomes, and economic outcomes?**
- b. Is implementation of comprehensive PCMH associated with unintended consequences (e.g., decrease in levels of indicated care for nonpriority conditions) or other harms?**

Key Points

- Studies varied widely in the range of outcomes reported and the specific measures used.
- The medical home in primary care settings has been evaluated in observational studies (n = 9) and RCTs (n = 8), and older adults in the United States with multiple chronic conditions were the most commonly studied population (8 of 17 studies [1 additional Canadian study among older adults]). Fewer studies evaluated the effects in general adult populations or among children with special health care needs.
- With the exception of one study that examined facilitated versus nonfacilitated PCMH implementation, all studies compared interventions meeting the definition of PCMH to usual care.
- Based on a combination of good- and fair-quality studies, there is evidence of moderate strength indicating that interventions meeting PCMH criteria are generally associated with small improvements in patient experiences, both on overall and care coordination measures.
- Based on a combination of good- and fair-quality studies, there is evidence of low strength that PCMH implementation is associated with improved clinical staff experiences.

- Based on a combination of good- and fair-quality studies, there is evidence of overall low strength that PCMH may improve care processes. This is based on a combination of moderate evidence of an effect for preventive services and insufficient evidence to evaluate impacts on care for patients with chronic illness.
- Based on a combination of predominantly good- and fair-quality studies, there is insufficient evidence to determine the impact of PCMH implementation on clinical outcomes.
- Based on a combination of good- and fair-quality studies, there is a low strength of evidence that PCMH implementation may lead to lower utilization (inpatient and emergency department) for some subgroups of patients, but this effect was not uniform. Moreover, total costs were not lowered in the reviewed studies.

Detailed Analysis

As a reminder, we categorized included studies into those that explicitly tested the PCMH model (“PCMH” studies) and those that met our functional definition for PCMH but did not use the terms “PCMH” or “medical home” (“functional PCMH” studies). Further, studies were excluded if the intervention was designed to address the needs only of patients with a single chronic condition (e.g., a study of disease management for patients with diabetes or asthma). However, studies were included if a broad-based intervention reported outcomes for a specific tracer condition.

In addition to examining interventions that met our definition of a PCMH or functional PCMH, studies included in the analysis for KQ 1 had to include a control group. Of 27 otherwise eligible studies, 17 comparative studies described in 42 publications reported outcomes relevant to this question. These studies include 6 with PCMH interventions and 11 with functional PCMH interventions. Sixteen studies were conducted in the United States and one in Canada. There were 8 clinical trials (all RCTs) and 9 observational studies. The majority of studies had a followup period for abstracted outcomes of approximately 2 years, with no meaningful difference between RCTs and observational studies. Most studies (9 of 17) enrolled older adults with multiple chronic health conditions; fewer studies were conducted in general adult or general pediatric populations. While a large number of patients are represented by the 4 studies with children, 98 percent of these are from one secondary data analysis study.⁵⁹ For most outcomes, the small number of studies conducted among children (4 of 17 studies [2 of 8 RCTs]) precluded formal comparison with studies conducted in adults. However, results in these two populations were generally congruent. Additional characteristics are described in Table 3.

Table 3. Characteristics of studies

Study Characteristic	Total (n = 17)	PCMH (n = 6)	Functional PCMH (n = 11)
Study Design (studies/patients) ^a	17/693,028	6/228,284	11/464,744
RCT	8/10,284	2/2083	6/8201
Observational	9/682,744	4/226,201	5/456,543
Country (studies/patients) ^a			
United States	16/692,546	6/228,284	10/464,262
Canada	1/482	0/0	1/482
Comparator (studies/patients) ^a			
Usual care	16/691,045	5/226,301	11/464,744
Nonfacilitated PCMH ^b	1/1983	1/1983	0/0
Setting/Population (studies/patients) ^a			
Older adults	9/23,838	1/15,310	8/8528
General adults	3/403,336	2/5336	1/398,000
Children	4/211,375	3/207,638	1/3737
All ages (high utilizers)	1/54,479	0/0	1/54,479
Setting/Organizations (studies/patients) ^a			
Integrated delivery system – private	8/424,006	2/18,663	6/405,343
Integrated delivery system – U.S. Federal	1/160	0/0	1/160
Independent primary care providers	4/6462	2/18,663	2/4,280
Payer-based (e.g., Medicaid)	3/261,918	2/207,439	1/54,479
Canadian Healthcare System	1/482	0/0	1/482
Duration of followup ^c			
6-11 months	2/250	1/100	1/150
12 to 23 months	2/69,789	1/15,310	1/54,479
24 to 26 months	11/411,913	3/5,535	8/406,378
> 26 months	1/3,737	0/0	1/3,737
Monthly estimates based on 4 years of data	1/207,339	1/207,339	0/0
Overall Study Quality (studies/patients) ^a			
Good	5/212,378	1/207,339	4/5039
Fair	11/480,168	5/20,945	6/459,223
Poor	1/482	0/0	1/482

^aThe number of patients given here represents the number of individuals presented in primary inclusion tables and/or primary analyses. Other study analyses may have included different numbers of patients.

^bIn one study,⁶⁰ a program of facilitated PCMH (intervention) was compared with providing practices with information on PCMH, but not facilitating the implementation (control).

^cBased on longest followup period among abstracted outcomes.

Note: PCMH = patient-centered medical home

Abstracted Outcomes

Over the past 5 years, multiple research agendas and recommendations for evaluation measurement have been proposed for PCMH evaluations.^{11,26,27,36,61} Because of the variability in recommended measures for evaluating PCMH, it was necessary to restrict the abstraction of outcomes to those that had face validity to the investigators and were reported across studies, and/or were collected using validated instruments or methods. With the exception of selected economic outcomes (namely, inpatient and emergency department utilization), studies were too heterogeneous in design and in outcomes reporting for quantitative syntheses. Therefore, with the exception of the economic outcomes noted immediately above, results are described qualitatively.

Results are described below for five major domains: (1) patient experiences (including reports from caregivers); (2) staff experiences; (3) care processes; (4) clinical outcomes; and (5) economic outcomes. Within each outcome domain, we focus first on PCMH studies (n = 6) and then on functional PCMH studies (n = 11). The qualitative description of results is further stratified by presenting information from clinical trials followed by observational studies.

No studies reported all five types of outcomes. Seven studies reported one type of outcome, three studies reported two types of outcomes, three studies reported three types of outcomes, and two studies reported four types of outcomes. Table 4 describes the number of studies and number of abstracted outcomes by specified study type.

Table 4. Number of studies with specific types of outcomes

Outcome Category	All Studies (n = 17) ^a	PCMH (n = 6) ^a	Functional PCMH (n = 11) ^a
Patient (or Caregiver) Experiences	7	3	4
Overall experience ^b	4	2	2
Coordination of care	7	3	4
Staff Experiences	3	2	1
Overall experience	3	2	1
Process of Care^c	6	1	5
Preventive services ^d	5	1	4
Chronic illness care services ^d	4	1	3
Clinical Outcomes	6	1	5
Biophysical markers	1	0	1
Health status	4	1	3
Mortality	2	0	2
Economic Outcomes	13	4	9
Inpatient utilization	11	4	7
Emergency department utilization	8	4	4
Total cost	9	3	6

^aSubcategories in each table cell do not necessarily add up to the total number of studies because each study may report multiple outcome types.

^bIncludes one measure focusing on satisfaction with mental health services.

^cDoes not include process outcomes not related to the provision of guideline concordant preventive or chronic illness care.

^dOne study reports a summary Health Plan Employer Data Set (HEDIS) composite measure that includes aspects of both preventive and chronic illness care services.

PCMH = patient-centered medical home

Comparators

With one significant exception, all comparisons presented in this report are between an intervention specifically labeled as PCMH or meeting the functional definition of PCMH and usual care. However, we also included the American Academy of Family Physicians (AAFP) National Demonstration Project (NDP), a fair-quality multicenter RCT that compared facilitated versus nonfacilitated implementation of the PCMH.⁶² When reading the NDP report it should be noted that while facilitated practices adopted more PCMH components than nonfacilitated practices (10.7 components vs. 7.7 components, $p = 0.005$), there was still substantial adoption of PCMH by nonfacilitated control clinics.⁶² As a result, the NDP does not represent a comparison between having PCMH and not having PCMH. However, we believed that including this large trial of PCMH implementation provides a fuller picture of the state of evidence regarding PCMH.

Patient Experiences

One or more patient experience outcomes were reported by seven studies (Table 5).^{60,63-68} Our summary of patient experience focuses on overall patient experience and coordination of care. If a study reported overall measures of patient experience, those measures were abstracted as opposed to individual component scales. However, care coordination was also abstracted because of the overall goal, highlighted in all major definitions of PCMH, of improving the coordination of health care services.²² For some studies, especially those involving children, experience measured may have been provided by caregivers.

Table 5. Results—patient experiences

Study ^a	Type of Study; Explicitly PCMH? (Yes/No); Population; Quality	Outcome (Length of Followup)	Difference Reported by Authors	Calculated Effect Size (if Available) ^b
Patient Experience: Overall Experience				
Jean, 2010 ⁶⁰ Jean, 2010 ⁶²	Trial Yes ^c Adults Fair	Overall practice experience (0-1 scale, higher is better) (26 months)	Scale mean 0.26 (intervention) vs. 0.33 (control); group time p-value 0.31	ES: -0.36 (95%CI, -1.10 to 0.37)
Farmer, 2011 ⁶⁴	Trial Yes Children Fair	Satisfaction with mental health care (1-3 scale, lower is better) (6 months)	Scale mean (SD) 1.3 (0.5) (intervention) vs. 1.5 (0.7) (control); p = 0.004	ES: 0.33 (95% CI, -0.15 to 0.80)
Boult, 2008 ⁶⁵ Boyd, 2010 ⁶⁹	Trial No Older Adults Good	Overall score: Patient Assessment of Chronic Illness (1-5, higher is better) (18 months)	Scale mean 3.14 (intervention) vs. 2.85 (control); adjusted treatment effect 0.20 (95% CI, 0.07 to 0.33)	ES: 0.21 (95% CI, 0.07 to 0.34)
Toseland, 1997 ⁶⁸ Toseland, 1997 ⁷⁰	Trial No Older Adults Good	Patient satisfaction scale (1-4, higher is better) (8 months)	Scale mean (SD) 3.28 (0.68) (intervention) vs. 3.13 (0.77) (control); p < 0.05	ES: 0.27 (95% CI, -0.06 to 0.61)
Patient Experience: Coordination of Care (as Perceived by Patients)				
Jean, 2010 ⁶⁰ Jaen, 2010 ⁶²	Trial Yes Adults Fair	Coordination of Care: Based on select questions from the Components of Primary Care Index (0-1 scale, higher is better) (26 months)	Scale mean 0.75 (intervention) vs. 0.73 (control); group time p-value = 0.46	ES: 0.33 (95% CI, -0.40 to 1.07)
Farmer, 2011 ⁶⁴	Trial Yes Children Fair	Parental satisfaction with care coordination (1-5 scale, lower is better) (6 months)	Scale mean (SD) 2.2 (0.95) (intervention) vs. 2.7 (1.4) (control); p = 0.058	ES: 0.42 (95% CI, -0.05 to 0.90)
Reid, 2009 ⁶³ Reid, 2009 ⁷¹	Observational Yes Adults Fair	Care Coordination: Ambulatory Care Experiences Survey-Short Form (1-100, higher is better) (1 and 2 years)	Year 1: Scale mean 83.1 (intervention) vs. 77.9 (control); adjusted difference 3.32; p < 0.001 Year 2: Scale mean 83.9 (intervention) vs. 78.9 (control); adjusted difference 3.06; p < 0.01	ES: 0.13 (95% CI, 0.05 to 0.21)
Boult, 2008 ⁶⁵ Boyd, 2010 ⁶⁹	Trial No Older Adults Good	Coordination of Care: Patient Assessment of Chronic Illness (1-5, higher is better) (18 months)	Scale mean 2.96 (intervention) vs. 2.57 (control) ; adjusted treatment effect 0.34 (95% CI, 0.18 to 0.50)	ES: 0.28 (95% CI, 0.15 to 0.42)
Toseland, 1997 ⁶⁸ Toseland, 1997 ⁷⁰	Trial No Older Adults Good	Satisfaction with help obtaining services (1-4, higher is better) (8 months)	Scale mean (SD) 3.11 (0.341) (intervention) vs. 1.57 (2.48) (control) ; p < 0.05	ES: 0.42 (95% CI, 0.09 to 0.76)

Table 5. Results—patient experiences (continued)

Study ^a	Type of Study; Explicitly PCMH? (Yes/No); Population; Quality	Outcome (Length of Followup)	Difference Reported by Authors	Calculated Effect Size (if Available) ^b
Boyd, 2007 ⁶⁶ Boyd, 2008 ⁷²	Observational No Older Adults Fair	Integration of Services: Primary Care Assessment Survey (1-100, higher is better) (6 months)	Between-group difference in change 0.10 (95% CI -5.72, 5.92)	Not calculable
Zuckerman, 2004 ⁶⁷ Minkovitz, 2007 ⁷³	Trial No Young Children Fair	% of parents reporting receiving needed support from their pediatrician/nurse practitioner (30–33 months and 5–5½ years)	30–33 months: Adjusted OR comparing intervention to control 2.70 (95% CI, 2.17 to 3.45) 5–5½ years: Adjusted OR comparing intervention to control 1.25 (95% CI, 1.02 to 1.53)	ES: 0.12 (95% CI, 0.01 to 0.24) at 5–5½ years

^aWhere more than one study citation is given, the first is to the primary study report and the second is to the secondary report that actually provided data for this table.

^bPositive effect sizes favor the intervention.

^cThe American Academy of Family Physicians National Demonstration Project⁶⁰ compared facilitated PCMH implementation to nonfacilitated PCMH implementation. This is different from other comparisons reported in this review which compare PCMH with usual care.

Notes: CI = confidence interval; ES = effect size; OR = odds ratio; PCMH = patient-centered medical home; SD = standard deviation

Overall Patient Experience

Overall patient experience was reported in four studies (all RCTs) at followup periods ranging from 6 to 26 months.^{60,64,65,68} Two of these studies evaluated PCMH interventions and two tested functional PCMH interventions.

The AAFP NDP, the fair-quality multicenter RCT that tested the impact of facilitated PCMH versus nonfacilitated PCMH, evaluated effects on overall practice experience on a 0–1 scale after 26 months.⁶² There was essentially no longitudinal change within arms over 26 months based on a 0–1 overall patient experience scale (intervention -0.02; control +0.01; within-group p-value 0.92). At 26 months, there was no difference between the facilitated and nonfacilitated arms (0.26 vs. 0.33, p = 0.31).

A fair-quality trial of a PCMH intervention among children with special health care needs in a state Medicaid program compared parent-reported satisfaction with various types of care after 6 months. While satisfaction with primary care was evaluated, results were not presented. Results indicating greater satisfaction with mental health services on a three-point scale (1 = excellent, 3 = fair/poor) were presented indicating greater satisfaction among intervention patients (1.3 [SD 0.5] vs. 1.5 [SD 0.7], p = 0.004).⁶⁴

A good-quality trial of guided care, meeting the definition of functional PCMH (designed using the Wagner Chronic Care Model),⁷⁴ reported the overall score from the Patient Assessment of Chronic Illness Care (1–5 scale)⁷⁵ at 18 months. The mean scores were higher for the guided care than usual care patients (adjusted mean difference 0.20; 95% CI, 0.07 to 0.33).⁶⁹ A separate good-quality trial of geriatric management found that after 8 months of the program intervention

patients were significantly more satisfied with care than with control on a 1–4 satisfaction scale developed for the study (3.28 [SD 0.68] vs. 3.13 [SD 0.77], $p < 0.05$).⁷⁰

Coordination of Care

Aspects of patient-perceived coordination of care were reported in seven studies (five RCTs, two observational studies) for followup periods ranging from 6 months to 5½ years.^{60,63-68} Three of these studies were PCMH studies, and four were functional PCMH studies. This review does not address the provision of services or processes that are designed to improve care coordination. Rather, the goal is to assess the degree to which patients perceive an improved experience as a result of improved care coordination.

The AAFP NDP, the fair-quality multicenter RCT that tested the impact of facilitated PCMH versus nonfacilitated PCMH, evaluated effects on patient-reported coordination of care on a 0–1 scale (Components of Primary Care Index) after 26 months. There was no difference between the facilitated and nonfacilitated arms (0.75 vs. 0.73, $p = 0.46$). There was also essentially no longitudinal change in the arms over 26 months (-0.01 vs. -0.02, within-group p -value 0.11).⁶²

A fair-quality trial of a medical home intervention among children with special health care needs in a state Medicaid program compared parent-reported satisfaction with care coordination after 6 months. Reflecting results for satisfaction with mental health services described above, the trend toward greater satisfaction with care coordination on a five-point scale (1 = excellent, 5 = poor) approached statistical significance (2.2 [SD 0.95] vs. 2.7 [SD 1.4], $p = 0.058$).⁶⁴

The fair-quality Reid et al. evaluation of implementation of PCMH in one practice of an integrated delivery system compares results on the care coordination scale of the Ambulatory Care Experiences Survey-Short Form⁷⁶ from the intervention and two control clinics (100-point scale, higher is better). Patients in the intervention clinic reported more care coordination after both 1 year (83.1 vs. 77.9, adjusted difference 3.32, $p < 0.001$) and 2 years (83.9 vs. 78.9, adjusted difference 3.06, $p < 0.01$).⁷¹

Three trials of functional PCMH interventions evaluated care coordination. A good-quality trial of guided care meeting with components meeting the functional definition of the medical home (designed using the Wagner Chronic Care Model)⁷⁴ reports the coordination of care score from the Patient Assessment of Chronic Illness Care (1-5 scale)⁷⁵ at 18 months. The mean scores were higher for the guided care than usual care patients (2.96 vs. 2.57, adjusted treatment effect 0.34 [95% CI, 0.18 to 0.50]).⁶⁹ A separate good-quality trial of geriatric management found that after 8 months of the program intervention patients reported significantly more help obtaining services than did control patients on a 1–4 satisfaction scale developed for the study (3.11 [SD 3.41] vs. 1.57 [SD 2.48], $p < 0.05$).⁷⁰ The third trial, a fair-quality study of enhanced developmental services for young children, examined whether parents indicated that they received needed support from their pediatrician/nurse practitioner (including with accessing needed services). The reported between-group adjusted odds ratios (95% CIs) at both 30-33 months (2.70 [2.17 to 3.45]) and 5–5½ years (1.25 [1.02 to 1.53]) indicate better care coordination in the intervention group.⁷³

The fair-quality nonrandomized pilot study of the same guided care intervention examined integration of services after 6 months using the Primary Care Assessment Survey.⁷⁷ There were no differences in changes in integration scale values between the study arms (0.10 [95% CI, -5.72 to 5.92]).⁷²

Summary

Based on a combination of good- and fair-quality studies, there is evidence of moderate strength indicating that interventions meeting PCMH criteria are generally associated with small improvements in patient experiences, both on overall and care coordination measures based on patient or family reports. These studies included a variety of patient populations. With one exception, followup time periods were still approximately 2 years and less.

Staff Experiences

Our summary of staff experience focuses on overall staff experience. If a study reported overall measures of staff experience, those measures were abstracted as opposed to individual component scales.

Overall Staff Experience

Measures that we classify as representing overall staff experience were reported for followup periods ranging from 1 year to 26 months in three studies (all RCTs; see Table 6).^{60,63,65} Two of these were PCMH studies and one evaluated a functional PCMH intervention.

The AAFP NDP, the fair-quality multicenter RCT that tested the impact of facilitated PCMH versus nonfacilitated PCMH, evaluated effects on practice-level adaptive reserve.⁷⁸ Practice-level adaptive reserve was based on aggregation of individual staff surveys using a 23-item scale developed for the study that included components of relationship infrastructure, facilitated leadership, sensemaking, teamwork, work environment, and culture of learning (summary scale of 0-1; higher score equates to more adaptive reserve). Intervention and control practices had the same mean level of adaptive reserve at baseline (0.69). At 26 months, intervention practices (n = 16) had greater adaptive reserve (mean 0.74, SD 0.38) than control practices (n = 15, mean 0.68, SD 0.46, p = 0.02).

In an observational study, Reid et al. examined the impact of PCMH implementation among clinicians at one intervention clinic compared to clinicians at two control clinics.^{63,71} Using the 22-item Masiach Burnout Inventory,⁷⁹ investigators reported three components (emotional exhaustion, depersonalization, and lack of personal accomplishment) representing staff experience. At baseline, 104 clinicians responded, declining to 82 at 12 months and 48 at 24 months. At 12 months followup, scores for emotional exhaustion (value/effect size) and lack of personal accomplishment (p = 0.06) improved more for PCMH than control clinicians.⁶³ Patterns were similar for the 48 clinicians responding to the survey after 24 months, with statistically significant lower levels of emotional exhaustion and depersonalization. However, the difference for personal accomplishment was not statistically significant (effect size not reported).⁷¹ These results are limited by the relatively low response rate at 24 months followup, which could bias the estimate of effect.

A good-quality clinical trial led by Boulton et al. compared comprehensive guided care for older adults to usual care and examined physicians' satisfaction with care at 1 year (18 intervention and 20 usual care physicians). There was no statically significant difference in satisfaction with chronic illness care between intervention and control physicians. However, intervention physicians were more likely to report satisfaction with patient/family communication (mean 4.40 [95% CI, 3.99 to 4.81] vs. 3.94 [3.58 to 4.30], p = 0.014) and knowledge of patients' clinical characteristics (scale mean 3.17 [95% CI, 2.88 to 3.46] intervention vs. 2.77 [2.50 to 3.03] control, p = 0.042). The small number of providers may have limited the lack of power to detect differences. However, it should be noted that results of all

nine measures of chronic illness care processes assessed had point estimates in the direction of being favorable to the intervention.⁸⁰

Table 6. Results—staff experiences (overall experience)

Study ^a	Type of Study; Explicitly PCMH? (Yes/No); Population; Quality	Outcome (Length of Followup)	Difference Reported by Authors	Calculated Effect Size (if Available) ^b
Jean, 2010 ⁶⁰ Nutting, 2010 ⁷⁸	Trial Yes Adults Fair	Practice Adaptive Reserve (higher = more reserve) (26 months)	Practice-level mean (SD) 0.74 (0.38) intervention vs. 0.68 (0.46) control; group*time p = 0.02	ES: 0.14 (95% CI, -0.53 to 0.80)
Reid, 2009 ⁶³ Reid, 2010 ⁷¹	Observational Yes Adults Fair	Emotional Exhaustion: Masslach Burnout Inventory (lower score is better) (1 and 2 years)	Year 1: mean (SD) 12.7 (8.9) intervention vs. 21.0 (12.1) control; p < 0.01 Year 2: 12.8 (NR) intervention vs. 25.0 (NR) control; p < 0.01	ES: 0.61 (95% CI, 0.16 to 1.06)
Reid, 2009 ⁶³ Reid, 2010 ⁷¹	Observational Yes Adults Fair	Depersonalization: Masslach Burnout Inventory (lower score is better) (1 and 2 years)	Year 1: mean (SD) 2.3 (3.0) intervention vs. 4.0 (4.1) control; p = 0.06 Year 2: 2.0 (NR) intervention vs. 4.4 (NR) control; p = 0.02	ES: 0.32 (95% CI, -0.12 to 0.76)
Reid, 2009 ⁶³ Reid, 2010 ⁷¹	Observational Yes Adults Fair	Lack of Personal Accomplishment: Masslach Burnout Inventory (lower score is better) (1 and 2 years)	Year 1: mean (SD) 4.2 (3.3) intervention vs. 4.6 (5.7) control; p = 0.02 Year 2: Scale scores NR; p > 0.05	ES: 0.49 (95% CI, 0.05 to 0.94)
Boult, 2008 ⁶⁵ Marsteller, 2010 ⁸⁰	Trial No Older Adults Good	Physician Satisfaction with Chronic Illness Care (1 year)	Scale mean (95% CI) 4.42 (3.99 to 4.85) intervention vs. 4.08 (3.70 to 4.45) control; p = 0.285	ES: 0.22 (95% CI, -0.42 to 0.86)

^aWhere more than one study citation is given, the first is to the primary study report and the second is to the secondary report that actually provided data for this table.

^bPositive effect sizes favor the intervention.

Notes: CI = confidence interval; ES = effect size; NR = not reported; PCMH = patient-centered medical home; SD = standard deviation

Summary

Based on a combination of good- and fair-quality studies, there is evidence of low strength that PCMH implementation is associated with improved clinical staff experiences. However, none of the studies reporting information on staff experiences were conducted in pediatric practices. Two of the three were conducted in an older adult population. None of the studies reported outcomes more than approximately 2 years following the implementation of the intervention under study. Relatively few practices and few clinicians have been involved in these studies, and these practices may not be representative of the wider primary care practices in the United States.

Process of Care

One or more process of care outcomes were reported by seven studies.^{59,60,63,67,81-83} We categorized process of care outcomes into preventive services and chronic illness care services. Prioritization was given to generally accepted, guideline-recommended processes as opposed to processes that would have been implemented or enhanced specifically because of the PCMH implementation.

Preventive Services

Information on preventive services was reported in five studies (three RCTs, two observational studies) for followup periods ranging from 12 to 26 months (Table 7).^{60,63,67,82,83} Two of these studies were explicit evaluations of PCMH, and three tested functional PCMH interventions.

The AAFP NDP, the fair-quality multicenter RCT that tested the impact of facilitated PCMH versus nonfacilitated PCMH, evaluated effects on preventive services recommended by the U.S. Preventive Services Task Force (USPSTF).⁶⁰ The facilitated PCMH practices did not significantly improve the rate of preventive services compared to the nonfacilitated PCMH practices (41.1 percent vs. 39.8 percent, $p = 0.09$).⁶²

In a fair-quality evaluation of PCMH at one Group Health Cooperative of Puget Sound clinic, Reid and colleagues reported on Healthcare Effectiveness Data and Information Set (HEDIS) results compared to the rest of the Group Health system. HEDIS includes both measures of preventive and chronic illness services. Prior to PCMH implementation, the intervention clinic had better overall quality, as measured by the average percentage of 22 quality indicators achieved for each patient (68.7 vs. 64.5, statistical significance not provided). Over the 1-year intervention period, the PCMH practice showed greater improvements than the rest of the Group Health clinics ($p < 0.05$). However, an analysis that adjusted for differences in baseline quality did not show a statically significant improvement compared to control practices (mean difference = 1.3 percentage points, $p < 0.05$).⁷¹

In addition, three functional PCMH studies examined the percentage of patients receiving specified preventive services: (1) a fair-quality trial conducted as part of a care coordination Medicare demonstration project;⁸² (2) a fair-quality trial of enhanced developmental services for young children,⁶⁷ and (3) a fair-quality observational study of team care implemented among adult patients of an integrated delivery system.⁸³ For the Medicare demonstration trial, there were no statistically significant differences in guideline-concordant preventive services reported. For example, comparing intervention to control, results were virtually identical for receipt of adult vaccines (influenza 87.3 percent vs. 87.7 percent, $p \geq 0.10$; pneumococcal 88.9 percent vs. 88.4 percent, $p \geq 0.10$). There was also no difference in cancer screening based on claims data (colon 23.7 percent vs. 23.5 percent, $p \geq 0.10$; mammography 74.8 percent vs. 71.2 percent, $p \geq 0.10$).⁸⁴ In the trial of adding developmental services for very young children (0-2 years for abstracted outcomes), intervention patients were more likely to have appropriate well-child care at 12 months (90 percent vs. 81.4 percent; OR 2.06 [95% CI, 1.65 to 2.56]) and 24 months (85.2 percent vs. 78.7 percent; OR 1.68 [95% CI, 1.35 to 2.09]). At 24 months, rates of age-appropriate vaccinations were higher in the intervention practices (83.0 percent vs. 75.3 percent; OR 1.68 [95% CI, 1.59 to 1.95]).⁸⁵ Finally, a team-based intervention in an integrated delivery system found higher rates of breast cancer and colorectal cancer screening rates in intervention patients after 2 years (breast 90.0 percent vs. 69.4 percent, $p < 0.05$; colorectal 38.1 percent vs. 23.9 percent, $p < 0.05$).⁸³

Table 7. Results—care processes, preventive services

Study ^a	Type of Study; Explicitly PCMH? (Yes/No); Population; Quality	Outcome (Length of Followup)	Difference Reported by Authors	Calculated Effect Size (if Available)
Jean, 2010 ⁶⁰ Jaen, 2010 ⁶²	Trial Yes Adults Fair	Prevention Score: % of eligible patients receiving services recommended by the USPSTF (26 months)	41.1% intervention vs. 39.8% control; group time interaction p = 0.09	RD: +1.3%
Reid, 2009 ⁶³ Reid, 2010 ⁷¹	Observational Yes Adults Fair	Healthcare Effectiveness Data and Information Set (HEDIS) (2 years)	75.9 intervention vs. 70.3 control; difference in quality from baseline = 7.3 intervention vs. 6.0 control; p < 0.05	RD: +5.6%
Schraeder, 2005 ⁸² Peikes, 2009 ⁸⁴	Trial No Older Adults Fair	% of patients receiving influenza vaccine (2 years)	87.3% intervention vs. 87.7% control; p ≥ 0.10	RD: -0.4%
Schraeder, 2005 ⁸² Peikes, 2009 ⁸⁴	Trial No Older Adults Fair	% of patients receiving pneumococcal vaccine (2 years)	88.9% intervention vs. 88.4% control; p ≥ 0.10	RD: +0.5%
Schraeder, 2005 ⁸² Peikes, 2009 ⁸⁴	Trial No Older Adults Fair	% of patients receiving colon cancer screening from claims data (2 years)	23.7% intervention vs. 23.5% control; p ≥ 0.10	RD: +0.2%
Schraeder, 2005 ⁸² Peikes, 2009 ⁸⁴	Trial No Older Adults Fair	% of patients receiving mammography (women only) (2 years)	74.8% intervention vs. 71.2% control; p ≥ 0.10	RD: +3.6%
Zuckerman, 2004 ⁶⁷ Minkovitz, 2003 ⁸⁵	Trial No Young Children Fair	% of children with age-appropriate well child care (1 and 2 years)	1 year: 90% intervention vs. 81.4% control; OR 2.06 (95% CI, 1.65 to 2.56) 2 years: 85.2% intervention vs. 78.7% control; : OR 1.68 (95% CI, 1.35 to 2.09)	1 year: RD: +8.6% 2 years: RD: +6.5%
Zuckerman, 2004 ⁶⁷ Minkovitz, 2003 ⁸⁵	Trial No Young Children Fair	% of children with age-appropriate vaccines (2 years)	83.0% intervention vs. 75.3% control; OR 1.68 (95% CI, 1.59 to 1.95)	RD: +7.7%
Taplin, 1998 ⁸³	Observational No Adults Fair	% of patients with mammograms in the past 2 years (2 years)	1 year: 80.6% intervention vs. 68.1% control; p < 0.05 2 years: 90.0% intervention vs. 69.4% control; p < 0.05	1 year: RD: +12.5% 2 years: RD: +20.6%

Table 7. Results—care processes, preventive services (continued)

Study ^a	Type of Study; Explicitly PCMH? (Yes/No); Population; Quality	Outcome (Length of Followup)	Difference Reported by Authors	Calculated Effect Size (if Available)
Taplin, 1998 ⁸³	Observational No Adults Fair	% of patients with colon cancer screening (fecal occult blood test) in the past 18 months (2 years)	1 year: 34.8% intervention vs. 26.1% control; p < 0.05 2 years: 38.1% intervention vs. 23.9% control; p < 0.05	1 year: RD: +8.7% 2 years: RD: +14.2%

^aWhere more than one study citation is given, the first is to the primary study report and the second is to the secondary report that actually provided data for this table.

Notes: CI = confidence interval; HEDIS = Healthcare Effectiveness Data and Information Set; OR = odds ratio; PCMH = patient-centered medical home; RD = risk difference; SD = standard deviation; USPSTF = U.S. Preventive Services Task Force

Chronic Illness Care Services

Information on chronic illness care services was reported in five studies (three RCTs, two observational studies) for followup periods ranging from 1 year to 26 months (Table 8).^{60,63,81-83} Two of these studies were explicit evaluations of PCMH and three tested functional PCMH interventions.

The AAFP NDP, the fair-quality multicenter RCT that tested the impact of facilitated PCMH versus nonfacilitated PCMH, evaluated effects on health status.⁶⁰ Among patients enrolled in facilitated PCMH practices, the percentage of eligible patients who received 17 recommended services for chronic conditions was not significantly improved (58.7 percent vs. 47.3 percent p = 0.92).⁶² Further, as noted above, in the Reid et al. evaluation of PCMH implementation, while the PCMH clinic had greater improvement in the patient average HEDIS measure that included preventive and chronic care quality measures, the difference was between the clinics was modest.⁷¹

A good-quality evaluation of a PCMH program in North Carolina that used pediatric asthma as a tracer condition found that patients in the PCMH program used 325 percent more maintenance medication than patients in the traditional fee-for-service program (5.6 percent vs. 1.6 percent, p < 0.01).⁵⁹

In addition, three functional PCMH studies examined the percentage of patients receiving specified services for chronic conditions: (1) a fair-quality trial conducted as part of a care coordination Medicare demonstration project;⁸² (2) a fair-quality observational study of team care implemented among adult patients of an integrated delivery system;⁸³ and (3) a fair-quality observational study of comprehensive disease management for high utilizers of different ages in a commercial health plan.⁸¹ For the Medicare demonstration trial, results for reported chronic illness care services were mixed. Among patients with diabetes, intervention patients had higher levels of lipid testing (93.1 percent vs. 86.9 percent, p < 0.01) and urine microalbuminuria testing (81.0 percent vs. 60.2 percent, p < 0.01). However, there was not a statistically significant difference for receipt of diabetes education (25.0 percent vs. 22.0 percent), eye exams (86.5 percent vs. 83.3 percent), or glycated hemoglobin (HbA1c) testing (94.9 percent vs. 94.7 percent). However all point estimates are in the direction of the intervention arm. In addition, patients with coronary artery disease had higher levels of lipid testing in the intervention compared to the control arm (89.4 percent vs. 82.5 percent, p < 0.01).⁸⁴

Although a team-based intervention significantly improved preventive services in an integrated delivery system, analogous results were not seen for the two indicators of chronic illness care, warfarin monitoring (no change from baseline among intervention patients or health system as a whole) and diabetic eye exams (no statistically significant improvement among intervention patients, but improvement for health system as a whole [$p < 0.0001$]). However, the number of eligible patients in the intervention panel was small, and the authors contend that improvements in the delivery system as a whole for eye exams among patients with diabetes were potentially the result of low baseline rates.⁸³

Finally, while the evaluation of enhanced disease management for high utilizers in an insurance plan provided percentages of patients meeting specific HEDIS measures for patients with diabetes, they did not provide p-values for these results. While the estimates were generally in favor of the intervention, the point estimate for the percentage of patients with eye exams was lower in the intervention than control group (57.9 vs. 65.0, p-value not reported).⁸¹

Table 8. Results—care processes, chronic illness care services

Study ^a	Type of Study; Explicitly PCMH? (Yes/No); Population; Quality	Outcome (Length of Followup)	Difference Reported by Authors	Calculated Effect Size (if Available)
Jean, 2010 ⁶⁰ Jaen, 2010 ⁶²	Trial Yes Adults Fair	Chronic Care Score: % of eligible patients receiving services recommended based on 17 guideline-recommended processes (26 months)	58.7% intervention vs. 47.3% control; group*time interaction $p = 0.97$ (approximately same difference between intervention and control clinics seen at baseline)	RD: +11.4%
Reid, 2009 ⁶³ Reid, 2010 ⁷¹	Observational Yes Adults Fair	Healthcare Effectiveness Data and Information Set (HEDIS) (2 years)	75.9 intervention vs. 70.3 control; difference in quality from baseline = 7.3 intervention vs. 6.0 control; $p < 0.05$	RD: + 5.6%
Domino, 2009 ⁵⁹	Observational Yes Children (asthma used as tracer condition for PCMH) Good	Monthly percentage use of maintenance medication for asthma	5.2% intervention vs. 1.6% control; 3.6 percentage points (325%) greater, $p < 0.01$	RD: +3.6%
Schraeder, 2005 ⁸² Peikes, 2009 ⁸⁴	Trial No Older Adults Fair	Diabetes patients: % of patients receiving lipid testing (2 years)	93.1% intervention vs. 86.9% control; $p < 0.01$	RD: +6.2%
Schraeder, 2005 ⁸² Peikes, 2009 ⁸⁴	Trial No Older Adults Fair	Diabetes patients: % of patients receiving urine microalbuminuria (2 years)	81.0% intervention vs. 60.2% control; $p < 0.01$	RD: +20.8%
Schraeder, 2005 ⁸² Peikes, 2009 ⁸⁴	Trial No Older Adults Fair	Diabetes patients: % of patients receiving eye exams (2 years)	86.5% intervention vs. 83.3% control; $p \geq 0.10$	RD: +3.2%

Table 8. Results—care processes, chronic illness care services (continued)

Study ^a	Type of Study; Explicitly PCMH? (Yes/No); Population; Quality	Outcome (Length of Followup)	Difference Reported by Authors	Calculated Effect Size (if Available)
Schraeder, 2005 ⁸² Peikes, 2009 ⁸⁴	Trial No Older Adults Fair	Diabetes patients: % of patients receiving HbA1c testing (2 years)	94.9% intervention vs. 94.7% control; p ≥ 0.10	RD: +0.2%
Schraeder, 2005 ⁸² Peikes, 2009 ⁸⁴	Trial No Older Adults Fair	Coronary artery disease patients: % of patients receiving lipid testing (2 years)	89.4% intervention vs. 82.5% control; p < 0.01	RD: +6.9%
Taplin, 1998 ⁸³	Observational No Adults Fair	% of patients with appropriate warfarin monitoring (2 years)	No change from baseline in study group of health system as a whole	Not calculable
Taplin, 1998 ⁸³	Observational No Adults Fair	Diabetes patients: % of patients with appropriate eye exams (2 years)	No statistically significant improvement among intervention patients, but improvement for health system as a whole (p < 0.0001)	Not calculable
Wise, 2006 ⁸¹	Observational No All Ages (high utilizers) Fair	Diabetes patients: HbA1c testing (1 year)	100.0% intervention vs. 87.1% control; no p-value provided	RD: +12.9%
Wise, 2006 ⁸¹	Observational No All Ages (high utilizers) Fair	Diabetes patients: Lipid profile (1 year)	94.2% intervention vs. 85.7% control; no p-value provided	RD: +8.5%
Wise, 2006 ⁸¹	Observational No All Ages (high utilizers) Fair	Diabetes patients: Monitoring for nephropathy (1 year)	81.4% intervention vs. 60.0% control; no p-value provided	RD: +21.4%
Wise, 2006 ⁸¹	Observational No All Ages (high utilizers) Fair	Diabetes patients: Eye exam done (1 year)	57.9% intervention vs. 65.0% control; no p-value provided	RD: -7.1%

^aWhere more than one study citation is given, the first is to the primary study report and the second is to the secondary report that actually provided data for this table.

Notes: HbA1c = glycated hemoglobin; HEDIS = Healthcare Effectiveness Data and Information Set; PCMH = patient-centered medical home; RD = risk difference

Summary

Based on a combination of good- and fair-quality studies, there is evidence of overall low strength that PCMH may improve care processes. This is based on a combination of moderate evidence of an effect for prevention services and insufficient evidence to evaluate impacts on care for patients with chronic illness. Evidence points to a potential for PCMH to positively impact care processes, especially for preventive services. While results are mixed in terms of whether differences are statistically significant, the point estimates for all but two of the

comparisons are in the direction of the intervention. As noted, a lack of power may account for at least some of the differences not being statistically significant. For the two studies claiming to examine PCMH, the AAFP NDP indicated that there was not a statistically significant difference between groups for preventive (although $p = 0.09$) or chronic illness services. However, among all practices in the study, there was an average of 46 percent of PCMH elements in place at baseline. Further, it should be noted that organizations that did not have facilitated implementation were given credit for having a significant number of PCMH components in place at the end of the study.⁶² The Reid et al. evaluation of PCMH implementation at one clinic in the Group Health Cooperative of Puget Sound found that the PCMH clinic had better HEDIS performance than the rest of the organization.⁷¹ Studies of functional PCMH interventions had mixed results for individual care processes; this often included mixed results within the same study. As a result, we conclude that evidence points to a hypothesis that PCMH may improve care processes. However, more research is needed to examine this possibility.

Clinical Outcomes

One or more clinical outcomes were reported by six studies (Table 9).^{60,68,81,86-88} Our summary of clinical outcomes is divided into biophysical markers, patient reported health status, and mortality.

Table 9. Results—clinical outcomes

Study ^a	Type of Study; Explicitly PCMH? (Yes/No); Population; Quality	Outcome (Length of Followup)	Difference Reported by Authors	Calculated Effect Size (if Available) ^b
Clinical Outcomes: Biophysical Markers				
Wise, 2006 ⁸¹	Observational No All Ages (high utilizers) Fair	Diabetes patients: HbA1c \leq 9.5% (1 year)	87.9% intervention vs. 76.4% control; no p-value provided	RD: +11.5%
Wise, 2006 ⁸¹	Observational No All Ages (high utilizers) Fair	Diabetes patients: LDL cholesterol \leq 130 mg/dL (1 year)	94.2% intervention vs. 67.5% control; no p-value provided	RD: 26.7%
Clinical Outcomes: Health Status				
Jean 2010 ⁶⁰	Trial Yes Adults Fair	Self-Reported Health Status - single item measure (1-5 Likert scale) (26 months, facility mean)	Facility mean 0.68 (intervention practices) vs. facility mean 0.70 (control practices); group*time interaction $p = 0.80$	Not calculable
Somers, 2000 ⁸⁸	Trial No Older Adults Good	Medical Outcomes Study (MOS) Short Form (SF) 36 (higher score = poorer function) (2 years)	Mean = 3.2 intervention vs. 3.3 control; 95% CI, -0.27 to 0.02; $p = 0.08$	Not calculable
Somers, 2000 ⁸⁸	Trial No Older Adults Good	Health Activities Questionnaire (higher score = poorer function) (2 years)	Mean = 0.44 intervention vs. 0.50 control; $p = 0.14$	Not calculable

Table 9. Results—clinical outcomes (continued)

Study ^a	Type of Study; Explicitly PCMH? (Yes/No); Population; Quality	Outcome (Length of Followup)	Difference Reported by Authors	Calculated Effect Size (if Available) ^b
Toseland, 1997 ⁶⁸ Toseland, 1996 ⁷⁰	Trial No Older Adults Good	MOS-SF 20 (2 years)	No statistically significant difference over 24 months (specific numbers not given)	Not calculable
Hebert, 2003 ⁸⁷	Observational No Older Adults Poor	Decline in Functional Status (1 and 2 years)	1 year: 31% intervention vs. 49% control; p = 0.002 2 years: 26% intervention vs. 36% control; p = 0.066	1 year: RD: -18% 2 years: RD: -10%
Hebert, 2003 ⁸⁷	Observational No Older Adults Poor	Institutionalization (2 years)	RR (referent = intervention): 1.44; p = 0.06	RR (referent = intervention): 1.44; p = 0.06
Clinical Outcomes: Mortality				
Toseland, 1997 ⁶⁸ Toseland, 1996 ⁷⁰	Trial No Older Adults Good	Mortality (2 years)	15.0% intervention vs. 22.5% control; p=0.24	RD: -7.5%
Dorr, 2008 ⁸⁶	Observational No Older Adults (with complex chronic illness) Good	Mortality – all patients (1 and 2 years)	1 year: 6.5% intervention vs. 9.2% control; : OR (referent = control): 0.68; p < 0.05 2 years: 13.1% intervention vs. 16.8% control; OR (referent = control): 0.77; p > 0.05	1 year: RD: -2.7% 2 years: RD: -3.7%
Dorr, 2008 ⁸⁶	Observational No Older Adults (with complex chronic illness) Good	Mortality – diabetes patients (1 and 2 years)	1 year: 6.2% intervention vs. 10.6% control; OR (referent = control): 0.56; p < 0.05 2 years: 12.9% intervention vs. 18.2% (control); OR (referent = control): 0.66; p > 0.05	1 year: RD: -4.4% 2 years: RD: -5.3%

^aWhere more than one study citation is given, the first is to the primary study report and the second is to the secondary report that actually provided data for this table.

^bA positive effect size indicates a benefit to the intervention (PCMH), except for the outcome “mortality,” where a negative effective size favors the intervention.

Notes: CI = confidence interval; ES = effect size; HbA1c = glycated hemoglobin; LDL = low-density lipoprotein; MOS-SF = Medical Outcomes Study Short Form; OR = odds ratio; PCMH = patient-centered medical home; RD = risk difference; RR = risk ratio; SD = standard deviation; USPSTF = U.S. Preventive Services Task Force

Biophysical Markers

One fair-quality observational study focusing on differences in costs among managed patients with high health care costs reported that patients receiving enhanced care coordination

meeting the PCMH definition were more likely to have HbA1c \leq 9.5 percent after 1 year (87.9 percent vs. 76.4 percent) and have low-density lipoprotein (LDL) cholesterol \leq 130 mg/dL (94.2 percent vs. 67.5 percent) after 1 year of the intervention. However, no information on the size of the group or p-values was provided.⁸¹ As a result, we conclude that there is no evidence base to assess the impact of comprehensive PCMH programs on biophysical markers.

Health Status

Overall health status was reported for followup periods ranging from 1-2 years in four studies (three RCTs, one observational study).^{60,68,87,88} One of these studies was an explicit evaluation of the medical home and three tested functional PCMH interventions.

The AAFP NDP, the fair-quality multicenter RCT that tested the impact of facilitated PCMH versus nonfacilitated PCMH, evaluated effects on health status.⁶⁰ Based on a single item measure (1-5 Likert scale), self-reported health status did not improve significantly (0.2 point improvement in each group; $p = 0.80$). The study authors concluded that the adoption of NDP-suggested components was not associated with change in health status.⁶⁰

Two RCTs comparing functional PCMH interventions to usual care among older adults assessed differences in health status using a validated health-related quality-of-life measure (versions of the Medical Outcomes Study [MOS] Short Form questionnaire^{89,90}). Neither study had a significant intervention effect.^{68,88} One of these studies⁸⁸ also found no difference when examining physical functioning using the Health Activities Questionnaire.⁹¹

One observational study of a Canadian program designed to improve care coordination for frail elderly patients found that of 272 patients with moderate to severe disability at baseline, 31 percent had a functional decline (combination of mortality, institutionalization, or increase in disabilities) at 12 months compared to 49 percent of control patients ($p = 0.002$). While this difference was also seen at 24 months, it was not statistically significant (26 percent vs. 36 percent; $p = 0.06$). Also with a p-value of 0.06, the risk ratio (RR) of being institutionalized among control patients was 1.44 when compared to intervention patients.⁸⁷

In summary, PCMH interventions were not associated with improved self-reported health status. Three clinical trials, two of good and one of fair quality, found no difference in self-reported health status.^{60,70,88} One poor-quality study found that a program designed to improve care coordination and patient autonomy decreased the proportion experiencing functional decline at 12 months (31 percent vs. 49 percent, $p = 0.002$) but not 24 months (26 percent vs. 36 percent, $p = 0.07$).⁸⁷

Mortality

Two functional PCMH studies reported data on mortality among older adults receiving enhanced older adult services meeting the PCMH definition.^{68,86} One good-quality clinical trial with 160 total older patients (mean age 72.2) who frequently used medical services (\geq 10 outpatient visits in the last 12 months), which also found no difference in health status as measured by the MOS SF-20, found no statistically significant impact of the intervention on 24-month mortality. However, fewer patients in the intervention arm died (15 percent vs. 22.5 percent, $p = 0.24$).⁷⁰ By contrast, a large, good-quality observational study of 1144 intervention and 2288 usual care control older patients (mean age 76.2) who were often quite sick (1.8 percent received hospice services within 90 days of the study start date) found that after 1 year 6.5 percent of intervention patients died compared to 9.2 percent of control patients (OR 0.68, $p = 0.01$). At 2 years, fewer patients in the intervention arm had died, but the difference was not

statistically significant (OR 0.77, $p = 0.07$). A similar pattern was seen when mortality was compared for the subset of patients with diabetes.⁸⁶

Summary

Based on a combination of predominantly good- and fair-quality studies, there is insufficient evidence to determine the impact of PCMH implementation on clinical outcomes. Only one of the studies had a stated goal of testing PCMH. That study did not compare PCMH against true usual care. Further, none of the studies reporting information on clinical outcomes were conducted among children. Most were conducted in an older adult population. Among the older adult population, there is some limited indication that PCMH may have a positive impact on mortality. However, the difference was only statistically significant in one good-quality observational study after 1 year of the intervention and no longer statistically significant in that study after 2 years.⁸⁶ This finding, along with nonsignificant findings of a good-quality clinical trial⁶⁸ and a poor-quality observational study that reports functional decline via a measure that includes mortality,⁸⁷ points to potential benefit of continuing to examine the possible link with mortality among seniors, particularly those with frailty.

Economic Outcomes

One or more abstracted economic outcomes were reported by 13 studies.^{59,63,65-68,81,82,86,88,92-94} Our summary of economic outcomes is divided into differences in inpatient utilization, emergency department utilization, and total costs. Inpatient and emergency department utilization may be expected to be reduced if exacerbations of disease, complications, or long-term consequences are avoided. Previous reviews of the impact of disease management programs have primarily found evidence of cost savings in situations where a primary clinical goal is prevention of disease exacerbation.⁹⁵ Differences in total cost reflect the overall impact of the program on per-patient economic impact.

Utilization Meta-Analysis

Utilization of services as reported by clinical trials represents one way of examining the economic impact of interventions meeting the functional definition of PCMH. Data on inpatient utilization were available from five trials. Data on emergency department utilization were available from three trials. None of these trials were specifically designed to test PCMH; rather, all evaluated functional PCMH interventions.

Meta-analyses were used to calculate summary risk ratios, initially for studies overall, and then for the subgroup of studies that enrolled adults. The results for the effect of PCMH interventions on hospital inpatient admissions are shown in Table 10. There was no evidence of an effect of treatment when including both adult and pediatric populations (RR 0.98; 95% CI, 0.86 to 1.12). Results were similar (RR 0.96; 95% CI, 0.84 to 1.10) when analyses were limited to older adults. There was some evidence of heterogeneity, but it was not statistically significant.

Table 10. Results—trials reporting inpatient admissions

Study ^a	Type of Study; Explicitly PCMH? (Yes/No); Population; Quality; Followup period	Risk Ratio	Lower Limit	Upper Limit
Boult, 2008 ⁶⁵ Boult, 2011 ⁹⁶	Trial No Older Adults Good Up to 26 months	0.83	0.64	1.08
Schraeder, 2005 ⁸² Peikes, 2009 ⁸⁴	Trial No Older Adults Fair 2 years	1.06	0.97	1.15
Toseland, 1997 ⁶⁸ Toseland, 1996 ⁷⁰	Trial No Older Adults Good 8 months	1.06	0.72	1.58
Sommers 2000 ⁸⁸	Trial No Older Adults Good 2 years	0.86	0.71	1.05
Zuckerman, 2004 ⁶⁷ Minkovitz, 2003 ⁸⁵	Trial No Young Children Fair 3 years	1.23	0.85	1.77
Combined^b	–	0.98	0.86	1.12
Combined (adult studies only)		0.96	0.84	1.10

^aWhere more than one study citation is given, the first is to the primary study report and the second is to the secondary report that actually provided data for this table.

^bTest of heterogeneity: Q-value = 6.765 for 4 degrees of freedom, p = 0.149.

Note: PCMH = patient-centered medical home

The results for the effect of PCMH interventions on emergency department utilization are shown in Table 11. When both adult and pediatric populations were included, there was no evidence of an effect for PCMH (RR 0.93; 95% CI, 0.72 to 1.20). There was evidence of heterogeneity (p = 0.022). In a subgroup analysis of studies examining older adults, the intervention significantly decreased emergency department visits (RR 0.81; 95% CI, 0.67 to 0.98).

Table 11. Results—trials reporting emergency department visits

Study ^a	Type of Study; Explicitly PCMH? (Yes/No); Population; Quality; Followup Period	Risk Ratio	Lower Limit	Upper Limit
Boult, 2008 ⁶⁵ Boult, 2011 ⁹⁶	Trial No Older Adults Good Up to 26 months	0.85	0.62	1.17
Toseland, 1997 ⁶⁸ Toseland, 1996 ⁷⁰	Trial No Older Adults Good 8 months	0.79	0.62	1.00
Zuckerman, 2004 ⁶⁷ Minkovitz, 2003 ⁸⁵	Trial No Young Children Fair 3 years	1.13	0.98	1.29
Combined^b	—	0.93	0.72	1.20
Combined (older adults only)		0.81	0.67	0.98

^aWhere more than one study citation is given, the first is to the primary study report and the second is to the secondary report that actually provided data for this table.

^bTest of heterogeneity: Q-value = 7.652 for 2 degrees of freedom, p = 0.022. Note that there is no evidence of an effect of treatment. There was evidence of heterogeneity (p = 0.022).

Note: PCMH = patient-centered medical home

Utilization Analysis of Observational Studies

Because of differences in study design and populations, we thought that it was not appropriate to include observational studies in the meta-analysis with trial results. Results for the observational studies are summarized in Table 12.

Table 12. Results—observational studies reporting inpatient or ED utilization

Study ^a	Type of Study; Explicitly PCMH? (Yes/No); Population; Quality	Outcome (Length of Followup)	Difference Reported by Authors
Reid, 2009 ⁶³ Reid, 2009 ⁷¹	Observational Yes Adults Fair	Inpatient admissions for all causes: rate per 1000 patients per month (over first 12, first 18, and first 21 months of implementation)	12 months: 4.7 (95% CI, 4.5 to 5.0) (intervention) vs. 4.8 (4.7 to 4.8) (control), relative % difference = 99 (95% CI, 94 to 104), p = 0.605 18 months: 5.1 (4.8, 5.3) (intervention) vs. 4.3 (5.2 to 5.4) (control), relative % difference = 96 (95% CI, 91 to 101), p = 0.091 21 months: 5.4 (5.4, 5.5) (intervention) vs. 4.8 (4.7 to 4.8) (control), relative % difference = 94 (95% CI, 89 to 98), p = 0.007

Table 12. Results—observational studies reporting inpatient or ED utilization (continued)

Study ^a	Type of Study; Explicitly PCMH? (Yes/No); Population; Quality	Outcome (Length of Followup)	Difference Reported by Authors
Reid, 2009 ⁶³ Reid, 2009 ⁷¹	Observational Yes Adults Fair	Inpatient admissions for ambulatory care sensitive conditions (not defined): rate per 1000 patients per month (over first 12, first 18, and first 21 months of implementation)	12 months: 0.22 (95% CI, 0.20 to 0.24) (intervention) vs. 0.26 (0.25 to 0.27) (control), relative % difference = 84 (95% CI, 78 to 90), p < 0.001 18 months: 0.25 (0.23 to 0.26) (intervention) vs. 0.28 (0.27 to 0.29) (control), relative % difference = 88 (95% CI, 82 to 94), p < 0.001 21 months: 0.24 (0.23 to 0.26) (intervention) vs. 0.28 (0.27 to 0.28) (control), relative % difference = 87 (95% CI, 81 to 93), p < 0.001
Steele, 2010 ⁹² Gilfillan, 2010 ⁹⁷	Observational Yes Older Adults Fair	Difference in expected inpatient admissions: rate per 1000 patients per year	257 (with PCMH) vs. 313 (without PCMH), 18% difference (95% CI, -30% to -5%), p < 0.01
Steele, 2010 ⁹² Gilfillan, 2010 ⁹⁷	Observational Yes Older Adults Fair	Difference in expected inpatient admissions among clinics not operated by the health system: rate per 1000 patients per year for Medicare beneficiaries in 2009	227.5 (with PCMH) vs. 316.7 (without PCMH), 28.0% difference, p-value NR
Steele, 2010 ⁹²	Observational Yes Older Adults Fair	Difference in expected inpatient admissions among clinics not operated by the health system: rate per 1000 patients per year for commercial insurance beneficiaries in 2009	40.5 (with PCMH) vs. 65.2 (without PCMH), 37.9% difference, p-value NR
Domino, 2009 ⁵⁹	Observational Yes Children (asthma used as tracer condition for PCMH) Good	Inpatient utilization rate use for all diagnoses: differences in monthly utilization rate	18% lower inpatient utilization than fee-for-service patients (= 0.47/2.6), p < 0.01
Domino, 2009 ⁵⁹	Observational Yes Children (asthma used as tracer condition for PCMH) Good	ED use for all diagnoses: differences in monthly utilization rate	10% lower inpatient utilization use than fee-for-service patients (= 0.03/0.3), p < 0.01
Martin, 2007 ⁹³	Observational Yes Children Fair	Inpatient yearly utilization rates (year 1 and year 2 after implementation)	Year 1: 7.7% (intervention) vs. 3.4% (control); p-value NR Year 2: 4.0% (intervention) vs. 2.6% (control), p-value NR
Boyd, 2007 ⁶⁶ Sylvia, 2008 ⁹⁸	Observational No Older Adults Fair	Mean inpatient admissions (6 months)	0.24 (95% CI, 0.09 to 0.39) (intervention) vs. 0.43 (95% CI, 0.19 to 0.67) (control), p = 0.185

Table 12. Results—observational studies reporting inpatient or ED utilization (continued)

Study ^a	Type of Study; Explicitly PCMH? (Yes/No); Population; Quality	Outcome (Length of Followup)	Difference Reported by Authors
Dorr, 2008 ⁸⁶	Observational No Older Adults (with complex chronic illness) Good	All hospitalizations, all patients (1 and 2 years)	1 year: 22.2% (intervention) vs. 23.3% (control) 2 years: 31.8% (intervention) vs. 34.7% (control)
Dorr, 2008 ⁸⁶	Observational No Older Adults (with complex chronic illness) Good	All hospitalizations, diabetes patients (1 and 2 years)	1 year: 21.2% (intervention) vs. 25.7% (control) 2 years: 30.5% (intervention) vs. 39.2% (control)
Dorr, 2008 ⁸⁶	Observational No Older Adults (with complex chronic illness) Good	Prevention Quality Indicator/Ambulatory Care Sensitive Condition ^b hospitalization, all patients (1 and 2 years)	1 year: 4.7% (intervention) vs. 5.3% (control) 2 years: 8.9% (intervention) vs. 8.7% (control)
Dorr, 2008 ⁸⁶	Observational No Older Adults (with complex chronic illness) Good	Prevention Quality Indicator/Ambulatory Care Sensitive Condition ^b hospitalizations, diabetes patients (1 and 2 years)	1 year: 5.5% (intervention) vs. 7.1% (control) 2 years: 8.1% (intervention) vs. 11.7% (control)
Reid, 2009 ⁶³ Reid, 2009 ⁷¹	Observational Yes Adults Fair	ED/urgent care use: rate per 1000 patients per month (over first 12, first 18, and first 21 months of implementation)	12 months: 26 (95% CI, 24 to 27) (intervention) vs. 36 (36 to 36) (control), relative % difference = 71 (95% CI, 67 to 74), p < 0.001 18 months: 27 (26 to 28) (intervention) vs. 38 (38 to 38) (control), relative % difference = 71 (95% CI, 68 to 74), p < 0.001 21 months: 27 (26 to 29) (intervention) vs. 39 (38 to 39) (control), relative % difference = 71 (95% CI, 68 to 74), p < 0.001
Steele, 2010 ⁹²	Observational Yes Older Adults Fair	ED use: rate per 1,000 patients per year for Medicare beneficiaries in 2009	282.2 (with PCMH) vs. 307.0 (without PCMH), 8.1% difference, p-value NR
Steele, 2010 ⁹²	Observational Yes Older Adults Fair	ED use: rate per 1000 patients per year for commercial insurance beneficiaries in 2009	157.5 (with PCMH) vs. 240.0 (without PCMH), 34.4% difference, p-value NR
Domino, 2009 ⁵⁹	Observational Yes Children (asthma used as tracer condition for PCMH) Good	ED use for all diagnoses: differences in monthly utilization rate	8% lower ED use than fee-for-service patients (= 0.53/6.7), p < 0.01

Table 12. Results—observational studies reporting inpatient or ED utilization (continued)

Study ^a	Type of Study; Explicitly PCMH? (Yes/No); Population; Quality	Outcome (Length of Followup)	Difference Reported by Authors
Domino, 2009 ⁵⁹	Observational Yes Children (asthma used as tracer condition for PCMH) Good	ED use for all diagnoses: differences in monthly utilization rate	6% lower ED use than fee-for-service patients (= 0.08/1.3), p < 0.01
Martin, 2007 ⁹³	Observational Yes Children Fair	ED yearly utilization rates (year 1 and year 2 after implementation)	Year 1: 14.5% (intervention) vs. 17.8% (control), p > 0.10 Year 2: 12.3% (intervention) vs. 16.6% (control), p = 0.09
Boyd, 2007 ⁶⁶ Sylvia, 2008 ⁹⁸	Observational No Older Adults Fair	Mean ED visits (6 months)	0.15 (95% CI, 0.00 to 0.32) (intervention) vs. 0.31 (95% CI, 0.12 to 0.49) (control), p = 0.200
Dorr, 2008 ⁸⁶	Observational No Older Adults (with complex chronic illness) Good	ED visits, all patients (1 and 2 years)	1 year: 33.3% (intervention) vs. 32.3% (control) 2 years: 49.9% (intervention) vs. 43.8% (control)
Dorr, 2008 ⁸⁶	Observational No Older Adults (with complex chronic illness) Good	ED visits, diabetes patients (1 and 2 years)	1 year: 32.8% (intervention) vs. 35.3% (control); 2 years: 51.3% (intervention) vs. 48.5% (control)

^aWhere more than one study citation is given, the first is to the primary study report and the second is to the secondary report that actually provided data for this table.

^bBased on 2004 Prevention Quality Indicators published by the Agency for Healthcare Research and Quality

Note: CI = confidence interval; ED = emergency department; NR = not reported; PCMH = patient-centered medical home

Two fair-quality studies of limited PCMH implementation in two large integrated delivery systems reported information on inpatient and emergency department utilization.^{63,92} The evaluation of PCMH implementation in one Group Health Cooperative of Puget Sound evaluated adult utilization against the rest of the system. Overall inpatient admissions for all causes were essentially the same over the first 12 months (relative percent difference 99; 95% CI, 94 to 104) and first 18 months (relative percent difference 96; 95% CI, 91 to 101) of the intervention. However, when examined for the first 21 months of the intervention, there were fewer admissions in the PCMH clinic (relative percent difference 94; 95% CI, 89 to 98). Based on the literature about disease management,⁹⁵ reduced use of resources may result from prevention of disease exacerbations. This possibility is reflected by the result that inpatient admissions for ambulatory care sensitive conditions were significantly lower (p < 0.001) for all followup time periods (21-month relative percent difference 87; 95% CI, 81 to 93). Likewise, there were approximately 30 percent fewer emergency department and urgent care visits for each followup period (21-month relative percent difference 71; 95% CI, 68 to 74).⁷¹

An evaluation of PCMH in the Geisinger Health Plan system utilized data from practice patients and a matched cohort to model the expected difference in hospital admissions per 1000 patients per year. Investigators estimated that there would be a difference of 56 fewer admissions

among older adults (257 vs. 313, 18 percent [95% CI, -30 percent to -5 percent] difference) with PCMH as opposed to what would be expected without it.⁹⁷ A separate analysis comparing patients in the health plan that had access to PCMH at non-Geisinger providers and those that did not in 2009 noted 28.0 percent fewer inpatient admissions per 1000 Medicare beneficiaries (227.5 vs. 316.7, p-value not reported) and 37.9 percent fewer inpatient admissions for commercial beneficiaries (40.5 vs. 65.2, p-value not reported). There were also 8.1 percent fewer emergency department visits among Medicare beneficiaries (282.2 vs. 307.0, p-value not reported) and 34.4 percent fewer among commercial beneficiaries (157.5 vs. 240.0, p-value not reported).⁹²

Using childhood asthma as a tracer condition, Domino et al.⁵⁹ conducted a good-quality evaluation of the impact of the often cited PCMH program Community Care of North Carolina^{99,100} on utilization and costs. Based on results of a multivariable regression model, investigators found that children in the medical home program had 8 percent fewer total monthly emergency department visits, 6 percent fewer monthly emergency department visits related to asthma, and 18 percent fewer monthly inpatient admissions than children with asthma in the Medicaid fee-for-service program. The p-value for all three comparisons was < 0.01.⁵⁹

The final observational study with the specified goal of evaluating PCMH was a small, fair-quality study (49 PCMH patients and 146 control patients for utilization analysis) among children with special health care needs in family practice. Although point estimates were in the direction of the PCMH intervention, there was not a statistically significant difference in emergency department visit rates in the 2 years after implementation (year 1, 15.5 percent vs. 17.8 percent [adjusted rate ratio 0.795]; year 2, 12.3 percent vs. 16.6 percent [adjusted rate ratio 0.651]), although the p-value was 0.086 in year 2. The authors did not provide significance tests for inpatient admissions. However, point estimates for hospitalization rates were higher for PCMH patients than for control patients in both years 1 and 2 following implementation (year 1, 7.7 percent vs. 3.4 percent; year 2, 4.0 percent vs. 2.6 percent).⁹³

Reflecting the meta-analysis of utilization reported in trials, the two fair-quality studies of interventions that met the functional definition of PCMH had no utilization results that favored the intervention.^{86,98} The one statistically significant result in fact indicated that over the 2 years following implementation of comprehensive care management at Intermountain Health Care, intervention patients had more emergency department visits (OR 1.28, p = 0.02).⁸⁶

Total Costs

The impact of PCMH on total costs was addressed for followup periods ranging from 6 months to 2 years in nine studies (four RCTs, five observational studies; see Table 13).^{59,63,65,66,68,81,82,92,94} Three observational studies were explicit evaluations of PCMH, and six studies evaluated functional PCMH interventions.

Table 13. Results—economic outcomes: total costs

Study ^a	Type of Study; Explicitly PCMH? (Yes/No); Population; Quality	Outcome (Length of Followup)	Difference Reported by Authors
Reid, 2009 ⁶³ Reid, 2009 ⁷¹	Observational Yes Adults Fair	Total costs (over first 12, first 18, and first 21 months of implementation)	<p>12 months: \$466 (95% CI, \$453 to \$480) (intervention) vs. 477 (\$471 to \$483) (control), relative % difference = -10.20 (95% CI, -22.85 to +2.45), p = 0.114</p> <p>18 months: \$480 (\$468 to \$491) (intervention) vs. \$490 (\$485, \$495) (control), relative % difference = -10.40 (95% CI, -21.19 to +0.38), p = 0.059</p> <p>21 months: \$488 (\$476 to \$500) (intervention) vs. \$498 (\$493 to \$503) (control), relative % difference = -10.31 (95% CI, -21.69 to +1.08), p = 0.076</p>
Steele, 2010 ⁹² Gillfillan, 2010 ⁹⁷	Observational Yes Older Adults Fair	Difference in expected total costs per member per month	\$107 (with PCMH) vs. \$116 (without PCMH), 7% difference (95% CI, -18% to 5%), p = 0.21
Domino, 2009 ⁵⁹	Observational Yes Children (asthma used as tracer condition for PCMH) Good	Mean monthly total costs among those with a cost	\$43 (9% [42.95/470.46]) lower total costs than fee-for-service patients, p < 0.01
Domino, 2009 ⁵⁹	Observational Yes Children (asthma used as tracer condition for PCMH) Good	Total per capita mean Medicaid expenditures – considers both reduced mean expenditures among users and 58% (= 37.56/63.5) rate of having a Medicaid expense in a month (including program fees)	\$148 (95% CI, \$140 to \$158) greater per capita costs than fee-for-service patients, p < 0.01
Boult, 2008 ⁶⁵ Leff, 2009 ¹⁰¹	Trial No Older Adults Good	Total cost (not including cost of the guided care program) (18 months)	-\$170.90 difference in total cost (intervention – control; 95% CI, -\$339.9, to +\$55.0)
Boult, 2008 ⁶⁵ Leff, 2009 ¹⁰¹	Trial No Older Adults Good	Total cost (including \$95.90 cost of the guided care program) (18 months)	\$75.00 difference in total cost (intervention – control; 95% CI, -\$244.00 to +\$150.90)
Schraeder, 2005 ⁸² Peikes, 2009 ⁸⁴	Trial No Older Adults Fair	Total Medicare expenditures (regression adjusted difference) – Not including program fee (1-2 years)	Treatment-control difference (90% CI) = +61 (\$4 to \$117), % difference = 8.7, p = 0.08
Schraeder, 2005 ⁸² Peikes, 2009 ⁸⁴	Trial No Older Adults Fair	Total Medicare expenditures (regression adjusted difference), including program fee (1-2 years)	Treatment-control difference (90% CI) = +\$209 (\$153 to \$265), % difference = 30.1, p < 0.001

Table 13. Results—economic outcomes: total costs (continued)

Study ^a	Type of Study; Explicitly PCMH? (Yes/No); Population; Quality	Outcome (Length of Followup)	Difference Reported by Authors
Toseland, 1997 ⁶⁸	Trial No Older Adults Good	Total costs incurred during the study for the 80 patients in each study arm (2-years)	\$25,844 (intervention) vs. 24,995 (control), $p \geq 0.05$
Rubin, 1992 ⁹⁴	Trial No Older Adults Fair	Medicare Parts A and B charges during the 26-month enrollment period (variable followup per individual)	\$8931 per patient (intervention) vs. \$11,664 (control), $p \geq 0.05$
Boyd, 2007 ⁶⁶ Sylvia, 2008 ⁹⁸	Observational No Older Adults Fair	Mean total insurance expenditures (6 months)	\$4586 (95% CI, \$2678 to \$6493) (intervention) vs. \$5964 (95% CI, \$3759 to \$8171) (control), $p = 0.347$
Wise, 2006 ⁸¹	Observational No All Ages (high utilizers) Fair	Total insurance costs (1 year)	\$63 less per member per month for intervention patients (2.4 to 1 return on investment, no p-value calculated)

^aWhere more than one study citation is given, the first is to the primary study report and the second is to the secondary report that actually provided data for this table.

Note: CI = confidence interval; HbA1c = glycated hemoglobin; PCMH = patient-centered medical home

There was no indication of a positive impact of PCMH on total costs. Despite showing a positive impact of PCMH interventions on inpatient and emergency department utilization at the Group Health Cooperative of Puget Sound and Geisinger Health Care, neither intervention was associated with reduced total cost.^{71,97} However, differences in costs reported comparing the one PCMH clinic to the rest of the health system (~10 percent) approached statistical significance ($p = 0.114$ over 12 months, $p = 0.059$ over 18 months, $p = 0.076$ over 21 months), indicating a potential trend toward lower costs.

The good-quality evaluation of Community Care of North Carolina (CCNC) using children with asthma as tracers found that while the mean costs for patients that had any services in a month were \$43 (9 percent) lower for patients in the PCMH program compared to fee-for-service program, per-member per-month Medicaid costs were actually higher by \$145 (95% CI, \$139 to \$153) than for patients in the fee-for-service system. However, as the authors point out, this may reflect greater access to service as well as billing for PCMH program components. Children in the medical home program were 58 percent more likely to have a Medicaid claim in any given month ($p < 0.01$). Further, this was an evaluation relatively early in the development of the CCNC program (data from 1998-2001).⁵⁹

Reflecting results of the utilization meta-analyses, results from the five clinical trials of interventions that meeting the functional definition of PCMH also generally do not point to PCMH related cost savings.^{65,68,82,94}

One fair-quality trial of enhanced care coordination found that intervention patients had higher overall annual costs when taking into account the \$148 mean program fee (\$209; 90 percent CI, \$153 to \$265; $p < 0.001$). Even when the fee is not taken into account, greater costs among the intervention group approached statistical significance (\$61; 90 percent CI, \$4 to \$117; $p = 0.08$).⁸⁴

One of the other two observational studies reporting total costs^{81,98} did report cost savings from an intervention that met the functional definition of PCMH. While a fair-quality evaluation

of differences in costs of high utilizing patients receiving enhanced case management compared to a control commercial insurance population reports relative saving of \$63 per member per month. However, statistical significance was not reported.⁸¹

Summary

Based on a combination of good- and fair-quality studies, there is a low strength of evidence that PCMH implementation may lead to lower utilization (inpatient and emergency department) for some subgroups of patients, but this effect was not uniform. Moreover, total costs were not lowered in the reviewed studies. Moreover, total costs are not consistently lowered in the reviewed studies. However, three observational studies specifically designed to test PCMH do report lower inpatient and emergency department utilization among patients in the PCMH program.^{59,71,92,97} However, total costs were not statistically different for PCMH and non-PCMH patients in the three studies. None of the clinical trials of functional PCMH interventions had statistically significant differences between intervention and control arms for inpatient or emergency department utilization.

No studies reported statistically significant cost savings among PCMH patients. In fact, when taking into account program costs, two studies, one good-quality trial and one fair-quality observational study, reported greater total costs among intervention patients.^{59,84}

Effects of Specific PCMH Components (KQ 1 a)

We intended to examine the relationship between inclusion of specific elements as part of the PCMH framework and effectiveness in the five domains reviewed above. In preparation for this analysis, we generated a priori hypotheses about which specific elements would have an impact. However, there were not enough studies for each outcome domain that also had appropriate variation in PCMH elements to conduct such an evaluation. As a result, we conclude that there is not currently sufficient evidence to evaluate whether specific PCMH components are associated with greater effects on patient and staff experiences, process of care, clinical outcomes, and economic outcomes.

For more information on the specific PCMH components implemented in the included studies, please see the results section for KQ 2, below.

Unintended Consequences (KQ 1b)

The issue of unintended consequences was not specifically addressed in any of these controlled studies. However, two studies, one a good-quality observational evaluation of a Medicaid medical home program⁵⁹ and another a fair-quality clinical trial of a Medicare disease management demonstration program meeting the functional definition of PCMH,⁸⁴ report that when costs of the program are taken into effect, overall costs are greater for the PCMH intervention. Questions concerning the potential of the costs of PCMH programs themselves leading to increased costs are an important potential area of future study.

Key Question 2. PCMH Components Implemented

KQ 2. In published, primary care–based evaluations of comprehensive PCMH interventions, what individual PCMH components have been implemented?

Key Points

- Eight of 27 studies addressed children and adolescents only, one study addressed all ages, and the remaining 18 studies addressed adult-only patient populations (9 of these 18 were specific to older adults).
- Twenty-one of 27 studies reported approaches that addressed all 7 major PCMH components. These included team based-care, sustained partnership, reorganized or structural changes to care, enhanced access, coordinated care, comprehensive care, and a systems-based approach to quality. We abstracted 51 different strategies or approaches across these seven major PCMH components and found considerable variability across studies based on what was reported.
- PCMH interventions used a greater number of approaches than functional PCMH interventions to address the seven major medical home components.
- Team-based care: 93 percent of the studies reported multiple disciplines as part of the team in addition to a physician and nurse.
- Comprehensive care: 93 percent of studies addressed chronic illness care, and only 26 percent included specialty care.
- Coordinated care: 63 percent of studies coordinated care transitions across settings. Only 11 percent reported integration of mental health.
- Quality: 41 percent of studies reported the use of electronic health records and 15 percent were reportedly new.

Detailed Analysis

This section of the report presents a synthesis of the individual PCMH components reported in the 27 included studies. Of the 27 studies, 8 included only children and adolescents, 1 included all ages, and the remaining 18 included adult-only patient populations, with 9 of the 18 specific to older adults.

PCMH is defined as a comprehensive intervention that includes items 1, 3, and 4, below, along with at least two components of item 2. The number of strategies or approaches (areas) examined for each component is noted:

1. Team-based care (six areas examined)
2. At least two of the following:
 - a. Enhanced access to care (nine areas examined)
 - b. Coordinated care (eight areas examined)
 - c. Comprehensiveness (four areas examined)
 - d. A systems-based approach to improving quality and safety (10 areas examined)
3. A sustained partnership oriented toward the whole person (six areas examined)
4. Reorganized care delivery (through structural changes to the traditional practice; eight areas examined)

For each component a comparison is made between PCMH studies (n = 10) and studies of functional PCMH (n = 17), and between studies with pediatric-only patient populations (n = 8),^{59,64,67,93,102-105} adult-only patient populations (n = 18),^{60,63,65,66,68,82,83,86-88,92,94,106-111} and the study with patients of all ages (n = 1).⁸¹ Seven of the eight pediatric-only studies were studies of PCMH.^{59,64,93,102-105} The oldest study, by Rubin and colleagues (1992),⁹⁴ was the only study to

report implementation of just two of the four elements listed under item 2. Four additional studies implemented three of these elements, and the remainder (81 percent) included all four. With the exception of the *enhanced access to care* component, there was little to no difference between PCMH and functional PCMH studies in reporting details for each component. It is important to note that while some studies reported multiple approaches or strategies for implementing a particular component, evidence of only one approach was required. Each component is analyzed independent of the next for this KQ and is described in more detail below.

Team-Based Care

The composition of teams varied widely across studies; within comparisons by physician, nurse, and mid-level provider groupings; and within analytic groups (PCMH vs. functional PCMH and pediatric vs. adult vs. both) (Table 14). It was most common to report having a physician and a nurse (56 percent). All but two studies reported other disciplines as part of the team. Four studies, two PCMH (one pediatric, one adult) and two functional PCMH (adult only), did not explicitly report having a designated physician for the patients. Nurses and case managers were more frequently reported as the primary contact, but no single discipline was reported in this role for ≥ 15 percent of the studies. Five of the nine studies with pediatric patients did not report a primary contact for the patients and/or their families. The majority of studies (67 percent) reported team members to have defined roles. A different set of 16 studies (67 percent) reported that team members had dedicated time for PCMH activities, and 63 percent had dedicated team meetings. Not all teams were co-located.

Table 14. Team-based care

	PCMH (n = 9 of 10) ^a				Functional PCMH (n = 17)			
	MD, NP/PA, RN	MD and/or NP/PA	MD and RN	MD	MD, NP/PA, RN	MD and/or NP/PA	MD and RN	MD
Studies	2 studies ^{63,92}	2 studies ^{102,103}	2 studies ^{64,104}	3 studies ^{59,60,93}	2 studies ^{82,83}	3 studies ^{68,94,109}	9 studies ^{65,66,81,88,106-108,110,111}	3 studies ^{67,86,87}
Other team members	Pharmacist ⁶³ Medical assistants ⁶³ Case manager ⁹² Admin staff ⁹²	Office staff ¹⁰² Parent consultant ^{102,103}	Family support specialist ⁶⁴ Paid parent consultant ⁶⁴ NR ¹⁰⁴	Social worker ⁹³ Case managers ⁵⁹ Admin staff ⁹³ Title V program staff ⁹³	Pharmacist ⁸³ Quality improvement nurse ⁸³ Case assistant ⁸² Clinic manager ⁸³	Social worker ^{68,94,109} Psychiatrist ⁹⁴	Geriatrician ¹⁰⁸ Resident ¹⁰⁶ Pharmacist ^{106,107} Social worker ^{81,88,108} Case manager ^{107,111} Psychologist ¹¹⁰ Dietician ¹⁰⁸ Office staff ⁶⁵	Medical assistant ⁸⁶ Developmental specialist ⁶⁷ Care manager ^{86,87} Office manager ⁸⁶
New staff added ^b	Yes ^{63,92}	Yes ¹⁰² NR ¹⁰³	Yes ⁶⁴	Yes ^{59,93} NR ⁶⁰	Yes ^{82,83}	Yes ⁹⁴ NR ^{68,109}	Yes ^{65,66,81,88,106-108,110,111}	Yes ^{67,86,87}
Primary contact	Case Manager ⁹² NR ⁶³	MD/NP/PA ¹⁰² NR ¹⁰³	Family support specialist ⁶⁴ NR ¹⁰⁴	Care coordinator ⁹³ NR ^{59,60}	NR ^{82,83}	NP ^{68,109} NR ⁹⁴	MD ⁸¹ RN ^{65,66,110} Care manager ¹¹¹ NR ^{88,106-108}	Care manager ⁸⁷ NR ^{67,86}
Designated PCP ^c	Yes ^{63,92}	Yes ^{102,103}	Yes ⁶⁴ NR ¹⁰⁴	Yes ^{59,93} NR ⁶⁰	Yes ^{82,83}	Yes ^{68,94,109}	Yes ^{65,81,88,106,108,110} Not 100% ¹¹¹ NR ⁶⁶	Yes ^{67,86} NR ⁸⁷
Defined roles (new noted ^b)	Yes ^{63,92}	Yes and new ¹⁰² NR ¹⁰³	Yes and new ^{64,104}	Yes ^{60,93} NR but new ⁵⁹	Yes ^{82,83}	Yes ^{68,109} NR but new ⁹⁴	Yes ^{65,88,106,108} Yes/new ^{81,111} NR but new ^{66,107,110}	Yes ⁸⁶ NR ⁸⁷ NR but new ⁶⁷
Dedicated time	Yes ^{63,92}	Yes ¹⁰³ NR ¹⁰²	Yes ⁶⁴ NR ¹⁰⁴	Yes ⁹³ NR ^{59,60}	Yes ^{82,83}	Yes ^{68,109} NR ⁹⁴	Yes ^{65,66,88,106,110,111} NR ^{81,108}	Yes ^{67,86} NR ⁸⁷
Team meetings	Yes ^{63,92}	NR ^{102,103}	Yes ^{64,104}	Yes ^{60,93} NR ⁵⁹	Yes ^{82,83}	Yes ⁶⁸ NR ^{94,109}	Yes ^{66,81,88,107,108,111} NR ^{65,106,110}	Yes ^{67,86} NR ⁸⁷
Location (new noted ^b)	Same ^{63,92}	Same ¹⁰³ Different ¹⁰²	Same ¹⁰⁴ Different ⁶⁴	Same ⁶⁰ Different ⁵⁹ NR ⁹³	Same ⁸³ Different ⁸²	Same ⁶⁸ Different ¹⁰⁹ NR ⁹⁴	Same ^{65,66,106,108} Different ^{81,88,110} Both ¹¹¹ New ¹⁰⁷	Same ⁸⁶ Same/new ⁶⁷ NR ⁸⁷

^aTreadwell 2009¹⁰⁵ (PCMH) did not report details on the team; however, the study reports new staff roles.

^bNew staff, staff roles, and locations are examples of structural changes.

^cDesignated PCP is an example of partnership.

Notes: MD = medical doctor; NP = nurse practitioner; NR = not reported; PA = physician's assistant; PCMH = patient-centered medical home; PCP = primary care provider; RN = registered nurse

Enhanced Access to Care

Several strategies were described that may enhance patient and family access to services and providers; these are presented by those reported most to least frequently in Table 15. A higher proportion of PCMH studies compared with functional PCMH reported advanced clinic access (40 percent vs. 12 percent), group visits (20 percent vs. 6 percent), telephone visits (40 percent vs. 29 percent), disease management (30 percent vs. 18 percent), and enhanced telephone or electronic communication options (50 percent vs. 29 percent). Access to a provider at all times (24/7 coverage) was rare and was only reported in two studies; both included only adults. Only one pediatric study offered advanced clinic access, and none offered group visits.

Table 15. Strategies reported that may enhance access to services and providers

Strategy	All Studies (n = 27)	PCMH Studies (n = 10)	Functional PCMH Studies (n = 17)
Home visits	48%	4 studies (40%), all pediatric ^{64,93,102,103}	9 studies (53%) <ul style="list-style-type: none"> • 8 adult^{65,66,82,88,107,109-111} • 1 pediatric⁶⁷
Telephone visits	33%	4 studies (40%) <ul style="list-style-type: none"> • 3 pediatric^{59,64,105} • 1 adult⁶³ 	5 studies (29%), all adult ^{82,86,88,107,109}
Enhanced communication options – electronic or telephone	38%	5 studies (50%): <ul style="list-style-type: none"> • 2 telephone, 1 adult⁹² and 1 pediatric¹⁰² • 1 electronic, adults only⁶⁰ • 2 both telephone and electronic, 1 adult⁶³ and 1 pediatric¹⁰⁴ 	5 studies (29%), all telephone <ul style="list-style-type: none"> • 4 adult^{65,87,108,109} • 1 pediatric⁶⁷
Advanced clinic access	23%	4 studies (40%) <ul style="list-style-type: none"> • 1 pediatric¹⁰⁵ • 3 adults^{60,63,92} 	2 studies, both adults (12%) ^{68,106}
Disease management – online or by phone	23%	3 studies (30%) <ul style="list-style-type: none"> • 2 telephone, 1 adult⁹² and 1 pediatric⁵⁹ • 1 online, adult⁶³ 	3 studies (18%), all telephone, all adults ^{65,66,109}
Group visits	12%	2 studies (20%), both adult ^{60,63}	1 adult study (6%) ⁸⁸
24/7 coverage	8%	1 study (10%), adult ⁶⁰	1 adult study (6%) ¹¹⁰
No enhanced access strategies reported	12%	0	3 studies (18%) <ul style="list-style-type: none"> • 2 adult studies^{83,94} • 1 all ages⁸¹

Note: PCMH = patient-centered medical home

Coordinated Care

Care coordination was not a required component for inclusion in this review but was addressed by all 27 studies. Examples are presented by those reported most to least frequently in Table 16. Coordination with community resources either with a community liaison or referral was addressed by 67 percent of the studies, more common among functional PCMH than PCMH (71 percent vs. 60 percent), and in 6 of the 9 studies that included pediatric patients. Also common, but not equally distributed between groups, was the focus on coordinated care transitions—only 3 of 9 studies that included pediatric patients and 76 percent of functional PCMH vs. 40 percent of PCMH studies. Previsit planning, tracking the results of tests, and tracking referrals were reported in six or fewer studies. None of the studies of pediatric patient populations coordinated home health, included pharmacist activities, tracked tests, or integrated mental health.

Table 16. Coordination of care strategies

Strategy	All Studies (n = 27)	PCMH Studies (n = 10)	Functional PCMH Studies (n = 17)
Community liaison or referral to resources	67%	6 studies (60%) ^{59,60,64,93,102,104}	12 studies (69%) ^{65-68,82,86-88,108-111}
Coordinated care transitions	63%	4 studies (40%) ^{60,92,103,104}	13 studies (75%) ^{65,66,68,81-83,87,94,106,108-111}
Coordinated home health	26%	1 study (10%) ⁹²	6 studies (31%) ^{65,66,87,107,109,111}
Previsit planning	22%	2 studies (20%) ^{63,105}	4 studies (24%) ^{81,82,86,108}
Referral tracking	22%	3 studies (30%) ^{59,63,92}	3 studies (18%) ^{82,87,109}
Inclusion of pharmacist activities	19%	2 studies (20%) ^{63,92}	3 studies (18%) ^{83,106,107}
Test tracking	15%	2 studies (22%) ^{60,63}	2 studies (12%) ^{82,109}
Integrated mental health	11%	0	3 studies (18%) ^{94,110,111}

Note: PCMH = patient-centered medical home

Comprehensiveness

Four service areas were examined to describe the comprehensiveness of the intervention (Table 17). All but two studies (one pediatric PCMH, one adult functional PCMH) addressed chronic illness care. In studies that addressed only one service area (n = 6), the focus was on chronic illness care rather than preventive care (five vs. one studies, respectively). Preventive wellness care was addressed by 18 studies, a higher proportion of PCMH than functional PCMH (80 percent vs. 59 percent). Also more frequently addressed by PCMH than functional PCMH was acute care (90 percent vs. 65 percent). Specialty care was only included in studies that addressed all other service areas (n = 6), and only one of these six studies was PCMH. PCMH studies more commonly addressed three of the service areas but not specialty care and this was true for all three of the PCMH studies of adult populations.

Table 17. Comprehensiveness—addressing patients’ needs measured across four service areas

Studies	Service Areas	Chronic Illness Care	Preventive Care	Acute Care	Specialty Care
PCMH (N = 10)	Number Addressed	9 studies	8 studies	9 studies	1 study
1 pediatric ¹⁰²	4	✓	✓	✓	✓
3 pediatric ^{93,103,104}					
3 adult ^{60,63,92}	3	✓	✓	✓	
1 pediatric ⁶⁴	1		✓		
2 pediatric ^{59,105}	1	✓			
Functional PCMH (N = 17)	Number Addressed	16 Studies	10 Studies	11 Studies	5 Studies
4 adult ^{68,87,109,110}					
1 all ages ⁸¹	4	✓	✓	✓	✓
3 adult ^{83,108,111}	3	✓	✓	✓	
3 adult ^{65,66,106}	2	✓		✓	
2 adult ^{88,107}	2	✓	✓		
3 adult ^{82,86,94}	1	✓			
1 pediatric ⁶⁷	NR	✓			
Total		25 studies	18 studies	20 studies	6 studies

Notes: NR = not reported; PCMH = patient-centered medical home

Systems-Based Approaches to Improving Quality and Safety

Several systems-based approaches to improving quality were reported but only two of these by more than 50 percent of the studies: 59 percent identified high-risk patients, and 52 percent reported to use evidence-based practice guidelines (Table 18). Performance monitoring and the

use of electronic health records were each reported in 11 studies. Reid and colleagues reported several approaches, including an orientation to the practice for new patients, a reduced panel size, longer appointment times, and electronic prescribing.⁶³ Electronic prescribing was also reported by Steele and Jaen.^{60,92} Like Reid, Zuckerman reported longer appointment times and providing an orientation to the practice for new pediatric patients.⁶⁷ Such an orientation was also addressed by Sommers 2000.⁸⁸

Table 18. Systems-based approaches to improving quality and safety

Approach	Total No. of Studies (n = 27)	No. of PCMH Studies (n = 10)	No. of Studies with Pediatric Patients (n = 9)
Identification of high-risk patients	16	6	3
Evidence-based practice guidelines	14	6	3
Performance monitoring	11	5	2
Electronic health record	11	4	1
Registry or method to track care/health	10	4	2
Decision support	6	2	0

Note: PCMH = patient-centered medical home

Sustained Partnership

Approaches to supporting a sustained partnership with patients were examined and are presented in order of how they are likely to present in working with a new patient (Table 19). Although all studies were required to address this component with indication of treating the “whole” patient, only three studies, each for adult populations, reported specific strategies to include patients in the decisionmaking for their care. Reported most frequently were care plans and comprehensive assessments of patients (67 percent and 63 percent respectively). The latter was more common among functional PCMH studies (71 percent) than PCMH studies (50 percent). Self-management support was more common among PCMH studies (50 percent vs. 35 percent of functional PCMH studies). The provision of family caregiver support was reported in 10 studies, 5 pediatric and 5 adult, and similar proportionally among PCMH and functional PCMH studies, 40 percent and 35 percent, respectively.

Table 19. Strategies reported to facilitate a sustained partnership

Strategy	All Studies (n = 27)	PCMH Studies (n = 10)	Functional PCMH Studies (n = 17)
Comprehensive assessment	63%	5 studies (50%) ^{60,64,93,102,104}	12 studies (71%) ^{65,66,68,81,82,86-88,106,109-111}
Care plan	67%	7 studies (70%) ^{59,64,92,93,102-104}	11 studies (65%) ^{65,68,81,82,86-88,107,108,110,111}
Shared decisionmaking	11%	1 study (10%) ⁶³	2 study (12%) ^{88,111}
Self-management	41%	5 studies (50%) ^{59,63,92,93,105}	6 studies (35%) ^{65,82,86,88,109,111}
Family caregiver support	37%	4 studies (40%) ^{64,93,102,104}	6 studies (35%) ^{65,67,68,82,86,108}
Other	15%	Team role transparency, motivational interviewing, mail care reminders ⁶³ Advance directives discussions ⁹² Care coordination visits with families ⁹³	

Note: PCMH = patient-centered medical home

Reorganized Care Delivery

Examples of reorganized care and structural changes were not reported in isolation of other PCMH components. Table 14 addresses team-based care and important elements of staff, roles,

and the location of the team. In describing the design of the intervention, 78 percent of studies reported that new staff were added, 12 studies indicated the roles that were defined were new roles, and two studies reported a new physical location for providing patient services (Table 14). New organizational affiliations were reported in four studies,^{87,92,108,109} and Domino and colleagues in their study addressing chronic illness care among pediatric patients reported to have established a “new entity.”⁵⁹ The creation of new services was reported in 63 percent of studies,^{59,60,64,65,81,82,86,87,92,102,105-111} similar among PCMH and functional PCMH studies (60 percent vs. 65 percent, respectively).

Key Question 3. Financial Models and Implementation Strategies

KQ 3: In published, primary care–based evaluations of comprehensive PCMH interventions, what financial models and implementation strategies have been used to support uptake?

Key Points

- Of the 27 studies included in our literature review, 22 studies (45 articles) reported information about the financial models and/or implementation processes (either organizational learning strategies or actual implementation strategies) used to support uptake of PCMH interventions. Nine of the 22 interventions studied were explicitly described as PCMH; the remaining 13 were not so described, but met our functional definition of PCMH.
- Seven of the 22 studies involved pediatric populations (6 PCMH and 1 functional PCMH). The financial models and implementations strategies were similar between the pediatric and adult studies; we therefore report the results for the full set of studies.
- Relatively few studies (11 of 22) described any aspect of change in financial models. The financial models described varied greatly in the scope of the financial changes implemented and in the level of detail reported.
- In both PCMH and functional PCMH studies, the most commonly used organizational learning strategies, implemented in 19 of 22 studies, were formal learning collaboratives and/or collaborative program planning for practice team members to learn about the new intervention and the processes of change being implemented.
- In both PCMH and functional PCMH studies, the most commonly employed implementation strategies, used in 13 of 22 studies, involved some form of audit and feedback, often in the form of quality improvement methodology.

Detailed Analysis

The shift of focus for primary care clinics away from a fee-for-service driven practice directed at acute medical care toward the medical home model, which is focused more holistically on prevention and the management of both acute and chronic medical conditions, requires many changes at the levels of the provider, practice, and health system. In our review of the literature, we were interested in processes of care that studies implemented to help practices become medical homes. We are not aware of studies that have rigorously tested these processes

of care for their efficacy, so we will qualitatively describe what has been done to date in this area.

We abstracted data related to financial models and implementation strategies used to change primary care clinics into medical homes or into clinics with functions similar to medical homes. In what follows, we begin by describing the financial models used for PCMH changes, that is, any changes made to the financing of providers, the practice, or health system as part of PCMH implementation. Next, we focus on two areas related to processes of care in the area of implementation: (1) organizational learning strategies, and (2) implementation strategies. Organizational learning strategies are mechanisms through which providers and staff gain knowledge about, or provide feedback about, how to make their practice more consistent with PCMH. Implementation strategies are strategies that are used, generally at the level of the practice, to implement the changes needed to be more consistent with PCMH, as well as the methods used to measure the impact of the PCMH transformation on clinical care processes or outcomes. In abstracting this information from the studies, we found that there was often overlap in the processes of change that could be considered both organizational learning strategies and implementation strategies, as described below.

Our literature review identified 22 studies (45 articles) that described strategies used for organizational learning or implementation of PCMH interventions; 11 of these also described some component of a financial model for these PCMH interventions. Nine of the 22 interventions studied were explicitly described as PCMH;^{59,60,63,92,93,102-105} six of these involved pediatric populations.^{59,93,102-105} The remaining 13 were not described to be a PCMH intervention, but met our functional definition of PCMH.^{65-67,82,83,86,88,94,107-111} Of these interventions, only one⁶⁷ involved a pediatric population. Table 20 summarizes the number of studies included in this section and the strategies employed. Below we describe in more detail the financial, organizational learning, and implementation strategies employed in these interventions. While we did not find any clear pattern of strategies that distinguished these interventions, we describe the interventions qualitatively according to whether the intervention was explicitly PCMH or functionally PCMH. We also did not find any clear pattern of strategies which distinguished interventions employed for pediatric versus adult populations, and so we have combined studies for all patient populations in our descriptions.

Table 20. Numbers of studies describing financial, organizational learning, and implementation strategies

Strategies	PCMH (n = 9)	Functional PCMH (n = 13)
Financial models:		
Bundled payments for most health services	0	0
PCMH per member, per month payment for PCMH activities	1	1
Pay for performance	1	0
Enhanced fee-for-service compensation	2	0
Accountable care organization	0	0
Revised pharmacy benefits	0	0
Other	3	6
Not described	4	7
Organizational learning strategies:		
Formal learning collaborative/collaborative program planning	8	11
Designated research/project team assistance	2	32
Community of practice	3	2
Implementation tool-kits	2	2
Not described	0	
Implementation strategies:		
Audit and feedback/quality improvement measures	6	7
Academic detailing/lectures and classes for staff	4	6
Designated clinical champion or project manager	4	1
Plan-Do-Study Act cycles/rapid cycle improvement mechanisms	3	1
Flow mapping of care system	0	0
Total quality management/continuous quality improvement	0	0
Strengths-weakness-opportunities-threats analysis	0	0
External benchmarking at the organizational level	0	0
Other	0	1
Not described	0	3

Note: PCMH = patient-centered medical home

Financial Models

Under the heading of “financial models,” we considered any change to the financial structure of clinics required for the financing of the PCMH or functional PCMH interventions. The types of financial restructuring we anticipated being reported included *bundled payments* for most health services; *PCMH per member, per month* payment for PCMH activities; *pay for performance*; *enhanced fee-for-service compensation*; *accountable care organization*; and *revised pharmacy benefits*. On reviewing the included studies, however, we found that the amount of detail provided about the short-term financing and the envisioned long-term financing of these interventions varied greatly and often did not correspond to these categories. In what follows, we describe the information actually provided as clearly as possible.

PCMH Studies

Five PCMH studies^{59,63,92,103,104} reported some aspect of the financing of the PCMH intervention. One study was small-scale and funded by an external grant.¹⁰⁴ Two studies received financial stipends for certain aspects of their interventions—one to fund a local parent consultant for each clinic,¹⁰³ and another to offer additional services such as enhanced phone access;⁹² only the latter study detailed the source of the stipend.

Some studies described more significant changes to the overall financial model of the clinic practices. One study⁵⁹ introduced *reimbursement on a per-member, per-month* basis and used the fees generated to cover the cost of case management. Two studies^{59,92} describe the use of an

enhanced fee-for-service program as part of their financial model. The Group Health PCMH pilot study⁶³ reduced providers' panel size and increased appointment time length to accommodate the different design component of the intervention; this study also changed provider compensation from a fee-for-service model to fixed-salary compensation without relative value unit (RVU)-based adjustments. In the Geisinger's ProvenHealth Navigator study,⁹² there were several changes to the reimbursement model. They created a hybrid program with *fee-for-service* payments, payments for achieving certain quality and efficiency targets determined jointly by the providers and health plan teams, and stipends to support the PCMH implementation changes within the practices.

Functional PCMH Studies

Six functional PCMH studies^{66,67,82,94,107,111} described some aspect of their financial model. Four studies received funding to support components of their interventions.^{66,67,94,111} One study was funded by a grant to support its intervention with a Geriatrics Assessment Team,⁹⁴ and another received separate funds from their health care system without significant changes to the care reimbursement of the clinic practices for funding of its Guided Care Nurse and for administrative support.⁶⁶ One large national intervention, called the Healthy Steps pediatric program,⁶⁷ was funded by The Commonwealth Foundation and by local organizations, which developed and supported certain aspects of the intervention. The Colorado Regional Integrated Care Collaborative (CRICC) pilot program¹¹¹ received some of its program funding from the Colorado Health Foundation.

One functional PCMH intervention implemented a *reimbursement program on a per member, per month* basis, and used these fees to cover the cost of the services provided as part of the intervention.⁸² Two studies^{82,107} offered extra compensation for providers' time spent on aspects of the intervention that detracted from their clinical time and productivity, such as collaborating with other providers who were often located in different clinics,¹⁰⁷ or developing and implementing guidelines for the intervention.⁸² The CRICC pilot program,¹¹¹ which provided care to certain Medicaid recipients, received much of its funds through a capitated risk contract with the state.

Organizational Learning Strategies

Organizational learning strategies were defined as the mechanisms through which providers and staff gained knowledge about, or provided feedback about, how to make their practice more consistent with PCMH. Categories of organizational learning strategies abstracted for this review included:

- a. *Formal learning collaboratives*, such as lectures and training sessions
- b. *Collaborative program planning*, such as team meetings to educate and to get feedback regarding ongoing processes for the purpose of improvement
- c. *Community of practice*, in which groups of professionals from different practices could consult each other and work together to improve care with a common goal
- d. *Designated research/project team assistance* for PCMH development and implementation, usually from the study team
- e. Use of *implementation toolkits*, often designed by the study team, to help practices develop PCMH functions, conduct audit and feedback, and learn other techniques to help with implementation of PCMH
- f. Other

When we abstracted data, we found that the first two categories were often combined, so we have grouped them together below and in Table 20.

PCMH Studies

Among the nine PCMH interventions, eight^{60,63,92,93,102-105} described the use of *formal learning collaboratives* and/or *collaborative program planning*, which were often combined. A majority of these strategies took the form of regularly scheduled team meetings to discuss issues such as clinic work-flow,⁹² to provide feedback regarding program design and interventions,^{60,105} and to provide a forum to discuss experiences.⁶⁰ Formal didactic sessions (with continuing medical education) were often offered on topics about PCMH,¹⁰⁴ community-based services and clinic policies,⁹³ or health literacy.¹⁰⁵ For example, the National Demonstration Project (NDP)⁶⁰ held four 2-day learning sessions over a 2-year period with two representatives from each intervention clinic. In the didactic sessions, presenters discussed PCMH programs and demonstrated technologies that enabled the implementation. Some sessions were interactive and allowed members of different teams to network and share ideas.

Three studies^{59,60,103} describe a *community of practice* in which intervention practices had regular contact for sharing their experiences. Two studies^{59,60} had monthly conference calls among practice providers to discuss their progress and barriers toward achieving PCMH intervention goals, while the third¹⁰³ had face-to-face meetings among physicians of six practices to discuss issues around practice management.

Two studies^{60,102} had *designated research/project team assistance* from study team members (external to the clinic staff) who provided training in PCMH process implementation and were available to help or advise clinic staff either on- or off-site, via email or phone. For example, the NDP⁶⁰ had a total of 3 facilitators for the 36 intervention clinic sites who assisted with clinic implementation of the PCMH components. These facilitators made initial site visits of 2-3 days' duration in order to get to know the practice via in-depth interviews and observations. They also made subsequent on-site visits during the intervention period. However, the majority of their facilitation was provided during monthly conference calls, when multiple intervention practices shared their ideas and experiences, or through email, where facilitators could provide more clinic-specific recommendations.

Two PCMH studies^{60,102} described their use of *implementation tool-kits*. These studies provided online resources and manuals to help clinic staff with implementation changes.

Functional PCMH Studies

Eleven of the 13 functional PCMH studies^{65-67,82,83,86,88,107,108,110,111} describe employing interventions that involved *formal learning collaboratives* and/or *collaborative program planning sessions*, which often overlapped in their function. For example, the Guided Care intervention^{65,66} contained an intensive 9-week program for nurses who were the designated Guided Care Nurses for a group of intervention clinics. The planning sessions consisted of didactic lectures, assigned readings, and learner participation in motivational interviewing, along with skill development through interactive role-playing. In addition, this intervention included meetings of the clinic managers, their assigned Guided Care Nurses, and study team members to discuss current implementation problems and plan future implementation steps. The CRICC pilot program¹¹¹ utilized an established training program, Care Management Plus, to train care

managers. This involved using many learning modules which covered aspects of care such as patient coaching, motivational interviewing, and chronic disease management issues.

Two studies^{67,108} described a mechanism for *community of practice*. For example, the Healthy Steps pediatric intervention⁶⁷ facilitated monthly telephone calls during which the practices received technical assistance from the study team and discussed issues surrounding implementation strategies and best practices.

Three of the larger, multi-site studies^{67,82,111} provided designated research/project team assistance. The Medicare Coordinated Care Demonstration (MCCD)⁸² designated a study team member (an advanced practice nurse [APN] consultant) to work closely on-site with multiple practices to guide program improvement, guideline development, and implementation. The Healthy Steps program⁶⁷ created a National Advisory Committee, which conducted an initial evaluation of the 15 implementation sites and provided resources, oversight, and leadership, but which did not provide on-site direct assistance. The CRICC pilot program assigned “highly experienced registered nurses” to supervise all care managers.

Two of these large studies^{67,82} created *implementation tool-kits* to help intervention practices with programmatic changes. Examples of tool-kits include pocket cards, Web resources,⁸² and a training videotape with manual.⁶⁷

Implementation Strategies

Implementation strategies are methods employed by the practices to implement the changes needed to be more consistent with PCMH, as well as the methods used to measure the impact of the PCMH transformation on clinical care processes or outcomes. The categories of implementation strategies initially used for data abstraction for this review include:

- a. *Audit and feedback* to providers, teams, and/or clinics
- b. *Quality improvement measures*
- c. *Academic detailing*
- d. *Lectures/classes for staff* (i.e., didactic education)
- e. *Designated clinical champion* (facility/practice level)
- f. *Designated project manager* (facility/practice level)
- g. *Plan-Do-Study-Act cycles/rapid cycle improvement mechanisms*
- h. *Flow mapping of care system*
- i. *Total quality improvement/continuous quality improvement*
- j. *Strengths-weakness-opportunities-threats analysis*
- k. *External benchmarking* at the organizational level
- l. Other

Through the data abstraction process, we found that we often had to draw some inferences regarding the implementation strategy from the description of the process of change in order to categorize them. We also combined some of these categories when clear distinctions could not be made, as described below, and as indicated in Table 20.

PCMH Studies

The most commonly described implementation strategy among the nine PCMH interventions was some form of *audit and feedback* or more formal measures of *quality improvement* either at the provider level or the practice level. Six interventions^{59,60,63,92,104,105} involved some form of practice performance review and feedback to the practice team, with the overall goal of

improving implementation of PCMH changes. Examples of the audit and feedback mechanism included a visual reporting system to track changes⁶³ and a compilation of outcomes and quality metrics, with performance reports and recommendations regarding modification of methods provided back to the practices.⁹² One study¹⁰⁴ conducted monthly meetings led by practice quality improvement (QI) teams, while most studies did not describe such formal meetings.

Some interventions employed an implementation strategy very similar to the previously described organizational learning forums. Four PCMH interventions^{60,102-104} employed *academic detailing* or *lectures and classes* for clinic staff, sometimes within the informal setting of team meetings, as forums to discuss changes in implementation strategies. For example, the Illinois Medical Home Project¹⁰⁴ held three learning sessions over an 18-month period for implementation training and practice quality improvement.

Four interventions^{59,60,93,105} had *designated clinical champions* or *project managers* to assist with implementation of PCMH changes. These individuals, primarily from the study team and not a part of the clinical practice, provided guidance on PCMH implementation and improvement strategies. For example, for the Medical Home project of the Texas Children's Health Plan (TCHP),¹⁰⁵ an individual from the TCHP Health Promotion Program was responsible for implementing PCMH changes within their assigned practices, taking into account each practice's unique environment.

Three interventions^{63,92,104} implemented *rapid cycle improvement* mechanisms for evaluating changes that occurred. The Group Health PCMH initiative⁶³ used "team-based rapid process improvements" to incorporate changes into their clinic practice. Geisinger's ProvenHealth Navigator program⁹² also used the process of rapid cycle innovation to make short-cycle changes to care coordination processes for patients with chronic medical conditions. Similarly, the Illinois Medical Home Project utilized the *Plan-Do-Study-Act* cycle of practice improvement for their PCMH implementation.¹⁰⁴

Functional PCMH Studies

Seven of the 13 functional PCMH studies^{65,67,82,83,86,108,109} employed techniques of *audit and feedback* or *QI initiatives* to enhance implementation of PCMH changes in their practices. One study⁸⁶ tracked tasks that were due but not yet completed from individual patient care plans and kept a "tickler list" for the practice care manager. The other six studies^{65,67,82,83,108,109} generated performance reports with process of care, clinical outcomes, and financial information for practice team members to review and improve performance.

Six interventions^{67,86,88,107,108,111} used *academic detailing* or *lectures/classes* for staff to implement the care coordination changes. As previously noted, this strategy was similar to *collaborative program planning* forums and could not necessarily be distinguished from them. Within these academic detailing sessions, the study team provided updated care guidelines or made recommendations of changes to their care processes for further implementation. For example, one study¹⁰⁸ conducted quarterly meetings to present data on quality indices and resource utilization in order to help optimize these measures in future performance audits. The CRICC pilot program¹¹¹ held weekly multidisciplinary consultations with a medical director and also held regular treatment team meetings at the larger clinic sites.

Only 1 of the 13 functional PCMH studies clearly described having a *designated clinical champion* or *project manager*. The Group Health Cooperative of Puget Sound intervention⁸³ designated a member of the practice team as the leader of the new intervention who would "...assume responsibility for organizing meetings, setting long-term strategy, and maintaining a

vision.” While in the four PCMH studies the clinical champion was a member of the study team and external to the practice, in the Group Health Cooperative study the champion was a member of the practice.

One of the functional PCMH studies¹¹¹ described a type of *rapid cycle improvement* mechanisms for evaluating changes that occurred during the implementation phase of the program. This internal evaluation process was said to be modeled on the multimethod assessment process/reflective adaptive process.¹¹² This study also collected both quantitative and qualitative data through meeting minutes, key informant interviews, and surveys as part of its internal evaluation process. However, this study did not describe exactly how these data were used to inform changes.

Key Question 4. Horizon Scan of Ongoing PCMH Studies

KQ 4: What primary care–based studies evaluating the effects of comprehensive PCMH interventions on patient and staff experiences, process of care, clinical outcomes, or economic outcomes are currently under way? In these ongoing studies, what are the study designs, PCMH components, comparators, settings, financial models, and outcomes to be evaluated?

Key Points

- We identified 31 ongoing studies of comprehensive PCMH interventions that specified a comparison group and met our other inclusion criteria.
- Studies included a broad representation of geographic areas, with individual studies mostly conducted within a single state.
- Only 2 of the 31 studies were RCTs; the remainder were quasi-experimental or observational studies.
- Seventy-one percent (71%) of studies are scheduled for completion in 2012.
- The studies differed in the specific PCMH components they specified. The median number of components specified across all studies was 3.5 (of a possible 7). The most infrequently reported PCMH components were *comprehensiveness* and a *sustained partnership* (27% each).
- Several different financial models for PCMH implementation were reported. Enhanced fee-for-service was reported in 19 percent of studies. Bundled payment per member and pay for performance were each reported in 23 percent of the ongoing studies.
- Most studies intend to collect outcomes pertaining to patient or staff experiences, processes of care, and economic outcomes. Only one-third of studies reported an intention to collect and report on clinical outcomes.
- Limited information reported on ongoing studies restricted our ability to ascertain study design, components of the PCMH included, comparison interventions, and planned outcomes with certainty. Many ongoing demonstration projects were excluded because they lacked sufficient detail to meet our inclusion criteria.

Detailed Analysis

The sources searched for KQ 4 are detailed in the Methods chapter. Searches of all sources identified 900 citations, of which 204 were selected for further independent review by two

investigators. After this review, we included 31 records that described ongoing or planned evaluations of PCMH interventions that were conducted in the United States and included a comparison group for the evaluation. Among the reviewed PCMH demonstration projects, the most common reason for exclusion was the lack of a comparison group specified in the evaluation plan. Most of the included records came from online databases that catalogued ongoing projects affiliated with the sponsoring organization. This included: 10 citations/studies from the Patient Centered Primary Care Collaborative (PCPCC);¹¹³⁻¹²² 10 citations/studies from enGrant scientific (a database of federally sponsored research);¹²³⁻¹³² 4 from The Commonwealth Fund;¹³³⁻¹³⁶ 2 each from Robert Wood Johnson Foundation^{137,138} and Clinicaltrials.gov;^{139,140} and one from the CMS Web site.¹⁴¹ Direct email contact to representatives of CMS and the Department of Veterans Affairs yielded one additional study.¹⁴² In addition to this primary search, we used a published horizon scan on PCMH based on semi-structured interview of lead personnel as an additional resource.⁴⁶ This review identified one additional study for inclusion.¹⁴³ These sources varied significantly in the level of detail provided, with most providing one to two paragraphs of description, while others provided reports exceeding 100 pages. Nearly three-quarters of these studies are targeted for completion in 2012.

The number of participating patients, providers, and clinics was reported for 56 percent of the included studies. Twelve studies were conducted exclusively in adults, 1 study in children, 5 studies in both adults and children, and 13 studies did not specify the population. Among studies for which data were available, the median number of patients was 27,000 (range 300–2,000,000); the median number of participating providers was 66 (range 8–7618); and the median number of participating clinics was 14 (range 1–1200). The number of patients was often based on the number of covered lives under a particular insurance program and may not reflect the number of patients receiving care within a PCMH.

Table 21 summarizes the most important characteristics of the 31 ongoing studies. The majority of these are being conducted in a single state, in cooperation with a single insurance payer. While several payers, such as Humana and Blue Cross/Blue Shield, supported projects in multiple states, the extent of collaboration across states was not clear. Overall, the included studies broadly represented different geographic areas of the United States. Two studies were RCTs with randomization at the patient level. There were no cluster randomized controlled trials, and the remainder of studies were quasi-experimental or observational evaluations of PCMH interventions. For many of the studies, it was difficult to ascertain clearly the level of care received by the comparator groups. The term “usual care” can vary substantially across different settings, yet this was the most common comparator reported. This was followed by studies comparing differing levels of PCMH implementation, in which practices were considered to be more or less of a comprehensive medical home.

Table 21. Characteristics of ongoing studies (n = 31)

Study Characteristic	Number of Studies (%)^a
Organizing entity:	
Commercial insurer	16 (52)
Federal government	4 (13)
State government	2 (6)
Other	7 (23)
Not reported	4 (13)
Research funder:	
AHRQ/NIH/CMS	11 (35)
Veterans Health Administration	2 (6)
Commercial insurer	1 (3)
Foundation	7 (23)
Not reported	10 (32)
Region:	
Multistate	7 (23)
Single state	24 (77)
Northeast/mid-Atlantic	6
Southeast	6
Midwest	6
West/mountain	6
Study design:	
RCT	2 (6)
Quasiexperimental or observational	29 (94)
PCMH components:	
Team-based care	15 (48)
Enhanced access	14 (45)
Coordinated care	14 (45)
Comprehensiveness	9 (29)
Systems-based quality improvement	17 (55)
Sustained partnership	9 (29)
Reorganization of care delivery	19 (61)
Median number of components implemented per study:	3.5
Comparators:	
Usual care	19 (61)
PCMH levels	14 (45)
Other quality improvement approach	1 (3)
Financial models:	
Enhanced fee for service	6 (19)
Bundled payments per member	7 (23)
Pay for performance	7 (23)
Other	5 (16)
No change reported	13 (42)
Outcomes:	
Patient or staff experiences	21 (68)
Process of care/quality	27 (87)
Clinical outcomes	11 (35)
Economic/utilization outcomes	28 (90)
Projected completion year:	
2010	3 (10)
2011	6 (19)
2012	13 (42)
2013	3 (10)
2014	1 (3)
2015	1 (3)
Not reported	4 (13)

^aNumbers of studies (percentages) do not total 31 (100%) for every row, as some studies had more than one of the characteristics listed.

Notes: AHRQ = Agency for Healthcare Research and Quality; NIH = National Institutes of Health; PCMH = patient-centered medical home; RCT = randomized controlled trial

The studies differed in the PCMH components specifically included in the ongoing study. The median number of components reported across all studies was 3.5 (of a possible 7). The most infrequently reported PCMH components were *comprehensive care* and a *sustained partnership*, each of which was reported in only 29 percent of the included studies. Nearly half of the ongoing studies did not specify any financial support for PCMH implementation. Among studies that did report details of their financial models, the most common approaches were enhanced fee-for-service, bundled payment (usually per member/per month), and pay for performance based on prespecified targets. Most studies intend to collect outcomes on patient or staff experiences, process of care measures, and economic outcomes; only one-third specified clinical outcomes as part of their planned analysis.

Further details of these studies are provided in Appendix J.

Discussion

Although few studies have evaluated the effects of the medical home specifically, a moderately well-developed series of trials and observational studies have tested interventions meeting the functional definition of the medical home. Most of these evaluations focused on older adults with multiple chronic conditions. The effects across a range of important outcomes (Key Question [KQ] 1) are summarized in Table 22.⁵⁷ In brief, there is moderately strong evidence that the medical home has a small positive impact on patient experiences and small to moderate positive effects on preventive care services. Staff experiences are also improved by a small to moderate degree (low strength of evidence [SOE]), but no study reported effects on staff retention. Current evidence is insufficient to determine effects on clinical and most economic outcomes. We judged the strength of evidence as low for an association between PCMH and lower healthcare utilization (combination of inpatient and primarily emergency department utilization), but estimated effects were imprecise. Further, we did not find evidence of an effect of PCMH on total costs. Given the relatively small number of studies directly evaluating the medical home, and the evolving approaches to designing and implementing the medical home model, these findings should be considered preliminary.

Rating the SOE for this body of evidence was challenging because the range of study designs, populations, and outcomes precluded quantitative summaries for most outcomes. We thus did not have the usual quantitative tools that are part of meta-analyses for assessing consistency and precision.

Key Findings and Strength of Evidence

KQ 1. Effects of PCMH Interventions

Table 22 summarizes the strength of evidence for various outcomes evaluated for KQ 1. Note that the information summarized relates to comprehensive patient-centered medical home (PCMH) and comprehensive functional PCMH interventions. It is uncertain whether particular PCMH components (e.g., enhanced access) or the particular methods used to implement those components (e.g., telephone visits) are associated with greater effects than usual primary care.

Table 22. Summary of the strength of evidence for KQ 1

Outcome [SOE & Magnitude of Effect^{a,b,c}]	Number of Studies (Subjects)	SOE Domain–Risk of Bias: Study Design/Quality	SOE Domain–Consistency	SOE Domain–Directness	SOE Domain–Precision	Effect Estimate (Range or 95% CI)
Patient Experiences [Moderate SOE: small positive effects]	5 (6,884)	RCT/Fair	Consistent	Direct	Precise	ES median (range): 0.27 (-0.36 to 0.42)
	2 (3,513)	Observational/Fair	Inconsistent	Direct	Precise	ES: ^d +0.13
Staff Experiences [Low SOE: small to moderate positive effects]	2 (NR)	RCT/Fair	Inconsistent	Some indirectness	Imprecise	ES median (range): 0.18 (0.14 to 0.87)
	1 (82)	Observational/Fair	Unknown	Direct	Imprecise	ES median (range): 0.49 (0.32 to 0.61)
Process of Care for Preventive Services [Moderate SOE: small to moderate positive effects]	3 (8,377)	RCT/Fair	Consistent	Direct	Precise	RD median (range): 1.3% (-0.4% to +7.7%)
	2 (57,832)	Observational/Fair	Consistent	Direct	Precise	RD median (range): 14.2% (5.6% to 20.6%)
Process of Care for Chronic Illness Care Services [Insufficient]	2 (4,640)	RCT/Fair	Inconsistent	Some indirectness	Precise	RD median (range): 6.6% (0.2% to 20.8%)
	3 (455,832)	Observational/Fair	Seriously inconsistent	Some indirectness	Precise	RD median (range): 7.1% (7.1% to 21.4%)
Clinical Outcomes: Biophysical Markers, Health Status, Mortality [Insufficient]	3 (2,586)	RCT/Good	Consistent	Some indirectness	Imprecise	Not reliably estimated
	3 (58,393)	Observational/Poor	Consistent	Some indirectness	Imprecise	Not reliably estimated

Table 22. Summary of the strength of evidence for KQ 1 (continued)

Outcome [SOE & Magnitude of Effect ^{a,b,c}]	Number of Studies (Subjects)	SOE Domain–Risk of Bias: Study Design/Quality	SOE Domain–Consistency	SOE Domain–Directness	SOE Domain–Precision	Effect Estimate (Range or 95% CI)
Economic Outcomes: Hospital Inpatient Admissions, ED Visits, Total Costs^e [Low SOE for Lower ED visits in older adults and no reduction in admissions; insufficient for total costs in adults; insufficient for all economic outcomes in children]	5 (8,001)	RCT/Fair	Consistent	Some indirectness	Imprecision	Admissions: RR 0.96 (95% CI, 0.84 to 1.10) in adults; ED visits: RR 0.81 (95% CI, 0.67 to 0.98) in adults; total costs: no summary estimate
	6 (229,883)	Observational/Fair	Consistent	Direct	Precise	Admissions: RD median (range): -0.2% (1.4% to -8.9%); ED visits: RD median (range): -1.2% (3.1% to -8.3%); total costs: no summary estimate
Unintended Consequences or Other Harms [Insufficient]	0	NA	NA	NA	NA	No estimate

^aSOE ratings are provided for outcomes overall (incorporating evidence from all studies), while magnitude-of-effect estimates are provided for RCTs vs. observational studies. The effect size for economic outcomes represents a summary estimate of effect from meta-analysis. Other effect sizes are presented as the range across individual studies.

^bIn one study,⁶⁰ a program of facilitated PCMH (intervention) was compared with providing practices with information on PCMH but not facilitating the implementation (control). This study generally showed no differences on the key outcomes addressed. Both arms implemented components of the PCMH model, and this may be why there were no significant differences between them.

^cThe small number of studies conducted among children precluded formal comparison with studies conducted in adults. However, results in these two populations were generally congruent.

^dThe effect size for one of the two available observational studies could not be calculated with available information.⁷² As a result, an effect size median and range could not be calculated.

^eTwo of the 13 studies that reported economic outcomes—one RCT⁹⁴ and on observational study⁸¹—reported only total costs and so did not inform the summary effect estimates reported in this table.

Notes: CI = confidence interval; ED = emergency department; ES = effect size; KQ = Key Question; NA = not applicable; NR = not reported; RCT = randomized controlled trial; RD = risk difference; RR = risk ratio; SMD = standardized mean difference; SOE = strength of evidence

KQ 2. PCMH Components Implemented

A summary of the most important findings for KQs 2–4 is provided in Table 23.

For KQ 2, 21 of 27 studies described interventions that included all 7 major PCMH components. Studies varied greatly in the number and types of approaches used to implement these core components; overall, 51 different strategies or approaches were used. PCMH studies used a greater number of strategies than did functional PCMH studies. Most studies addressed chronic illness, preventive care needs, and acute care needs; used multidisciplinary teams; and

coordinated care transitions. Over three-quarters reported adding new staff. All but three studies used strategies to enhance access, but no single strategy was employed by a majority of studies. Identifying high-risk patients and using evidence-based clinical guidelines, performance monitoring, and electronic health records were the most commonly used approaches to improving quality and safety.

KQ 3. Financial Models and Implementation Strategies

Implementation of PCMH requires significant restructuring for most primary care practices. Recognizing the increased range of services required and the cost of implementation, some definitions of the medical home include a financial component, but this was not a requirement for inclusion in our review. Among the 27 included studies, only 11 described aspects of their financial model. These studies used a variety of methods to fund PCMH implementation, including receipt of external study funding, capitation payments or salaried providers, or a hybrid approach.

While it is likely that both organizational learning and implementation strategies are necessary for implementation of complex interventions,^{16,144} we recognize that there can be significant overlap in these concepts. The most commonly employed organizational learning strategy, used in a majority of studies (n = 19), was either a formal learning collaborative or collaborative program planning forums for practice team members to learn about PCMH or its components. For implementation, over one-half of studies used audit and feedback, usually employing quality improvement methodology. The largest trial of PCMH found that facilitated PCMH was associated with better staff experience than nonfacilitated PCMH,⁷⁸ which qualitatively was shown to be important for PCMH implementation.¹⁴⁵ This may indicate that the impact of PCMH on practices may go beyond simply having the identified elements in place. The process of facilitation may also represent an important part of the process for making PCMH successful.

KQ 4. Horizon Scan of Ongoing PCMH Studies

We identified 31 ongoing studies evaluating the medical home. Only two of these are randomized controlled trials (RCTs). Most studies report plans to evaluate patient or staff experiences, process of care outcomes, and economic outcomes. Many studies also plan qualitative and quantitative assessments of implementation to better understand how care can be successfully transformed according to this model. These studies appear to be broadly representative of the U.S. health care system, both in geography and in the complexity of private and public health care payers and delivery networks. The cooperation of many of these evaluation projects with commercial insurers is particularly encouraging given the importance of implementing medical homes in a way that is financially sustainable for payers and providers alike. Most of these studies will be complete within the next 2 years, which means that the extant literature will grow significantly in the near future.

There are many ongoing PCMH demonstration projects that were not included in this horizon scan. Some of these are large and may contribute important information, such as the CMS Federally Qualified Health Center Advanced Primary Care Practice Demonstration, which plans to include 500 health centers and almost 200,000 Medicare beneficiaries.¹⁴⁶ However, we chose to include only those studies that specified a comparator group for evaluating the PCMH. Many of the excluded demonstration projects may in fact include appropriate comparators to determine the impact of PCMH, but did not provide this detail in the limited grey literature available to us.

Because of this limitation, we believe the number of studies reporting the impact of the PCMH in the next few years will exceed the list catalogued in the horizon scan.

Table 23. Summary of findings for KQs 2–4

KQ2 – PCMH Components Implemented
Variability in components: Although most studies reported implementing most of the seven major medical home domains, studies varied considerably in their approach to implementing major components (e.g., variable approaches to enhancing access to care).
Evaluation of specialty care: Few medical home studies directly address medical specialty care (n = 6) or mental health specialty care (n = 3).
KQ3 – Financial Models and Implementation Strategies
Financial models: Few medical home studies (n = 11) provided detailed information about the financial models used to support the medical home. Financial models described included enhanced fee-for-service, additional per-member per-month payments, stipends to support aspects of the intervention, and payments linked to quality and efficiency targets.
Organizational implementation strategies: Audit and feedback were the most commonly used specific strategies to implement the medical home, described in 13 studies.
Organizational learning strategies: Learning collaboratives and collaborative program planning were the most commonly used organizational learning strategies, described in 19 studies.
KQ4 – Horizon Scan of Ongoing PCMH Studies
Ongoing studies: A relatively large number of studies evaluating the medical home are scheduled to conclude within the next 2 years. However, only 2 of the 31 studies are RCTs. Most studies report planned outcomes of: patient or staff experiences, process of care outcomes, and economic outcomes. These studies appear to have the potential for improving our understanding and the strength of evidence for a range of important outcomes.

Notes: KQ = Key Question; PCMH = patient-centered medical home; RCT = randomized controlled trial

Findings in Relationship to What Is Already Known

The PCMH model is built on a solid research foundation, including findings that greater access to primary care is associated with better population health outcomes and lower costs.¹⁴⁷ The chronic care model (CCM),^{15,16} a conceptual model for organizing chronic illness care, is the cornerstone of the medical home model. In adults, interventions based on the CCM have been shown to improve health outcomes across a range of chronic conditions, including congestive heart failure, diabetes mellitus, and major depression.¹⁷ In children and adolescents, the CCM is associated with better outcomes for obesity¹⁴⁸ and asthma.¹⁴⁹ However, these studies typically focused on single chronic conditions. By contrast, this review evaluated PCMH interventions that were more broadly conceptualized and tested in more general populations.

For our review, we evaluated the effects of interventions designed to improve care for all or most patients served by a health care organization, not just a specific group of patients such as those with a given illness or set of illnesses. Compared with narrative reviews of PCMH,^{50,150} or reviews of selected components of the medical home,⁴⁷ our results suggest less certainty about the benefits of the PCMH. These narrative reviews often included a broader range of study designs, including designs with a higher risk of bias, than did our review. Compared with systematic reviews of care models tested for single diseases,^{17,151,152} our review is generally consistent with the findings of improvements in patient experiences, but contrasts with these reviews in finding insufficient evidence for improved clinical outcomes. A recent systematic evaluation of 14 higher quality medical home studies covering 12 separate interventions^{153,154} found similar results to our review, concluding that: (1) there were some positive effects for quality, costs, and patient/family experience, and a few negative effects on costs and many inconclusive results; (2) the model is rapidly evolving; and (3) PCMH is a promising innovation, but stronger evaluations are needed to guide model development and implementation. In a related work,¹⁵⁵ the same research group found that extant studies are underpowered for some

key outcomes, particularly economic outcomes. Our review adds new information by showing some support for positive effects on staff experiences, and by providing detailed descriptions of the components implemented and the financial models and implementation strategies used to facilitate adoption. Our review is also consistent with a previous horizon scan⁴⁶ showing that a wide range of ongoing studies are evaluating the medical home, with the potential to address important gaps in evidence.

Applicability to Primary Care in the United States

Overall, studies tended to focus on specific populations of patients (e.g., older adults, children with special health care needs). Many included priority populations as identified by the Agency for Healthcare Research and Quality (AHRQ) or the Institute of Medicine (IOM), but applicability to broader, generally healthier primary care populations is uncertain. Most studies tested an intervention that met the AHRQ definition of PCMH but were not an explicit test of the medical home. Further, these “functional PCMH” studies had fewer strategies for implementing the core components of PCMH than studies explicitly evaluating PCMH. Therefore, these studies collectively may be a less robust test of PCMH and less applicable than ongoing studies of PCMH. With one important exception, controlled studies included for KQ 1 evaluated the effect of PCMH interventions against usual care. The American Academy of Family Physicians National Demonstration Project (AAFP NDP), a multicenter RCT, compared facilitated versus nonfacilitated implementation of the PCMH.⁶⁰ This study demonstrated that motivated practices, even without expert facilitation, can implement the key elements of the PCMH model of care.

Among comparative studies, we abstracted outcomes in five broad domains. Collectively, these studies evaluated a broad range of clinical and economic outcomes. However, studies did not report unintended consequences or effects on staff retention; few reported a comprehensive set of outcome measures; and the longest followup was 2 years. Some outcomes (e.g., mortality, overall costs) may require larger and longer-term studies to show an effect.

Most comparative studies were fielded in integrated delivery systems (9 of 17 studies included in KQ1). Many of these health care systems have lengthy histories of extensive quality improvement programs.¹⁵⁶⁻¹⁵⁹ For example, the CCM, which forms much of the basis of current PCMH definitions, was developed at the Group Health Cooperative of Puget Sound.⁷⁴ Two studies included in KQ 1 were conducted at Group Health.^{63,83} Practices participating in the large AAFP-NDP had a mean of 46 percent of the model components in place at baseline (range 20 percent to 70 percent).⁶² Studies conducted in organizations that are early adopters or with multiple PCMH components already in place may have limited the observed effects of the PCMH intervention. It is possible that greater differences in various outcomes may be seen if the PCMH model were evaluated in organizations with fewer PCMH components in place or with a less robust history of quality improvement efforts.

Implications for Clinical and Policy Decisionmaking

Despite the fact that the United States spends a greater proportion of its gross domestic product on health care than any other country in the world (17.6% in 2009),¹ it frequently falls short on measures of quality and efficiency.²⁻⁶ The PCMH is a model of primary care transformation that seeks to meet the variety of patient health care needs and improve patient and staff experiences, health outcomes, safety, and system efficiency.⁸⁻¹¹ Based largely on studies of programs aimed at improving care for patients with chronic illnesses,²⁰ numerous large organizations have begun to implement PCMH. Some have described PCMH as having the

potential to redefine primary care and transform the organization of health care in the United States.

PCMH interventions are associated with improvements in both patient and staff experiences and preventive care processes. For policymakers concerned about the sustained viability of primary care, these results are encouraging. However, for chronic illness care and clinical outcomes, we were unable to estimate intervention effects due to the small number of studies and the varied outcome measures used. Moreover, there is insufficient evidence to determine the effects on most economic outcomes. Two recent evaluations of PCMH implementation in two highly regarded health care systems point to reduced inpatient and emergency department utilization, but these results were not reflected in reduced total cost.^{71,97} Two studies reporting significant cost differences actually pointed generally towards higher costs. This was related to having increased access to services⁵⁹ and/or reduced program fees.^{59,84} Lowering costs or improving outcomes can increase the value of health care. The improvements in patient experience and preventive care suggest that PCMH may increase value, but until better data are available for effects on chronic illness care, clinical outcomes, and total costs, this value metric will remain uncertain.

For some organizations, the conceptual promise of PCMH, coupled with the current positive but limited evidence, will be sufficient to proceed with implementation. Which strategies are the most promising to implement and how should implementation be facilitated? Published studies of PCMH interventions by definition have similar broad components (e.g., teams, enhanced access, coordinated care, a comprehensive focus, system-based approaches to improving quality and safety, sustained partnerships, and reorganization of care); however, precise components of care vary widely. As a result, one organization's version of PCMH may not look like another organization's version. We were not able to identify specific PCMH components that were associated with greater effects, but our descriptions of the range of strategies employed, helps to answer the "What is possible?" question. From a practical perspective, payers may require a medical home designation that meets requirements by NCQA or other certifying bodies. The processes used to actually implement the PCMH components were often not well described. As a result, we do not yet know details about "the best way" to implement PCMH. However, complex interventions and practice transformation do not happen spontaneously; they require support and a viable financial structure. Most studies included in our review used structured implementation approaches.

Finally, the 31 ongoing studies identified through the KQ 4 horizon scan, most to be completed within the next 2 years, have great potential to add to our understanding of the impact of PCMH. These second-generation studies have the potential to show greater impacts than has been reported in the literature published to date.

Limitations of the Review Process

The PCMH is a model of care with considerable flexibility, not a narrowly defined intervention or manualized protocol. Further, multiple definitions of the PCMH model have been proposed by various professional and patient organizations.²² We developed an operational definition, derived from the AHRQ definition of the medical home,⁸ which does not require an enhanced payment model, to identify eligible interventions. Because we used the AHRQ definition, our review was more inclusive of studies that tested the critical principles that embody the IOM concept of patient-centered care.¹⁶⁰ However, greater inclusivity came with the trade-off of greater variability in study interventions. The general nature of the intervention also

complicated our literature search, given the potential for relevant studies that did not use the term “medical home” and the lack of MeSH terms for this topic. An additional challenge was identifying relevant non-RCTs since search filters for these study designs are not as well-developed or as well-validated as for RCTs.

There is no standard nomenclature for many of the concepts that form part of the definition of the medical home or for the methods used for implementing programs designed to operationalize these concepts. This lack of standard definitions also leads to a wide variety of measures for PCMH components. The lack of standardized nomenclature and measures is a particular issue for studies seeking to describe quality improvement approaches or financial models used to implement PCMH. Similarly, some specific PCMH features (e.g., electronic health record) could fit into more than one PCMH component. The lack of a standard nomenclature and the often sparse reporting of interventions made uniform data abstraction and classification of intervention components particularly challenging.

Heterogeneity in study designs, populations, and outcomes meant that standard quantitative summary methods were generally not possible. Much of this variability is appropriate. For example, studies included different populations (e.g. adults, children). The needs of these patients differ, as do the locations in which they are often treated. Further, there is no consensus on what types of outcomes should be addressed when determining if PCMH “works.” We also faced difficulties in implementing our planned qualitative cross-case analysis to determine components and approaches most associated with benefit. There were simply too few studies for each outcome to complete this planned analysis.

The variable number of publications per study, some using multiple publications and others using only a single publication to describe the intervention, may have limited the description of the different PCMH components, financial models, and leaning and implementation strategies. Queries to study authors may have reduced missing information, but may also have introduced recall bias.

Finally, the horizon scan conducted for KQ 4 has important limitations. Many of the included citations provided only sparse detail on the population, design, and outcomes, which limited our ability to completely evaluate each PCMH project. This may have led to the exclusion of studies that would have met our criteria had they reported sufficient detail. Even among the included studies, the paucity of detail carries with it the risk of misclassification, with the likely bias toward underrepresentation of the full study detail.

Limitations of the Evidence Base

Only 6 of the 27 studies included in this review evaluated an intervention that was explicitly developed using current definitions of PCMH, and only 2 of these 6 were RCTs. Across all studies, only six were judged to be good quality. Some of the limitations that led to lower quality ratings were failure to account for clustering within practices and/or the organization in the analyses, lack of clear eligibility criteria, lack of blinding when assessing outcomes, and clinical outcome measures of uncertain validity.

As described above, PCMH is a flexible model of care as opposed to a more discrete intervention such as a drug or device. Given this flexibility, detailed descriptions are particularly important, but study descriptions were often inadequate to fully characterize the intervention, much less permit replication. Complex interventions like PCMH will likely require separate publications to fully describe the intervention. We encourage editors to support this practice and

authors to consider recommendations for intervention reporting such as described by Glasziou et al.¹⁶¹

Relatively few studies reported outcomes for any of the five outcome domains used in this report. More than one-third of studies reported outcomes for one domain, only two reported outcomes across four domains, and no study reported results in all five domains. We did not expect that individual studies would report the entire range of outcomes; such studies would likely require a prohibitive level of resources. However, the lack of more comprehensive outcomes, combined with the wide variability in outcome measures, limited our ability to draw strong conclusions about the effectiveness of PCMH. Most of the 31 ongoing studies identified through the horizon scan intend to collect outcomes pertaining to patient or staff experiences, processes of care, and economic outcomes. However, only one-third of these studies reported an intention to report clinical outcomes. To the degree that effects on clinical outcomes are needed for policymaking, the ongoing research may not adequately address this specific gap in evidence.

The process used to implement PCMH was often not described or was described at only a superficial level. As a result, there is limited guidance on the best way for organizations to go about putting PCMH into place. Other studies have shown that complex organizational change is difficult to implement. More complete descriptions of the methods used to implement change and planned analyses to evaluate the most effective strategies are needed.

Research Gaps

The horizon scan conducted for this review identified 31 ongoing PCMH studies that are broadly representative of the U.S. health care system, both in geography and in the complexity of private and public health care payers and delivery networks. Many of these studies are being done in cooperation with payer organizations, and most are expected to be completed in the next 2 years. As a result, the evidence base related to PCMH will soon be greatly expanded. We encourage investigators to report the interventions in detail, adjust for clustering when appropriate, report meaningful quality indicators for chronic illness (both processes and clinical outcomes), and provide data related to the impact of PCMH on staff. If researchers clearly link intervention components to the core components of PCMH, this could greatly improve our understanding of the conceptual basis for interventions tested and ultimately the key features of successful models. Finally, we encourage long-term followup of results. Outcomes examined in this report rarely had followup periods longer than 2 years.

In addition to a lack of data on key outcomes addressed in KQ 1, there is an important lack of evidence concerning how programs need to be implemented if there is to be a genuine opportunity to affect outcomes. Broad changes in organizations likely require a combination of factors, such as practice guidelines to indicate aspects of high-quality care, system changes such as the PCMH to provide a roadmap for how to organize care, organizational learning strategies (e.g., learning collaboratives), and change models (e.g., Plan-Do-Study-Act cycles) to put changes into place.^{144,162} As described in the analysis of KQ 3, even basic descriptions of these aspects of interventions are often not provided in the published literature. While the AAFP NDP study, which specifically compared implementation strategies, used a variety of quantitative and qualitative methods to examine these issues,^{60,145,163} other studies generally have not done so. We encourage the explicit use of techniques of implementation research to examine the process of putting PCMH into place, aspects of the interventions that may affect effectiveness, and micro- and macro-level organizational and policy factors (e.g., readiness to implement PCMH,

organizational structure, governance, organizational culture, and healthcare market environment) that influence both implementation and effectiveness of PCMH and its components.¹⁶⁴⁻¹⁶⁷

Although ongoing studies have the potential to fill important gaps, the lack of detail contained in published research plans generates uncertainty about how well these studies will address these gaps. We therefore describe a series of research priorities in what follows.

Missing Outcomes

The strength of evidence was judged to be low or insufficient for most outcomes. Studies that address quality indicators for chronic illness care and clinical outcomes (e.g., symptom status or functional status) are urgently needed. Because PCMH is oriented towards broad populations of patients and not focused on specific illnesses, the impact on chronic illness could be attenuated. Cluster randomized controlled trials would provide the strongest evidence for effects on these outcomes, but given their high costs, quasiexperimental designs may be more feasible and could yield valuable data. Within the context of a trial, assessing unintended consequences or other potential harms would provide important new information. Unintended consequences have been observed with other quality improvement innovations,^{168,169} and considering the significant time demands required to provide guideline-concordant care,¹⁷⁰ it is possible that unintended consequences of PCMH may emerge. Evaluators should also carefully consider the outcomes most relevant to the population studied, particularly considering differences in the emphasis of the medical home and relevant outcomes for pediatric versus adult populations.¹⁷¹ For example, developmental outcomes, effects on family, school performance and school absences may be particularly important in pediatric studies.

Observational and mixed-methods designs can also provide valuable evidence, particularly with regards to real-world effects of PCMH. These designs might be particularly valuable for assessing effects on staff retention and economic outcomes. Economic outcomes reported to date focus on per-patient utilization and/or costs. This is a viewpoint that may be most helpful to payer organizations. Information on the impact of PCMH on practice costs and patient out-of-pocket costs would provide an additional important perspective on economic outcomes.

Most Important PCMH Components

We were unable to determine the PCMH components most associated with benefit. Understanding the “active ingredients” of PCMH is important to help practices with limited resources realize the greatest return on investment and to assist organizations developing certifying standards for medical home practices. Observational studies from natural experiments, comparing differing levels and different approaches to PCMH, could address this gap. In addition, as the evidence base grows, an updated systematic review could be valuable. For this latter approach to succeed, studies will need to report the details of the PCMH intervention and ideally use a more consistent set of outcome measures and nomenclature for PCMH components and measures of PCMH components. These common measures and definitions will further allow for estimates of the “dose” of the PCMH intervention (i.e., degree to which PCMH concepts are implemented).

Most Effective Implementation Approaches

PCMH is a complex intervention that will require substantial changes to most practices. Understanding the level of support needed to implement and sustain the model, including the

necessary financial context, is critical to any long-term success. Our horizon scan identified a number of studies that planned formative evaluations to identify factors associated with successful implementation. Additional studies that examine long-term sustainability are needed.

Effects of PCMH in More Representative Populations

Most PCMH studies were conducted in older adults with multiple chronic health conditions or in children with special health care needs. Studies that examine the effects in more broadly representative primary care samples are needed to fully understand the impact of this care model. Because PCMH has the potential to reduce health disparities, evaluating effects in important subgroups (e.g., socioeconomically disadvantaged) will be important.

Conclusions

Published studies of PCMH often have similar broad interventions; however, precise components of care vary widely. The interventions tested—both PCMH and functional PCMH interventions—appear to be associated with improvements in both patient and staff experiences and potentially care processes. However, there is insufficient evidence to determine the effects on clinical or most economic outcomes. Current ongoing studies identified through the horizon scan have potential to greatly expand the evidence base relating to PCMH.

In conclusion, the PCMH model is a conceptually sound approach to organizing patient care and appears to hold promise, especially for improving the experiences of patients and staff involved in the health care system. Evidence points to the possibility of improved care processes. If ongoing and future studies indicate that these improvements translate into improved clinical outcomes or economic benefit, the health care value would be increased.

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Abbreviations

AAFP NDP	American Academy of Family Physicians National Demonstration Project
ACP	American College of Physicians
AHRQ	Agency for Healthcare Research and Quality
CCM	chronic care model
CDC	Centers for Disease Control and Prevention
CDSR	Cochrane Database of Systematic Reviews
CI	confidence interval
CINAHL	Cumulative Index to Nursing & Allied Health Literature
CMS	Centers for Medicare & Medicaid Services
CRICC	Colorado Regional Integrated Care Collaborative
EHR	electronic health record
EPC	Evidence-based Practice Center
EPOC	Cochrane Effective Practice and Organisation of Care Review Group
HbA1c	glycated hemoglobin
HEDIS	Healthcare Effectiveness Data and Information Set
HMO	health maintenance organization
HRSA	Health Resources and Services Administration
HSR&D	Health Services Research & Development Service
HSRProj	Health Services Research Projects in Progress
IOM	Institute of Medicine
MD	medical doctor
MeSH	medical subject headings
NASHP	National Academy for State Health Policy
NCQA	National Committee for Quality Assurance
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIH	National Institutes of Health
NIMH	National Institute of Mental Health
NP	nurse practitioner
NR	not reported
OR	odds ratio
P4P	pay for performance
PA	physician's assistant
PACT	Patient Aligned Care Team
PCMH	patient-centered medical home
PCP	primary care provider
PCPCC	Patient-Centered Primary Care Collaborative
PDSA	Plan-Do-Study-Act
PICOTS	Populations, Interventions, Comparators, Outcomes, Timing, Settings
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QI	quality improvement
RN	registered nurse
RWJ	Robert Wood Johnson Foundation
SD	standard deviation
SMD	standardized mean difference

SOE	strength of evidence
TCHP	Texas Children's Health Plan
TEP	Technical Expert Panel
USPSTF	U.S. Preventive Services Task Force
VA	United States Department of Veterans Affairs

Appendix A. Exact Search Strings

The PubMed® search strategies described below (updated search date December 6, 2011) were adapted for use in the Cumulative Index to Nursing & Allied Health Literature database (CINAHL®, search date March 30, 2011) and the Cochrane Database of Systematic Reviews (CDSR, search date March 30, 2011). Results from Searches A and B, described below, were combined to form the full citation set.

PubMed® search strategies:

Search A (December 6, 2011):

1. “medical home” OR “health-care home” OR “advanced primary care” OR “guided care” OR “patient aligned care team” OR “pcmh[tiab]
2. Clinical[tiab] AND trial[tiab]
3. clinical trials[MeSH] OR clinical trial[PT] OR random*[tiab] OR random allocation[MeSH] OR “time points”[tiab]
4. “time series AND interrupt[tiab]
5. pretest[tiab] OR pre-test[tiab] OR posttest[tiab]
6. quasi-experiment*[tiab] OR quasiexperiment*[tiab] OR quasirandom*[tiab] OR quasi-random*[tiab] OR quasi-control*[tiab] OR quasicontrol*[tiab]
7. cluster[tiab] AND trial[tiab]
8. (study[tiab] AND continuing[tiab] OR follow-up[tiab] OR longitudinal[tiab] OR demonstration[tiab] OR intervention[tiab])
9. treatment outcome[MeSH] OR multicenter study[PT] OR comparative study[PT] OR clinical trial OR comparative[tiab] OR comparison[tiab] OR matched[tiab] OR “Evaluation Studies as Topic”[MeSH:noexp] OR “Program Evaluation”[MeSH] OR “Validation Studies as Topic”[MeSH] OR “Multicenter Studies as Topic”[MeSH] OR “Controlled Clinical Trials as Topic”[MeSH:noexp] OR “evaluation studies”[PT]
10. #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9
11. #1 AND #10

Limits:

Language: English

Not: Editorial, Letter, Practice Guideline

Search B (December 6, 2011):

1. “Patient-Centered Care”[MeSH] OR “Delivery of Health Care, Integrated”[MeSH] OR “Patient Care Team”[MeSH:noexp] OR “chronic care model” OR “system redesign” OR “systems redesign” OR “disease management”[mh] OR “patient care management”[MeSH:noexp] OR collaboratives
2. “Primary Health Care”[Mesh:noexp] OR “family practice”[mesh] OR “internal medicine”[Mesh] OR “physicians, family”[mesh] OR geriatrics[Mesh] OR “primary care”[tiab] OR chronic disease[mh] OR “ambulatory Care”[Mesh] OR “Health Services for the Aged”[MeSH] OR “Community networks”[mesh] OR “pediatrics”[Mesh] OR

- “Child Health Services”[Mesh] OR “Health Care Coalitions”[Mesh] OR (child*[tiab] AND special[tiab] AND health*[tiab]) OR “diabetes mellitus”[Mesh] OR “diabetes mellitus”[tiab] OR “depressive disorder”[Mesh] OR “major depression”[tiab] OR “heart failure”[Mesh] OR “heart failure”[tiab] OR “coronary disease”[Mesh] OR “angina pectoris”[Mesh:noexp] OR hypertension[Mesh] OR hypertension[tiab] OR hyperlipidemias[Mesh] OR hyperlipidemia[tiab]
3. clinical[tiab] AND trial[tiab]) OR clinical trials[MeSH] OR clinical trial[PT] OR random*[tiab] OR random allocation[MeSH] OR “time points”[tiab] OR (“time series” AND interrupt[tiab]) OR pretest[tiab] OR pre-test[tiab] OR post-test[tiab] OR posttest[tiab]
 4. quasi-experiment*[tiab] OR quasiexperiment*[tiab] OR quasirandom*[tiab] OR quasirandom*[tiab] OR quasi-control*[tiab] OR quasicontrol*[tiab]
 5. (cluster[tiab] AND trial[tiab]) OR (study[tiab] AND continuing[tiab] OR follow-up[tiab] OR longitudinal[tiab] OR demonstration[tiab] OR intervention[tiab])
 6. treatment outcome[Mesh] OR multicenter study[pt] OR comparative study[pt] OR clinical trial OR comparative[tiab] OR comparison[tiab] OR matched[tiab] OR “Evaluation Studies as Topic”[Mesh:noexp] OR “Program Evaluation”[Mesh] OR “Validation Studies as Topic”[Mesh] OR “Multicenter Studies as Topic”[Mesh] OR “Controlled Clinical Trials as Topic”[Mesh:noexp] OR “evaluation studies”[pt]
 7. #3 OR #4 OR #5 OR #6
 8. #1 AND #2 AND #7

Limits:

Language: English

Not: Editorial, Letter, Practice Guideline

Not: Citations from Search A

Appendix B. Data Abstraction Elements (KQs 1–3)

Primary Study Citation (Please list the first author, year, and RefID# for primary article of this study) _____

Study Objective

Does this study specifically state that it is an evaluation of PCMH or the Medical Home?

- Yes
 No

If no, is there a specific conceptual or organizational model that the study claims it is testing? (check all that apply)

- Yes – Accountable Care Organization
 Yes – Chronic Care Model
 Yes – Clinical Microsystems
 Yes – Community-based Primary Care
 Yes – Population Health Management
 - Yes – Other (please specify): _____
 None reported

What is the stated objective of this study (typically the objective from the abstract)? _____

POPULATION

Study Type and Summary

Design Detail (click one)

- RCT – Patient-level randomization
 RCT – Cluster (e.g. study location/clinic) randomization
 Non-randomized Controlled Trial
 Prospective Cohort/Observational Study – Defined by patient groups
 Prospective Cohort/Observational Study – Study location/clinic
 Retrospective Cohort/Observational Study – Defined by patient groups
 Retrospective Cohort/Observational Study – Study location/clinic
 Interrupted Time series
 Intervention and Control Groups, Pre-Post design
 Other (specify): _____

Study Sponsor

What type of organization funded the study? (pick the primary funder from acknowledgements)

- None reported
 Federal (US) – National Institutes of Health
 Federal (US) – Agency for Healthcare Research and Quality

- Federal (US) – Centers for Medicare and Medicaid Services (CMS)
- Federal (US) – Indian Health Services
- Federal (US) – Other Health and Human Services Agency
- Federal (US) – Department of Veterans Affairs
- Federal (US) – Department of Defense
- State Government (can include State Medicaid program)
- Foundation (specify) _____
- Professional Society (specify) _____
- Staff or Group Model health maintenance organization (HMO)
- International government-operated health system (not US)
- Other (specify) _____

Study Setting – Country

In what country was this study conducted? (check all that apply)

- United States
- Other (specify country) _____

Study Setting – Organization Intervention Site

In what type of organization(s) was/were the PCMH intervention done? (check all that apply)

- Not reported
- Federal (US) – Department of Veterans Affairs
- Federal (US) – Department of Defense
- Federal (US) – Indian Health Service
- State Government
- Federally Qualified Health Center
- Staff or Group Model health maintenance organization (HMO) (specify) _____
- Other insurance organization (specify, including who owns) _____
- Integrated delivery system (includes hospital and outpatient services) (specify, including who owns) _____
- Stand-alone primary care provider (specify, including who owns) _____
- Government-operated health system outside US (specify, including who owns) _____
- Other (specify) _____

Comments:

Study Setting – Number of Study Locations

How many intervention locations were included in the study (e.g. how many intervention clinics)? _____

How many control locations were included in the study (e.g. how many control clinics)? _____

Study Population

Overall population category (pick most appropriate level)

- Adults
- Children (<= 18 years)
- Mixed

How many intervention groups (e.g. intervention arms of a clinical trial)? _____

Overall Description (label) for intervention and control arms (e.g. intervention + PCMH implemented; control = usual care)

a. Intervention arm 1:	
b. Intervention arm 2:	
c. Intervention arm 3:	
d. Control arm:	

Patient enrolled (if variable number of patients per outcome, record the largest number for any baseline measure)

a. Total Patient n=	
b. Intervention arm 1 n=	
c. Intervention arm 2 n=	
d. Intervention arm 3 n=	
e. Control arm n=	

Enrollee characteristics (PATIENTS] (only abstract total enrolled if that is available; otherwise, abstract arms separately)

Characteristic:	Total Enrolled (preferred data) N =	Arm 1 N =	Arm 2 N =	Arm 3 N =	Control arm N =
a. Mean Age (SD)					
b. Sex – Men (n)					
c. Sex – Women (n)					
d. Race – White (n)					
e. Race – African American (n)					
f. Race – Latino (n)					
g. Race – Asian (n)					
h-1. Mean education (years) (SD) OR					
h-2. >High School education (n)					
i. Disease Burden (e.g. risk score) specify:					
j-1. Top 3 Diseases - #1 specify					
j-2. Top 3 Diseases - #2 specify					
j-3/ Top 3 Diseases - #3 specify					

Comments (related to baseline descriptors):

Staff Studied

Are staff outcomes (e.g. staff burn-out, etc.) reported?

- No
- Yes

If staff outcomes were included, please indicate the number of staff included in each category (n)

Total n=	
Primary Care Provider (i.e. physician, nurse practitioner, and/or physician assistant) n=	
Nurses (can be any level of licensed nurse not acting as a primary care provider) n=	
Other (specify profession) n=	

Comments:

INTERVENTION – Specific PCMH Components

What specific PCMH components have been included regarding the **Primary Care Team**?

- no team (defined as ≥ 2 people)
- team, but no details given
- team, details given

If team (details given) then check all that apply to the team composition

- Physician
- NP/PA
- Nurse (RN and/or LPN)
- Clinical Pharmacist
- Social Worker
- Psychologist
- Other (specify) _____

Other team details (check all that apply)

Defined roles for team members (paper does not need to describe each role for this item to be checked)

Dedicated time for one or more members of the care team to address expanded PCMH activities

A team member is designated as the patient's primary contact (if reported, please indicate discipline) specify MD/PA/NP; RN/LPN; Other _____

Regular meetings of team or other mechanism to discuss/communicate about patient care

Team located in the SAME physical location

Team located in DIFFERENT physical locations (e.g. telemedicine, care manager covering multiple practices)

Other key aspects (specify): _____

Were specific PCMH components regarding **Enhanced Access** included?

Yes

No

If yes, check all that apply:

There is "enhanced access" but no details reported

Telephone visits (a telephonic contact by a health care provider to address clinical issues or telephone disease management)

Group visits to address a clinical problem (not one or limited-time classes) or shared medical appointments (group visit that includes medication management)

Home visits by a team member

Web-based visits or web-based disease management

Telephone disease management or home tele-monitoring of disease condition (e.g. home BP monitoring, scales for CHF patients that transmit data to the primary care provider)

Two-way e-mail or other mode of electronic messaging to address a clinical issue (e.g. secure messaging)

Enhanced telephone system (e.g. system for directing calls to specific care team, adding telephone lines, adding system for returning messages)

Expanded office hours

Advanced clinic access, open access scheduling, or changes to appointment types or availability

24/7 coverage (e.g. nurse call line or other system where a patient can talk directly to a clinician on demand or in a short period of time)

Other (specify) _____

Were specific PCMH components regarding **Coordinated Care** included?

If yes, check all that apply

There is "coordinated care," but no details reported

Integrated mental-health services (mental health professional is co-located or care management services for mental illness)

Clinical pharmacist provides medication counseling or other direct care patient services (e/t/ chronic disease management)

- Community liaison/enhance system for referral to community resources (system to refer patients to services such as food banks, social services, public health dept.)
- Pre-visit planning (e.g. review appointment schedules or charts to plan how to meet patient needs during visits)
- Coordinates home health services
- Coordination of care transitions (e.g. hospital to outpatient care)
- Test tracking (system to confirm that diagnostic test results have been reviewed and proper follow-up occurred)
- Referral Tracking or f/u by PCMH team (e.g. a system to track referral status and reports from consultants to ensure proper services are received)
- Other (specify) _____

Were specific PCMH components regarding **Comprehensiveness** included?

If yes, check all that apply

- All or most CHRONIC care included
- All or most ACUTE care included
- All or most CHRONIC ILLNESS and/or PREVENTIVE care included
- All or most SPECIALTY care included
- Other (specify services) _____

Were specific PCMH components regarding a **system-based approach to improving quality and safety** included?

If yes, check all that apply

- There is “system-based approach to improving quality and safety,” but no details reported
 - Reduced provider/team panel size
 - Longer appointment times
 - Orientation to the practice (e.g. Medical Home structure/service)
 - Evidence-based practice guidelines
 - Electronic health records
 - Electronic prescribing
 - Patient registries or tracking of preventive or chronic illness services (lists of patients, sortable by conditions and/or interventions) and or tracking of preventive or chronic illness services
 - Mechanism for identifying high-risk patients (e.g. health risk appraisal, patients with markers of poor disease control, claims data predictive index)
 - Point-of-care decision support (e.g. preventive care reminders or guideline based clinical reminders)
 - Performance monitoring for quality of care (e.g. performance indicators on process of care, patient experience, patient outcomes)
 - Other (specify) _____

Were specific PCMH components regarding a **Sustained Partnership** (with ‘Whole Person’ focus) included?

If yes, check all that apply

- Sustained partnership, but no details reported
- Designated MD/PA/NP primary care provider
- Care plans used (care plans developed with patients)
- Shared decision making (decision aids introduced or staff training on shared decision making)
- Comprehensive patient health assessments
- Self-management support (e.g. written self-management plan, self-management tools [written/web], staff training on self-management; specific self-management program)
- Programs for family/caregiver support (e.g. family education or psychoeducation; caregiver training)
- Other (specify) _____

Were specific PCMH components regarding **structural changes to care** included?

If yes, check all that apply

- There were 'structural changes to care,' but no details reported
- New staff
- New services or programs (e.g. group visits, telephone disease management)
- New locations of care
- New organizational entities (e.g. formation of an Accountable Care Organization)
- New organizational affiliations (e.g. new service agreement between a physician practice group and hospital)
- New staff roles (may overlap with team)
- New electronic health record
- New payment model
- Other (specify) _____

Financial Models Introduced as Part of PCMH

What specific models were used as part of the PCMH implementation? (check all that apply)

- No change or nothing reported on financial models
- Bundled payments for most health services (i.e. similar to capitation not specifically related to PCMH support)
- Pay for Performance (i.e. payment based on meeting pre-specified quality targets)
- Enhanced Fee for service (e.g. additional payments for participating in PCMH)
- Accountable Care Organization (or other interorganizational agreement with shared financial risk)
- Revised pharmacy benefits
- Other (specify) _____

Organization Learning Strategies

What mechanisms did the organization use for learning about PCMH and the related components? (check all that apply)

- Learning strategies not reported
- Designated research/project team assistance
- Collaborative program planning involving the clinic staff
- Participated in a formal learning collaborative
- Community of practice (e.g. group of professionals seeking to improve care supported by phone calls, web site, etc.)
- Implementation toolkits (i.e. availability of a set of tools to help organizations implement new programs, can include things like instructions on how to develop PCMH structures, conduct rapid cycle improvement, map current care systems)
- Other (specify) _____

System Change Strategies

What strategies were used to actually implement the changes needed for PCMH? (check all that apply)

- Strategies not reported
- Plan-Do-Study-Act Cycles (also sometimes called Plan-Do-Check-Act cycles)
- Academic detailing
- Lectures/classes for staff (i.e. didactic education)
- Flow mapping of care system
- Total quality management (TQM)/Continuous Quality Improvement (CQI)
- Audit and feedback to providers, teams, and/or clinics
- Strengths-Weakness-Opportunities-Threats Analysis
- External benchmarking at the organizational level (comparing one's organizational quality/performance to that of other organization or an industry standard)
- Designated clinical champion (facility/practice level)
- Designated project manager (facility/practice level)
- Quality Improvement Team
- Other (specify) _____

COMPARATOR

Please check the type of comparator against which PCMH was compared.

- Usual care – no changes
- Changed system other than PCMH (specify basic changes)
- _____ Non-Facilitated PCMH Implementation (as opposed to facilitated PCMH implementation) (specify basic aspects of any “non-facilitation”)
- _____ KQ2/3 = “no comparator necessary”

Please indicate reported aspects of the comparator (e.g. usual care) (check all that apply)

- Aspects not reported
- Electronic Health Record
- Teams (mentioned in any way)
- Designated primary care providers

- Clinical practice guidelines
- Disease management programs for specific diseases
- Group visits
- Telephone care
- Programs for families/caregivers
- Quality Improvement programs (any mentioned)
- Quality measurement
- Access enhancement programs (e.g. open access)
- Other (specify) _____

Comments:

Is this study relevant to Key Question 1?

KQ1: In published, primary care-based evaluations of comprehensive PCMH interventions, what are the effects of the PCMH on patient and staff experiences, process of care, clinical outcomes, and economic outcomes?

- a. Are specific PCMH components associated with greater effects on patient and staff experiences, process of care, clinical outcomes, and economic outcomes?
- b. Is implementation of comprehensive PCMH associated with unintended consequences (e.g. decrease in levels of indicated care for non-priority conditions) or other harms?

- Yes
- No

If yes, please complete the following Outcomes Table:

Type of Outcome:	Name of Outcome:	How Was Outcome Measure Reported:	Timepoint(s):	Comments
a. Patient/Facility, Staff, N/A				
b. Patient/Facility, Staff, N/A				
c. Patient/Facility, Staff, N/A				
d. Patient/Facility, Staff, N/A				
e. Patient/Facility, Staff, N/A				

f. Patient/Facility, Staff, N/A				
g. Patient/Facility, Staff, N/A				
h. Patient/Facility, Staff, N/A				
i. Patient/Facility, Staff, N/A				
j. Patient/Facility, Staff, N/A				
k. Patient/Facility, Staff, N/A				
l. Patient/Facility, Staff, N/A				
m. Patient/Facility, Staff, N/A				
n. Patient/Facility, Staff, N/A				
o. Patient/Facility, Staff, N/A				
p. Patient/Facility, Staff, N/A				
q. Patient/Facility, Staff, N/A				
r. Patient/Facility, Staff, N/A				
s. Patient/Facility, Staff, N/A				
t. Patient/Facility, Staff, N/A				

Appendix C. Data Abstraction Elements (KQ 4)

Distiller Reference ID: _____

Search Source (choose one):

- enGrant
- Commonwealth
- PCPCC
- RWJ
- ClinicalTrials.gov
- CMS
- NASHP
- Medline/PubMed
- Other (specify) _____

ClinicalTrials.gov identifier (or unique grant #): _____

Study Title: _____

Principal Investigator/Contact: _____

End/Completion date (mm/yyyy): _____

Funder (use data provided on ClinicalTrials.gov form): _____

Health Care Delivery Organization (check all that apply):

- Not Reported
- Federal (US) – Department of Veterans Affairs
- Federal (US) – Department of Defense
- Federal (US) – Indian Health Service
- State government
- Federal Qualified Health Center
- Staff or Group Model health maintenance organization (HMO) (specify): _____
- _____ Other insurance organization (specify, including who owns): _____
- Integrated delivery system (includes hospital and outpatient services) (specify, including who owns): _____
- Stand-alone primary care provider (specify, including who owns): _____
- Government-operated health system outside US (specify, including who owns): _____
- _____ Other (specify): _____

Geographic Location(s):

- Single State (specify): _____
- Multi-state

Study Size (enter n or NR for each):

Data Element	Total
Patients:	
Clinics:	
Providers:	

Study Design:

- RCT – Patient-level randomization
- RCT – Cluster (e.g. study location/clinic) randomization
- Non-randomized controlled trial
- Prospective cohort/observational study – defined by patient groups
- Prospective cohort/observational study – study location/clinic
- Retrospective cohort/observational study – defined by patient groups
- Retrospective cohort/observational study – study location/clinic
- Interrupted time series
- Intervention and control groups, Pre-Post design
- Other longitudinal comparative study (specify): _____

Detailed PCMH components reported (answer yes/no to each):

Team-based care:	Yes/No/NR
Enhanced access to care:	Yes/No/NR
Coordinated care:	Yes/No/NR
Comprehensive care:	Yes/No/NR
Systems-based QI:	Yes/No/NR
Sustained partnership/personal physician:	Yes/No/NR
Reorganization of care delivery:	Yes/No/NR

Comparators (check all that apply – use comments field for any further information)

- Usual care
- Other QI approaches
- PCMH levels

Comments:

PCMH Financial/Reimbursement Model Reported (check all that apply):

- No change or nothing reported on financial models
- Bundled payments for most health services (i.e., similar to capitation not specifically related to PCMH support)

- PCMH per member (typically per month) payment for PCMH/care management activities
- Pay for Performance (i.e., payment based on meeting pre-specified quality targets)
- Enhanced Fee for service (e.g., additional payments for participating in PCMH)
- Accountable Care Organization (or other inter-organizational agreement with shared financial risk)
- Revised pharmacy benefits
- Other (specify): _____

Outcomes assessed (check all that apply):

- Patient or Staff experiences/satisfaction
- Process of Care – access
- Process of Care – quality
- Clinical outcomes
- Economic outcomes

Appendix D. Quality (Risk of Bias) Assessment of Individual Studies (KQ 1)

Was this study randomized?

yes
 no

If yes, then the following appear (Randomized questions):

Were the study subjects randomized?

yes
 no
 unclear

Was the randomization process described?

yes
 no
 unclear

Was the outcome assessor blinded to study assignment?

yes
 no
 unclear

Were patients blinded to study intervention?

yes
 no
 unclear

Were results adjusted for clustering?

yes
 no
 unclear

Were measures of outcomes based on validated procedures or instruments?

yes
 no
 unclear

Conducted an intent to treat analysis?

yes
 no
 unclear

Were all outcomes reported (i.e. was there evidence of selective outcome reporting?)

- yes
- no
- unclear

Were incomplete data adequately addressed (i.e. no systematic differences between groups in withdrawals/loss to follow-up AND no high drop-out or loss to follow-up rate [$>30\%$])?

- yes
- no
- unclear

Was there adequate power (either based on pre-study or post-hoc power calculations [80% power for primary outcome])?

- yes
- no
- unclear

Were systematic differences observed in baseline characteristics and prognostic factors across the groups compared?

- yes
- no
- unclear

Were comparable groups maintained? (includes crossovers, adherence, and contamination. Consider issues of crossover [e.g. from one intervention to another], adherence [major differences in adherence to the interventions being compared], contamination {e.g. some members of control group get intervention}, or other systematic difference in care that was provided.)

- yes
- no
- unclear

Was there absence of potential important conflict-of-interest? (Focus on financial conflicts with for-profit capacities; government or non-profit funding = 'yes')

- yes
- no
- unclear

Overall Study Rating:

Please assign each study an overall quality rating of "Good," "Fair," or "Poor" based on the following definitions:

A **"Good"** study has the least bias, and results are considered valid. A good study has a clear description of the population, setting, interventions, and comparison groups; uses a valid approach to allocate patients to alternative treatments; has a low dropout rate; and uses appropriate means to prevent bias, measure outcomes, and analyze and report results.

A “Fair” study is susceptible to some bias but probably not enough to invalidate the results. The study may be missing information, making it difficult to assess limitations and potential problems. As the fair-quality category is broad, studies with this rating vary in their strengths and weaknesses. The results of some fair-quality studies are possibly valid, while others are probably valid.

A “Poor” rating indicates significant bias that may invalidate the results. These studies have serious errors in design, analysis, or reporting; have large amounts of missing information; or have discrepancies in reporting. The results of a poor-quality study are at least as likely to reflect flaws in the study design as to indicate true differences between the compared interventions.

The Overall Quality Assessment of this RCT is:

- Good
- Fair
- Poor

If no, then the following appear (Observational questions):

This tool is intended to evaluate the quality of studies examining the outcomes of PCMH interventions. Use this quality/risk of bias tool for the following study designs: non-randomized controlled trials, cohort studies, interrupted time series.

Instructions for use:

1. Items are organized by risk of bias domains (selection, performance, attrition, detection and reporting bias). Rate each question using the response categories listed. Focus on study design and conduct, not quality of reporting.
2. Two questions: basic study design, sample size/power are not used in overall ratings but are collected for descriptive purposes.
3. After answering each item, rate the study overall as “good” (low risk of bias), “fair” (moderate risk of bias), or “poor” (high risk of bias) based on the definitions printed in a later section.

Study Design

Is the study design prospective, retrospective, or mixed? (Prospective design requires that the investigator plans a study before any data are collected. Mixed design includes case-control or cohort studies in which one group is studied prospectively and the other retrospectively.)

- Prospective
- Retrospective
- Mixed
- Cannot determine

Selection Bias

Inclusion/Exclusion Criteria

Are the inclusion/exclusion criteria clearly stated (does not require the reader to infer)? (Key eligibility criteria are: age, medical conditions for patients, specialty if selected by physician, payment structure/vertical integration if selected by clinic.)

Use ‘partially’ if only some criteria are stated or if some criteria are not clearly stated.

- yes
- partially (only some criteria stated or some criteria not stated clearly)
- no

Did the study apply inclusion/exclusion criteria uniformly to all comparison groups?

- yes
- partially (only some criteria stated or some criteria not clearly stated)
- no
- N/A (study does not include comparison groups)

Recruitment

Did the strategy for recruiting participants into the study differ across study groups? (Also applies if physicians/clinic recruited.)

- yes
- no
- cannot determine
- N/A (retrospective study design)

Baseline characteristics similar or appropriate adjusted analysis

Are key characteristics of study participants similar between intervention and control groups? (Patients’ age, race, gender, illness severity)

If not similar, did the analysis appropriately adjust for important differences?

- yes (similar or appropriate adjusted analysis)
- partially (only some characteristics described or some characteristics not clearly described; analysis adjust for some)
- no (important baseline differences; unadjusted analysis)

Comparison Group

Is the selection of the comparison group appropriate? (Patients exposed to usual care or enhanced usual care is appropriate; if comparison group determined at the physician or practice level, the comparison groups should be drawn from the same system.)

- yes
- no
- cannot determine (no description of the derivation of the comparison cohort)
- N/A (study does not include a comparison cohort – case series, one-arm study)

Performance Bias

Intervention Implementation

Did variation from the study protocol compromise the conclusions of the study? (Similar to a psychologist following a manualized procedure to deliver psychotherapy, the PCMH intervention should be implemented as planned.)

- unclear (no data reported on fidelity to protocol or PCMH components used)
- low fidelity (few components of PCMH implemented)
- medium fidelity (most key components of PCMH implemented)
- high fidelity (all key components of PCMH were implemented)

Did researchers rule out any impact from concurrent interventions? (Such as other quality improvement initiatives, changes in payment structure – e.g. through multivariate analysis, stratification, or subgroup analysis?)

- yes
- partially (only some concurrent interventions eliminated)
- not described

Attrition Bias

Equality of length of follow-up for participants

In cohort studies, is the length of follow-up different between the groups? (Where follow-up was the same for all study patients the answer is ‘yes.’ If different lengths of follow-up were adjusted by statistical techniques, for example, survival analysis, the answer is ‘yes.’ Studies where difference in follow-up are ignored should be answered ‘no.’)

- yes
- no
- cannot determine

Completeness of Follow-up

Was there a high rate of differential or overall attrition? (Attrition is measured in relation to the time between baseline [allocation in some instances] and outcome measurement. Standard for overall attrition is <20% for <1 year f/u and <30% for longer term \geq 1 year. Standard for differential attrition is \geq 10% absolute difference.)

- yes
- no
- cannot determine

Attrition affecting participant composition

Did attrition result in a difference in group characteristics between baseline and followup?

- yes

- no
- cannot determine

Any attempt to balance the allocation between the groups? (e.g. through stratification, matching, propensity scores)

- yes
- no
- cannot determine

Intention-to-treat analysis

Is the analysis conducted on an intention-to-treat (ITT) basis. i.e., the intervention allocation status rather than the actual intervention received? (Evaluate whether the analysis takes into account loss to follow-up.)

- yes
- no
- cannot determine
- N/A (retrospective study)

Detection Bias

Blind outcomes assessment

Were the outcomes assessors blinded to the intervention or exposure status of participants?

- yes
- no
- N/A (not an intervention study)

Are interventions/exposures assessed using valid and reliable measures, implemented consistently across all study participants?

- yes
- no
- cannot determine (measurement approach not reported)

Source of information re: outcomes

Are process of care outcomes (e.g. performance measures, access metrics) assessed using valid and reliable measures and implemented consistently across all study participants?

- yes
- no
- cannot determine (measurement approach not reported)

Are clinical outcomes (e.g. symptoms, change in biophysical indicator of disease state) assessed using valid and reliable measures and implemented consistently across all study participants?

- yes
- no

cannot determine (measurement approach not reported)

Are economic outcomes (e.g. utilizations, costs) assessed using valid and reliable measures and implemented consistently across all study participants?

yes

no

cannot determine (measurement approach not reported)

Are confounding variables assessed using valid and reliable measures, implemented consistently across all study participants? (Major potential confounders include: age, gender, race, disease severity, overall burden of disease.)

yes

no

cannot determine (measurement approach not reported)

Reporting Bias

Primary Outcomes Assessment

Are findings for all primary outcomes reported?

(Abstractor needs to identify all pre-specified, primary outcomes that should be reported in the study.)

yes

partially (some outcomes not reported)

no

primary outcomes not pre-specified

Other quality/risk of bias issues

Are the statistical methods used to assess the primary outcomes appropriate to the data?

(The statistical techniques used must be appropriate to the data and take into account issues such as controlling for small sample size, clustering, rare outcomes, and multiple comparison.)

yes

partially

no

cannot determine

Power and sample size

Did the authors report conducting a power analysis or some other basis for determining the adequacy of study group sizes for the primary outcome(s) being abstracted?

yes

no

N/A (primary outcomes statistically significant)

Quality – Observational Studies

Definitions of “Good,” “Fair,” and “Poor” quality:

A **“Good”** study has the least bias, and results are considered valid. A good study has a clear description of the population, setting, interventions, and comparison groups; uses recruitment and eligibility criteria that minimizes selection bias; has a low attrition rate; and uses appropriate means to prevent bias, measure outcomes, and analyze and report results. These studies will meet the majority of items in each domain.

A **“Fair”** study is susceptible to some bias but probably not enough to invalidate the results. The study may be missing information, making it difficult to assess limitations and potential problems. As the fair-quality category is broad, studies with this rating vary in their strengths and weaknesses. The results of some fair-quality studies are possibly valid, while others are probably valid. These studies will meet the majority of items in most but not all domains.

A **“Poor”** rating indicates significant bias that may invalidate the results. These studies have serious errors in design, analysis, or reporting; have large amounts of missing information; or have discrepancies in reporting. The results of a poor-quality study are at least as likely to reflect flaws in the study design as to indicate true differences between the compared interventions.

The Overall Quality Rating of this observational study is:

- Good (low risk of bias)
- Fair (moderate risk of bias)
- Poor (high risk of bias)

Appendix E. List of Included Studies (KQs 1–3)

The Table below lists all studies included for KQs 1–3, broken down into primary and secondary publications.

Table. Included studies (KQs 1–3)

Primary Publication	Secondary Publications
KQs 1–3	
Boult, 2008 ¹	Boult, 2011 ² Boyd, 2010 ³ Leff, 2009 ⁴ Marsteller, 2010 ⁵ Wolff, 2009 ⁶ Wolff, 2010 ⁷
Boyd, 2007 ⁸	Boyd, 2008 ⁹ Sylvia, 2008 ¹⁰
Domino, 2009 ¹¹	Mercer, 2008 ¹² Steiner, 2008 ¹³
Dorr, 2008 ¹⁴	Dorr, 2006 ¹⁵
Farmer, 2011 ¹⁶	None
Hebert, 2003 ¹⁷	None
Jaen, 2010 ¹⁸	Crabtree, 2010 ¹⁹ Jaen, 2010 ²⁰ Miller, 2010 ²¹ Nutting, 2009 ²² Nutting, 2010 ²³ Nutting, 2010 ²⁴ Stewart, 2010 ²⁵
Martin, 2007 ²⁶	None
Reid, 2009 ²⁷	Coleman, 2010 ²⁸ Reid, 2010 ²⁹
Rubin, 1992 ³⁰	None
Schraeder, 2005 ³¹	Peikes, 2009 ³²
Sommers, 2000 ³³	None
Steele, 2010 ³⁴	Gilfillan, 2010 ³⁵
Taplin, 1998 ³⁶	None
Toseland, 1997 ³⁷	Toseland, 1996 ³⁸
Wise, 2006 ³⁹	None
Zuckerman, 2004 ⁴⁰	Minkovitz, 2003 ⁴¹ Minkovitz, 2007 ⁴²
KQs 2–3 only	
Chandler, 1997 ⁴³	None
Farmer, 2005 ⁴⁴	None
Farris, 2004 ⁴⁵	Dieleman, 2004 ⁴⁶
Palfrey, 2004 ⁴⁷	Samuels, 2005 ⁴⁸
Peleg, 2008 ⁴⁹	None
Rankin, 2009 ⁵⁰	None
Schifalacqua, 2000 ⁵¹	None
Treadwell, 2009 ⁵²	None
Vedel, 2009 ⁵³	None
Waxmonsky, 2011 ⁵⁴	None

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50. Rankin KM, Cooper A, Sanabria K, et al. Illinois medical home project: pilot intervention and evaluation. *Am J Med Qual* 2009;24(4):302-9. PMID: 19515943.
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Appendix F. List of Excluded Studies (KQs 1–3)

All studies listed below were reviewed in their full-text version for possible inclusion for KQs 1–3 and were excluded. Following each reference, in italics, is the reason for exclusion. Reasons for exclusion signify only the usefulness of the articles for this review and are not intended as criticisms of the articles.

Adam P, Brandenburg DL, Bremer KL, et al. Effects of team care of frequent attenders on patients and physicians. *Fam Syst Health* 2010;28(3):247-57. PMID: 20939629. *Exclude—does not meet PCMH definition*

Adams EK, Bronstein JM, Florence CS. The impact of Medicaid primary care case management on office-based physician supply in Alabama and Georgia. *Inquiry* 2003;40(3):269-82. PMID: 14680259. *Exclude—does not meet PCMH definition*

Afifi AA, Morisky DE, Kominski GF, et al. Impact of disease management on health care utilization: evidence from the “Florida: A Healthy State (FAHS)” Medicaid Program. *Prev Med* 2007;44(6):547-53. PMID: 17350086. *Exclude—does not meet PCMH definition*

Ahmed S, Gogovor A, Kosseim M, et al. Advancing the chronic care road map: a contemporary overview. *Healthc Q* 2010;13(3):72-9. PMID: 20523157. *Exclude—not original data*

Aita V, McIlvain H, Backer E, et al. Patient-centered care and communication in primary care practice: what is involved? *Patient Educ Couns* 2005;58(3):296-304. PMID: 16122641. *Exclude—does not meet PCMH definition*

Alkema GE, Shannon GR, Wilber KH. Using interagency collaboration to serve older adults with chronic care needs: the Care Advocate Program. *Fam Community Health* 2003;26(3):221-9. PMID: 12829944. *Exclude—does not meet PCMH definition*

Al-Khaldi YM, Al-Sharif AI, Al-Jamal MN, et al. Difficulties faced when conducting primary health care programs in rural areas. *Saudi Med J* 2002;23(4):384-7. PMID: 11953760. *Exclude—does not meet PCMH definition*

Allen JK, Scott LB. Alternative models in the delivery of primary and secondary prevention programs. *J Cardiovasc Nurs* 2003;18(2):150-156. PMID: 2003092559. *Exclude—does not meet PCMH definition*

Alvarado R, Zepeda A, Rivero S, et al. Integrated maternal and infant health care in the postpartum period in a poor neighborhood in Santiago, Chile. *Stud Fam Plann* 1999;30(2):133-41. PMID: 16617547. *Exclude—does not meet PCMH definition*

Amorim DG, Adam T, Amaral JJ, et al. Integrated Management of Childhood Illness: efficiency of primary health in Northeast Brazil. *Rev Saude Publica* 2008;42(2):183-90. PMID: 18372970. *Exclude—does not meet PCMH definition*

Andersen MD, Smereck GA, Hockman EM, et al. Nurses decrease barriers to health care by “hyperlinking” multiple-diagnosed women living with HIV/AIDS into care. *J Assoc Nurses AIDS Care* 1999;10(2):55-65. PMID: 10065410. *Exclude—does not meet PCMH definition*

Anderson LA, Persky NW, Whall AL, et al. Interdisciplinary team training in geriatrics: reaching out to small and medium-size communities. *Gerontologist* 1994;34(6):833-8. PMID: 7843614. *Exclude—does not meet PCMH definition*

Anderson RJ, Pickens S, Boumbulian PJ. Toward a new urban health model: moving beyond the safety net to save the safety net—resetting priorities for healthy communities. *J Urban Health* 1998;75(2):367-78. PMID: 9684248. *Exclude—does not meet PCMH definition*

Anfinson TJ, Bona JR. A health services perspective on delivery of psychiatric services in primary care including internal medicine. *Med Clin North Am* 2001;85(3):597-616. PMID: 11349475. *Exclude—does not meet PCMH definition*

Angstman KB, MacLaughlin KL, Rasmussen NH, et al. Age of depressed patient does not affect clinical outcome in collaborative care management. *Postgrad Med* 2011;123(5):122-8. PMID: 21904094. *Exclude—does not meet PCMH definition*

Anker-Unnever L, Netting FE. Coordinated care partnership: case management with physician practices. *J Case Manag* 1995;4(1):3-8. PMID: 7795541. *Exclude—does not meet PCMH definition*

Anonymous. Integrated management of the sick child. *Bull World Health Organ* 1995;73(6):735-40. PMID: 8907767. *Exclude—does not meet PCMH definition*

Anonymous. Asthma DM effort slashes utilization, produces substantial ROI. *Dis Manag Advis* 2001;7(10):145-9. PMID: 11697023. *Exclude—does not meet PCMH definition*

Anonymous. HCFA demo sites offer a smorgasbord of managed care innovation. *Dis Manag Advis* 2001;7(4):52-7, 49. PMID: 11345904. *Exclude—not original data*

Anonymous. Role of the pediatrician in family-centered early intervention services. *Pediatrics* 2001;107(5):1155-7. PMID: 11331701. *Exclude—not original data*

Anonymous. Medicare demonstration project creeping to the starting line. *Capitation Manag Rep* 2004;11(10):109-11. PMID: 15566118. *Exclude—does not meet PCMH definition*

Anonymous. Blue Cross/Blue Shield promotes medical home demonstrations. *Dis Manag Advis* 2008;14(1):suppl 1-4, 1. PMID: 18290277. *Exclude—not original data*

Anonymous. Medical home payment structure offered. Report issued in preparation of CMS demonstration project. *Dis Manag Advis* 2008;14(7):1-2, 6. PMID: 18683595. *Exclude—not original data*

Anonymous. Patient-Centered Medical Homes. *Health Aff (Millwood)* 2010. . *Exclude—background (other)*

Anonymous. Peds program reduces ED visits by 55%. *ED Manag* 2010;22(6):66-7. PMID: 20535895. *Exclude—not original data*

Ansari Z, Barbetti T, Carson NJ, et al. The Victorian ambulatory care sensitive conditions study: rural and urban perspectives. *Soz Praventivmed* 2003;48(1):33-43. PMID: 12756887. *Exclude—does not meet PCMH definition*

Antonelli RC, Stille CJ, Antonelli DM. Care coordination for children and youth with special health care needs: a descriptive, multisite study of activities, personnel costs, and outcomes. *Pediatrics* 2008;122(1):e209-16. PMID: 18595966. *Exclude—does not meet PCMH definition*

Anumanrajadhon T, Rajchagool S, Nitisiri P, et al. The community care model of the Intercountry Centre for Oral Health at Chiangmai, Thailand. *Int Dent J* 1996;46(4):325-33. PMID: 9147120. *Exclude—does not meet PCMH definition*

Appleton PL, Boll V, Everett JM, et al. Beyond child development centres: care coordination for children with disabilities. *Child Care Health Dev* 1997;23(1):29-40. PMID: 9023029. *Exclude—does not meet PCMH definition*

Art B, De Roo L, De Maeseneer J. Towards unity for health utilising community-oriented primary care in education and practice. *Educ Health (Abingdon)* 2007;20(2):74. PMID: 18058692. *Exclude—does not meet PCMH definition*

Artz N, Whelan C, Feehan S. Caring for the adult with sickle cell disease: results of a multidisciplinary pilot program. *J Natl Med Assoc* 2010;102(11):1009-1016. PMID: 2010886437. *Exclude—population and/or setting is not eligible*

Asch SM, Baker DW, Keeseey JW, et al. Does the collaborative model improve care for chronic heart failure? *Med Care* 2005;43(7):667-675. PMID: 2009095549. *Exclude—population and/or setting is not eligible*

Bachmann MO, Reading R, Husbands C, et al. What are children's trusts? Early findings from a national survey. *Child Care Health Dev* 2006;32(2):137-46. PMID: 16441848. *Exclude—does not meet PCMH definition*

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Battersby M, McDonald P, Pearce R, et al. The changing attitudes of health professionals and consumers towards a coordinated care trial—SA HealthPlus. *Aust Health Rev* 2001;24(2):172-8. PMID: 11496460. *Exclude—does not meet PCMH definition*

Beland F, Bergman H, Lebel P, et al. Integrated services for frail elders (SIPA): a trial of a model for Canada. *Can J Aging* 2006;25(1):5-42. PMID: 16770746. *Exclude—does not meet PCMH definition*

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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. PMID: 20467907. *Exclude—background (other)*

Blomquist KB. Health, education, work, and independence of young adults with disabilities. *Orthop Nurs* 2006;25(3):168-187. PMID: 2009206863. *Exclude—does not meet PCMH definition*

Bodenheimer T, Wang MC, Rundall TG, et al. What are the facilitators and barriers in physician organizations' use of care management processes? *Jt Comm J Qual Saf* 2004;30(9):505-14. PMID: 15469128. *Exclude—study design (not a longitudinal evaluative study and not relevant to KQ4)*

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Byng R, Jones R. Mental Health Link: the development and formative evaluation of a complex intervention to improve shared care for patients with long-term mental illness. *J Eval Clin Pract* 2004;10(1):27-36. PMID: 14731149. *Exclude—does not meet PCMH definition*

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Callahan CM, Boustani MA, Weiner M, et al. Implementing dementia care models in primary care settings: The Aging Brain Care Medical Home. *Aging Ment Health* 2011;15(1):5-12. PMID: 20945236. *Exclude—does not meet PCMH definition*

Calman NSP. A Study Of The Patient-Centered Medical Home: Lessons From A New York State Commu. Agency for Health Care Research and Quality (Funding Institution) 2010. *Exclude—study design (not a longitudinal evaluative study and not relevant to KQ4)*

Calnan M, Cant S, Williams S, et al. Involvement of the primary health care team in coronary heart disease prevention. *Br J Gen Pract* 1994;44(382):224-8. PMID: 8204337. *Exclude—does not meet PCMH definition*

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Carlo ME, Powers JS. Ambulatory care sensitive emergency department use among low-cost medical home patients. *Tenn Med* 2010;103(1):31-3. PMID: 20108865. *Exclude—does not meet PCMH definition*

Caruso LB, Clough-Gorr KM, Silliman RA. Improving quality of care for urban older people with diabetes mellitus and cardiovascular disease. *J Am Geriatr Soc* 2007;55(10):1656-62. PMID: 17714460. *Exclude—does not meet PCMH definition*

Casey PH, Lyle RE, Bird TM, et al. Effect of hospital-based comprehensive care clinic on health costs for Medicaid-insured medically complex children. *Arch Pediatr Adolesc Med* 2011;165(5):392-8. PMID: 21300650. *Exclude—population and/or setting is not eligible*

Cashman S, Reidy P, Cody K, et al. Developing and measuring progress toward collaborative, integrated, interdisciplinary health care teams. *J Interprof Care* 2004;18(2):183-96. PMID: 15203676. *Exclude—does not meet PCMH definition*

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Appendix G. Characteristics of Included Studies (KQs 1–3, RCTs)

Table G1. Characteristics of included studies (KQ1, RCTs)

Study	Country; Organization	Explicitly PCMH?; Intervention Components	Practices (n)	Subjects	Outcomes Reported; Followup Period ^a	Study Quality ^b
Farmer, 2011 ¹	U.S.A. Other insurance: Medicaid managed care plan	Yes 1. Coordinated care 2. Team 3. Sustained partnership 4. Comprehensive 5. Enhanced access 6. Structural changes	Intervention (32) Usual care (0) – crossover design	CSHCN – 100 Practice staff - NR	Patient experiences 6 months	Fair – Randomization process not described – Blinding of outcomes assessment unclear
Jaen, 2010 ²⁻⁹	U.S.A. Stand-alone primary care provider: Physician and hospital/health system owned	Yes 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (18) Usual care (17)	Adults – 1983 Practice staff – NR	Patient experiences Staff experiences Process of care Clinical 26 months	Fair – Outcomes assessment not blinded – Incomplete data not adequately addressed – Potentially significant conflict of interest

Table G1. Characteristics of included studies (KQ1, RCTs) (continued)

Study	Country; Organization	Explicitly PCMH?; Intervention Components	Practices (n)	Subjects	Outcomes Reported; Followup Period ^a	Study Quality ^b
Boult, 2008 ¹⁰⁻¹⁶	U.S.A. HMO: Kaiser-Permanente Mid-Atlantic States; Integrated delivery system: Johns Hopkins Community Physicians; Stand-alone primary care provider: MedStar Physician Partners (multisite group practice)	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (7 PC care teams; 8 practices) Usual care (7 PC care teams; 8 practices)	Older adults with chronic illness – 904 Practice staff - 49	Patient experiences Staff experiences Economic 26 months	Good
Rubin, 1992 ¹⁷	U.S.A. Other: Parkland Memorial Hospital	No 1. Coordinated care 2. Team 3. Sustained partnership 4. Comprehensive 5. Structural changes	Intervention (1) Usual care (NR)	Older adults at high risk for rehospitalization – 200 Practice staff - NR	Economic 26 months	Fair – Outcomes not assessed using validated procedures/instruments – Significant differences in baseline characteristics across groups
Schraeder, 2005 ^{18,19}	U.S.A. Integrated delivery system: Carle Health System in Urbana, IL	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (12) Usual care (0)	Older adults with COPD, CAD, DM, CHF, or Afib – 2657 Practice staff – NR	Process of care Economic 2 years	Fair – Outcomes assessment not blinded

Table G1. Characteristics of included studies (KQ1, RCTs) (continued)

Study	Country; Organization	Explicitly PCMH?; Intervention Components	Practices (n)	Subjects	Outcomes Reported; Followup Period ^a	Study Quality ^b
Sommers, 2000 ²⁰	U.S.A. Stand-alone primary care provider	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (9) Usual care (9)	Older adults with chronic illness – 543 Practice staff – NR	Clinical Economic 2 years	Good
Toseland, 1997 ^{21,22}	U.S.A. Federal (U.S.) – Department of Veterans Affairs	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (1) Usual care (1)	Older adults with chronic illness – 160 Practice staff - NR	Patient experiences Process of care Clinical Economic 2 years	Good

Table G1. Characteristics of included studies (KQ1, RCTs) (continued)

Study	Country; Organization	Explicitly PCMH?; Intervention Components	Practices (n)	Subjects	Outcomes Reported; Followup Period ^a	Study Quality ^b
Zuckerman, 2004 ²³⁻²⁵	U.S.A. Other: multiple separate primary care practices across 14 states	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (15) Usual care (15)	Young children – 3737 Practice staff - NR	Patient experiences Process of care 5.5 years	Fair – Blinding of outcomes assessment unclear – Unclear whether Incomplete data adequately addressed – Significant differences in baseline characteristics across groups

^aBased on longest followup period among abstracted outcomes.

^bThe most significant quality limitations are listed for all “Fair” and “Poor” studies.

Abbreviations: Afib = atrial fibrillation; CAD = coronary artery disease; CHF = congestive heart failure; CSHCN = children with special health care needs; COPD = chronic obstructive pulmonary disease; DM = diabetes mellitus; HMO = health maintenance organization; KQ = key question; NR = not reported; PC = primary care; PCMH = patient-centered medical home; RCT = randomized controlled trial

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Appendix H. Characteristics of Included Studies (KQs 1–3, Observational Studies)

Table H1. Characteristics of included studies (KQ1, observational studies)

Study	Country; Organization	Explicitly PCMH?; Intervention Components	Practices (n)	Subjects	Outcomes Reported; Followup Period ^a	Study Quality
Domino, 2009 ¹	U.S.A. Other: State-wide medical home network	Yes 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (NR) Usual care (NR)	Children with asthma – 207,439 Practice staff – NR	Process of care Economic Monthly estimates based on 4 years of data	Good
Martin, 2007 ²	U.S.A. Stand-alone primary care provider: Family practice	Yes 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (1) Usual care (NR)	CSHCN – 199 Practice staff - NR	Economic 2 years	Fair – Possible selection bias – Possible detection bias

Table H1. Characteristics of included studies (KQ1, observational studies) (continued)

Study	Country; Organization	Explicitly PCMH?; Intervention Components	Practices (n)	Subjects	Outcomes Reported; Followup Period ^a	Study Quality
Reid, 2009 ^{3,5}	U.S.A. HMO: Group Health Cooperative of Puget Sound	Yes 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (1) Usual care (19)	Adults – 3353 Practice staff – 82	Patient experiences Staff experiences Process of care Economic 2 years	Fair – Possible selection bias – Possible detection bias
Steele, 2010 ^{6,7}	U.S.A. HMO: Geisinger	Yes 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (11) Usual care (75)	Older adults with chronic illness – 15,310 Practice staff – NR	Economic 1 year	Moderate risk of bias – Possible detection bias

Table H1. Characteristics of included studies (KQ1, observational studies) (continued)

Study	Country; Organization	Explicitly PCMH?; Intervention Components	Practices (n)	Subjects	Outcomes Reported; Followup Period ^a	Study Quality
Boyd, 2007 ⁸⁻¹⁰	U.S.A. Integrated delivery system Health plan for military retirees; Other: University affiliated community PC practices	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (1) Usual care (1)	Older adults with chronic illness – 150 Practice staff – 2	Patient experiences Economic 6 months	Fair – Possible selection bias – Possible attrition bias – Analysis not adjusted for clustering
Dorr, 2008 ^{11,12}	U.S.A. Integrated delivery system: Intermountain Group Health	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (7) Usual care (6)	Older adults with chronic illness – 3432 Practice staff – NR	Clinical Economic 2 years	Good

Table H1. Characteristics of included studies (KQ1, observational studies) (continued)

Study	Country; Organization	Explicitly PCMH?; Intervention Components	Practices (n)	Subjects	Outcomes Reported; Followup Period ^a	Study Quality
Hebert, 2003 ¹³	Canada (Quebec) Non U.S. government: Canadian Healthcare System	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (1 region; # of clinics NR) Usual care (1 region; # of clinics NR)	Older adults with chronic illness – 482 Practice staff - NR	Clinical 2 years	Poor – Possible selection bias – Possible performance bias – Possible detection bias
Taplin, 1998 ¹⁴	U.S.A. HMO: Group Health Cooperative of Puget Sound	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Structural changes	Intervention (1) Usual care (27)	Adults – 398,000 Practice staff - NR	Process of care 2 years	Fair – Possible selection bias – Possible performance bias

Table H1. Characteristics of included studies (KQ1, observational studies) (continued)

Study	Country; Organization	Explicitly PCMH? Intervention Components	Practices (n)	Subjects	Outcomes Reported; Followup Period ^a	Study Quality
Wise, ¹⁵ 2006	U.S.A. Other insurance organization: Partnership Health in partnership with University of Michigan's Medical Management Center	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive	Intervention (NR) Usual care (NR)	All ages; high utilizers – 54,479 Practice staff - NR	Process of care Clinical Economic 1 year	Fair – Possible performance bias

^aBased on longest followup period among abstracted outcomes.

^bThe most significant quality limitations are listed for all “Fair” and “Poor” studies.

Abbreviations: CSHCN = children with special health care needs; HMO = health maintenance organization; KQ = key question; NR = not reported; PC = primary care; PCMH = patient-centered medical home

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Appendix I. Characteristics of Included Studies (KQs 2–3 Only)

Table I1. Characteristics of included studies (KQs 2–3 only)

Study	Country; Organization	Explicitly PCMH?; Intervention Components	Practices (n)	Subjects
Farmer, 2005 ¹	U.S.A. Other: University-affiliated PC clinics	Yes 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (3) Usual care (n/a)	CSHCN – 51 Practice staff – NR
Palfrey, 2004 ^{2,3}	U.S.A. Other: Pediatric Alliance for Coordinated Care	Yes 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (6) Usual care (n/a)	CSHCN – 150 Practice staff – NR
Rankin, 2009 ⁴	U.S.A. Stand-alone PC provider	Yes 1. Quality included 2. Coordinated care 3. Sustained partnership 4. Comprehensive 5. Enhanced access	Intervention (6) Usual care (n/a)	CSHCN – 47 Practice staff – NR
Treadwell, 2009 ⁵	U.S.A. Stand-alone PC provider: 47 PC practices	Yes 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (47) Usual care (NR)	Children with asthma, DM, or ADHD – Practice Staff - NR
Chandler, 1997 ⁶	U.S.A. Federal (U.S.) – Department of Veterans Affairs; Other: Northwestern Memorial Hospital	No 1. Coordinated care 2. Team 3. Sustained partnership 4. Comprehensive 5. Enhanced access 6. Structural changes	Intervention (2) Usual care (n/a)	Adults – 16,000 Practice staff – 3
Farris, 2004 ⁷	Canada Government-operated Health System outside U.S.; Private delivery, but government funded health care system	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (6) Usual care (n/a)	Adults with chronic illness – 199 Practice staff – NR

Table 11. Characteristics of included studies (KQs 2–3 only) (continued)

Study	Country; Organization	Explicitly PCMH?; Intervention Components	Practices (n)	Subjects
Peleg, 2008 ⁸	Israel Non U.S. Government: Israel – PC clinic	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (1) Usual care (n/a)	Older adults – 4620 Practice staff – NR
Schifalacqua, 2000 ⁹	U.S.A. Integrated delivery system: Aurora Health Care of WI	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (NR) Usual care (n/a)	Older adults at medium to high health risk – NR Practice staff – NR
Vedel, 2009 ¹⁰	Paris, France Non U.S. Government: French Health Care System	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (NR) Usual care (2)	Older adults with chronic illness – 100 Practice staff – NR
Waxmonsky, 2011 ¹¹	U.S.A. Colorado Access	No 1. Quality included 2. Coordinated care 3. Team 4. Sustained partnership 5. Comprehensive 6. Enhanced access 7. Structural changes	Intervention (NR) Usual care (n/a)	Adults – 3314 Practice staff - 14

Abbreviations: ADHD = attention deficit hyperactivity disorder; CSHCN = children with special health care needs; DM = diabetes mellitus; KQ = key question; n/a = not applicable; NR = not reported; PC = primary care; PCMH = patient-centered medical home; RCT = randomized controlled trial

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Appendix J. Characteristics of Included Studies (KQ 4)

Table J1. Characteristics of ongoing or planned studies evaluating PCMH

Study Title	Projected End Date	Funding Source	Health Care Delivery Organization	Location	Number of Patients ^a	Number of Clinics	Number of Providers
WellStar Health System/Humana Patient-Centered Medical Home ¹	NR	NR	Insurance organization: Humana	Georgia	720	2	12
Metcare of Florida/Humana Patient-Centered Medical Home ²	11/2010	NR	Insurance organization: Humana	Florida	NR	9	17
Queen City Physicians/Humana Patient-Centered Medical Home ³	12/2010	NR	Insurance organization: Humana	Ohio	5200	4	18
TriHealth Physician Practices/Humana Patient-Centered Medical Home ⁴	5/2011	NR	Insurance organization: Humana	Ohio	1100	1	8
Using Multi-Payer Payment Reform to Integrate Medical Home Concepts into Primary Care Practice in Washington State ⁵	1/2012	RWJ	NR	Washington	NR	NR	NR
Transforming Primary Care Practice in North Carolina ⁶	7/2012	AHRQ	NR	North Carolina	NR	12	NR
National Naval Medical Center Medical Home Program ⁷	NR	NR	Federal (U.S.): Department of Defense	Maryland	22,500	1	25
EmblemHealth Medical Home High Value Network Project ⁸ (planned as an RCT)	1/2010	NR	Insurance organization: EmblemHealth	New York	12,000	33	159
Alabama Health Improvement Initiative—Medical Home Pilot ⁹	9/2012	NR	Insurance organization: Blue Cross Blue Shield of Alabama	Alabama	NR	14	70
Maine Patient-Centered Medical Home Pilot ¹⁰	11/2012	NR	MaineCare(Medicaid); Maine Health Management Coalition Maine Quality Forum	Maine	30,000 to 50,000	26	221

Table J1. Characteristics of ongoing or planned studies evaluating PCMH (continued)

Study Title	Projected End Date	Funding Source	Health Care Delivery Organization	Location	Number of Patients ^a	Number of Clinics	Number of Providers
Transformed Primary Care—Care By Design ¹¹	6/2012	AHRQ	Multidisciplinary, University-owned primary care practices	Utah	NR	10	NR
Using Health Information Technology and Health Information Exchange to Help Physician Practices Improve Patient Care in Cincinnati ¹²	1/2012	RWJ	Multipayer	Ohio	30,000	11	40
Evaluating the Effects of EHRs, P4P and Medical Home Redesign in the Hudson Valley ¹³	12/2011	Weill Medical College; NY State Dept of Health; The Commonwealth Fund	Taconic Independent Practice Association	New York (Hudson Valley)	250,000	13	210
The Medical HOME Study ¹⁴ (planned as an RCT)	1/2015	NIMH	Community Mental Health Centers	Georgia	300	NR	NR
Transforming Primary Care: Evaluating the Spread of Group Health's Medical Home ¹⁵	6/2012	AHRQ	Group model health maintenance organization (HMO): Group Health	Washington	NR	9 for qualitative outcomes; NR for other outcomes	NR
Understanding the Transformation Experiences of Small Practices with NCQA's Medical Home ¹⁶	7/2012	AHRQ	Multiple primary care clinics across the country	Multistate	NR	300	NR
Evaluating Statewide Transformation of Primary Care to Medical Homes ¹⁷	8/2012	AHRQ	All primary care in the state of Minnesota	Minnesota	2,000,000	180	1500
Evaluating the Role of the Medical Home Model in the Successful Management of Diabetes ¹⁸	1/2012	NIH (NIDDK)	NR	California	NR	NR	NR
UnitedHealth Group PCMH Demonstration Program (Arizona) ¹⁹	4/2012	United Health Insurance	Insurance organization: United Health	Arizona	14,000	7	25

Table J1. Characteristics of ongoing or planned studies evaluating PCMH (continued)

Study Title	Projected End Date	Funding Source	Health Care Delivery Organization	Location	Number of Patients ^a	Number of Clinics	Number of Providers
Informing Sound Policy: Linking Medical Home Measures and Child Health Outcomes ²⁰	9/2013	AHRQ	Indiana patient care network of pediatric practices	Indiana	NR	NR	NR
Primary Care Transformation in a NCQA Certified Patient-Centered Medical Home ²¹	7/2011	AHRQ	Palo Alto Medical Foundation	California	NR	NR	NR
Multi-Method Evaluation of Physician Group Incentive Programs for PCMH Transformation ²²	12/2011	AHRQ	Insurance organization: BCBS of Michigan's	Michigan	1,700,000	NR	7618
Implementation and Impact of VA Patient-Centered Medical Home ²³	9/2012	VA HSRD	Federal (U.S.): Department of Veterans Affairs	Multistate	NR	> 200	NR
What Makes Medical Homes Work: Lessons for Implementation and Spread ²⁴	4/2012	The Commonwealth Fund	Group model health maintenance organization (HMO): Geisinger	Pennsylvania	50,000	26	110
Evaluation of The Commonwealth Fund's Safety-Net Medical Home Initiative, Phase 2 ²⁵	10/2013	The Commonwealth Fund	Network of safety-net clinics	Multistate	NR	68	NR
Evaluating a Medical Home Demonstration in Colorado and Ohio ²⁶	6/2011	The Commonwealth Fund	Collaborative of five of the nation's leading insurers (unnamed)	Multistate	NR	NR	NR
Evaluating Models of Medical Home Payment Within the Pennsylvania Chronic Care Initiative ²⁷	6/2013	The Commonwealth Fund	Partnership of multiple health insurers	Pennsylvania	1093246	170	780
Rhode Island Chronic Care Sustainability Initiative ²⁸	10/2011	NR	Unnamed commercial insurers and stand-alone primary care provider	Rhode Island	46,000	13	66
Blue Cross Blue Shield Patient-Centered Medical Home Initiative (Tennessee) ²⁹	NR	NR	Insurance organization: Blue Cross Blue Shield	Tennessee	25,000	31	NR
VA PACT Demonstration Lab Initiative ³⁰	NR	VA HSR&D	Federal (U.S.): Department of Veterans Affairs	Multistate	NR	NR	NR

Table J1. Characteristics of ongoing or planned studies evaluating PCMH (continued)

Study Title	Projected End Date	Funding Source	Health Care Delivery Organization	Location	Number of Patients ^a	Number of Clinics	Number of Providers
Multi-Payer Advanced Primary Care Practice (MAPCP) Demonstration ³¹	2014	CMS	Multiple participating practices across 8 states	Multistate	150,000	1200	NR

^aThe number of patients may mean the number of covered lives potentially eligible, or the number of patients specifically participating in the project.

Abbreviations: AHRQ = Agency for Healthcare Research and Quality; CMS = Centers for Medicare & Medicaid Services; EHR = electronic health record; HMO = health maintenance organization; HSR&D = Health Services Research & Development Service; NCQA = National Committee for Quality Assurance; NIDDK = National Institute of Diabetes and Digestive and Kidney Diseases; NIH = National Institutes of Health; NIMH = National Institute of Mental Health; NR = not reported; P4P = pay for performance; PACT = Patient Aligned Care Team; PCMH = patient-centered medical home; RCT = randomized controlled trial; RWJ = Robert Wood Johnson Foundation; VA = United States Department of Veterans Affairs

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