Comparative Effectiveness Research Review Disposition of Comments Report

Research Review Title: *Closing the Quality Gap Series: Revisiting the State of the Science The Patient-Centered Medical Home*

Draft review available for public comment from December 6, 2011, to January 3, 2012.

Research Review Citation Williams JW, Jackson GL, Powers B, Chatterjee R, Prvu Bettger J, Kemper AR, Hasselblad V, Dolor RJ, Irvine RJ, Heidenfelder BL, Kendrick AS, Gray R. Closing the Quality Gap Series: Revisiting the State of the Science. The Patient-Centered Medical Home. Evidence Report 208 Part 2 (Prepared by the Duke Evidence-based Practice Center under Contract No. 290-2007-10066-I.) AHRQ Publication 12-E008-EF. Rockville, MD. Agency for Healthcare Research and Quality. July 2012. Available at: www.effectivehealthcare.ahrq.gov/reports/final.cfm.

Comments to Research Review

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The tables below include the responses by the authors of the review to each comment that was submitted for this draft review. The responses to comments in this disposition report are those of the authors, who are responsible for its contents, and do not necessarily represent the views of the Agency for Healthcare Research and Quality.

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Published Online: July 3, 2012

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer 1	General	ES2-3 clearly defines the key questions and puts them into a sensical logic model. The clinical pertinence of this article is potentially high but the inability of the authors to glean from the current research the aspects of PCMH that drive clinical indicators and cost somewhat limits its clinical meaningfulness. This is likely more related to the complexities of PCMH, its nascent stature in delivery reform and lack of evidence in the literature (vs. a true failure of authorship to identify clinical meaningful aspects of the literature). Authors do a nice job of identifying that PCMH promotes patient experience and suggesting that future research to dissect PCMH components or establish more rigorous RCTs intended to investigate clinical/cost outcomes is appropriate.	Thank you for the comment.
Peer Reviewer 1	General (Clarity/Usability)	Yes, manuscript is well organized.	Thank you for the comment.
Peer Reviewer 1	Introduction	Excellent background and summary of problem. Role of PCMH in health reform is rather central and authors clearly make a case for its utility and furthermore the import of evaluating if/how the PCMH influences the elements of the Triple Aims of care.	Thank you for the comment.
Peer Reviewer 1	Methods	Very logical. Limiting to primary research done in developed countries (ie, high spending health care systems) are appropriate filters. Additionally considering research that looked at practice level change (and not patient/cohort specific groups) makes the lessons learned from this meta analysis more appropriate to large policy consideration.	Thank you for the comment.
Peer Reviewer 1	Results	I do not feel any major studies would have been excluded. There is a clear logic pathway shown for how they arrived at the type and number of studies that met ultimate inclusion criteria. Data shown in results section is somewhat spare but appendices are robust. Would perhaps like to see simplified but greater number of tables in results section, more clearly separated by Key Question.	Thank you for your comment concerning the logic of included studies. We reviewed and updated the results tables and the tables in the appendices, but did not add additional tables.
Peer Reviewer 1	Discussion	Yes. This aspect of the manuscript is excellent.	Thank you for the comment.
Peer Reviewer 2	General	This report is a thorough analysis. Key questions are well-defined and described.	Thank you for the comment.
Peer Reviewer 2	General (Clarity/Usability)	Though long, the report covers a wide range of material and will allow interested readers to focus in on specifics.	Thank you for the comment.
Peer Reviewer 2	Introduction	Excellent setting of the paper.	Thank you for the comment.
Peer Reviewer 2	Methods	Though I am not health services researcher, these look appropriate.	Thank you for the comment.
Peer Reviewer 2	Results	Yes...to all. Well-written, presented.	Thank you for the comment.
Peer Reviewer 2	Discussion	All well-done and written constructively.	Thank you for the comment.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer 3	General	The report is an excellent summary of the state of the literature published on outcomes of implementation of PCMH in primary care practice. The audience, target population are explicitly defined and the key questions are appropriate and explicitly stated.	Thank you for the comment.
Peer Reviewer 3	General (Clarity/Usability)	The report is well structured and organized, points are clearly presented, and the conclusions will be useful to inform policy and future research. I appreciate having the opportunity to assist in review of this important work.	Thank you for the comment.
Peer Reviewer 3	Introduction	Introduction is a good summary of the history of PCMH and rationale for literature review.	Thank you for the comment.
Peer Reviewer 3	Methods	Inclusion and exclusion criteria make sense. Search strategies are logical. Definitions are appropriate. Statistical methods limited by literature but appropriate.	Thank you for the comment.
Peer Reviewer 3	Results	Specific comments follow: Page 61 "Data on impatient."	Thank you, we have corrected this typographical error in the final report.
Peer Reviewer 3	Results	Page 67, "As expected based on the literature about disease management however, measures that would be expected to be impacted heavily by prevention of disease exacerbations." (fragment)	Thank you for spotting this. We have corrected to: "Based on the literature about disease management, reduced use of resources may result from prevention of disease exacerbations. This possibility is reflected by the result that inpatient admissions…."
Peer Reviewer 3	Results	Page 67 "investigators found that children in the medical home program had 8% total monthly emergency department visits" (should it be 8% fewer total monthly ED visits?)	Yes, 8 percent fewer is correct. This has been corrected in the final report.
Peer Reviewer 3	Results	Page 67 "The final observation study with the specified goal of evaluation PCMH" (should it be "goal of evaluation of PCMH"?)	Thank you for spotting this. We have corrected to "The final observational study with the specified goal of evaluating PCMH…."
Peer Reviewer 3	Results	Overall, the level of detail is appropriate, studies are clearly described, figures are clear and helpful. I am not aware of any studies that should have been included but which were not.	Thank you for the comment.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer 3	Discussion	I think the discussion and conclusions clearly lay out the state of the evidence to date. The most important section pertains to suggestions to future researchers on this topic. I particularly agree with the importance of understanding what the effects are of PCMH on health outcomes, and which elements of PCMH lead to improvements in outcomes. It is also important to better understand the economic impact. At BCBSNC, our studies have consistently shown lower ED and inpatient utilization but less so significant cost savings. This discrepancy is difficult to explain. It may be that "full" PCMH is too expensive, but that there are critical elements that can produce improved health effects and lower costs, at a lower implementation cost.	Thank you for the comment.
Peer Reviewer 4	General	I think the report is clinically meaningful. It sums up evaluates the current diverse set of studies, in the most scientific manner possible, given the limitations and diverse set of metrics and missing data. Target populations and audience is clearly defined and key questions and clear, appropriate and explicitly stated.	Thank you for the comment.
Peer Reviewer 4	General (Clarity/Usability)	It is well structured and organized and the main points are clearly presented. The conclusions can be used to inform policy and practice decisions.	Thank you for the comment.
Peer Reviewer 4	Introduction	The authors do a nice job in the executive summary laying out the background and rational for this work, with clear objectives, methods, data analysis, results and a discussion that clearly highlights the main points from a fairly data heavy evaluation of each of the key questions.	Thank you for the comment.
Peer Reviewer 4	Methods	The inclusion and exclusion criteria are justifiable. The search strategies are explicit, logical and comprehensive. The definitions for outcome measures are appropriate as are statistical methods.	Thank you for the comment.
Peer Reviewer 4	Results	The amount of detail in the results is appropriate. It is presented in a manner using easy to read tables and summaries. Rigorous and scientific rational about studies to include were used and in my opinion the appropriate studies were included.	Thank you for the comment.
Peer Reviewer 4	Discussion	Discussion/ Conclusion: The implications of the findings are clearly stated and the limitations of this data analysis are well described. It does not appear that any important literature was excluded. The research gap section is clear on what researchers should focus on in future research to improve the types of data important to gather & data analysis, to move the science in this area forward.	Thank you for the comment.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer 5	General	The report is very well-organized and very well-written. The authors have done an outstanding job tackling a very complex set of questions, sorting through a complex and somewhat nebulous body of literature, and presenting a review that is precise, clear, well-balanced and understandable to the intended audience.	Thank you for the comment.
Peer Reviewer 5	General (Clarity/Usability)	The report is well structured and organized, clearly presented and informative. The conclusion that "there is little to no evidence of improved clinical outcomes or reduced economic burden" should be more strongly coupled to the point that a greater program evaluation investment is going to be needed to be able to gather sufficient evidence one way or another. (I think that most lay readers will interpret that sentence to mean "PCMH doesn't work"-- thus it is important to make the strong distinction between the issue of paucity of data vs. evidence of lack of effect).	Thank you for raising this important point. We agree that we are not saying PCMH does not work. We have revised this statement to "Current evidence is insufficient to determine effects on clinical and most economic outcomes." Further, we have added the caution "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."
Peer Reviewer 5	Introduction	Well done. The authors' operational definition of PCMH is, in my opinion, a good one, and well-explained. The components of PCMH emphasized in this definition differ importantly from emphasis placed on certain PCMH characteristics in other popular definitions or implementations of that term (such as, the relative emphasis placed on information technology and electronic health record in NCQA PCMH certification). It may be helpful to the reader if you elaborate on those differences.	Thank you for the comment and for raising this important point. We have reiterated the lack of consensus concerning the definition of PCMH. As you suggest, we point out that certain elements receive differing levels of emphasis, based primarily on the AHRQ definition of PCMH. For example, the use of an electronic health record is an important tool that can be used to implement PCMH elements. The following sentences have been added to the Introduction: "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. As described in detail below, we have based the operational definition of PCMH for this review on the definition outlined by the Agency for Healthcare Research and Quality (AHRQ)."

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer 5	Methods	I questioned the inclusion criteria related to study population (Table 1). In the first criterion, you attempted to include only studies that targeted populations representative of general adult primary care practice. Scanning your included studies, however, most truly focused on a defined higher risk subset of the practice population. (e.g. geriatric, or multiple complex chronic conditions). That focus on higher-risk subpopulations is not inappropriate, and is arguably desirable or necessary (in the context of a study designed to test effects related to clinical and cost/utilization outcomes). You may be misleading the reader, however, to claim that you reviewed a body of literature testing PCMH effects on the general primary care population.	We appreciate the concern. We included studies of programs that addressed at least two conditions or the entire population of patients. As pointed out, most studies enrolled patients with multiple chronic conditions, rather than the general primary care population. We've emphasized this point in the Results and Discussion.
Peer Reviewer 5	Methods	In the second inclusion criterion related to population, it appears that you required pediatric studies to have a focus on children with special health care needs? This sounds like a conceptually opposite approach than the one you took for adult population studies? This implies that you may have excluded studies that examined effects on the general pediatric population?	Our eligibility criteria restricted inclusion to CSHCN. However, please note that on our initial screening of studies, we did not identify any eligible studies in child and adolescent primary care patients selected to represent the practice rather than on the basis of a particular chronic illness.
Peer Reviewer 5	Results	The Results are well presented. For KQ4, however, the search term of "medical home" was likely too narrow. Many important demonstration projects on the near horizon have not been mentioned, many of which are sponsored or supported by the federal government. CHIPRA, CMS Health Homes Waiver, the Multipayer Advanced Primary Care Demonstration Program, to name a few. These demonstration programs have a required evaluation component for participating states, as well as CMS-funded cross-state evaluations to be conducted by an external evaluator (Mathematica for CHIPRA, RTI for MAPCP). Given the momentum around PCMH adoption, fueled now by substantial public and private payer investment in these demonstration efforts, we may need to rely more heavily on these types of program evaluations (rather than the traditional academic literature) for future assessment of the body of knowledge around PCMH effectiveness.	Thank you for the statement about presentation of results. Regarding demonstration projects, we used the term "medical home" in searchable databases (e.g., enGrant Scientific) but also explored any promising web links on individual websites (e.g., Commonwealth). Based on updated information, we were able to include the CMS MAPCP project in the KQ4 results sections. Other demonstration projects identified, but not included, were excluded because a comparison group was not specified.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer 5	Discussion	In the discussion, I would like to see even more advocacy for standardized nomenclature and methodologies to facilitate future systematic evaluation efforts. The authors have described well the difficulties of conducting this sort of review given the complexity of this topic and state of the literature. Organizations that sponsor PCMH interventions (which are more likely to be payers, government agencies, provider institutions, or even large employers rather than traditional sponsors of research) need, and would likely embrace and enforce, a consensus set of tools to standardize characterization of specific medical home components. Standardized, open-source (affordable) methodologies for operationalizing key outcome variable are also needed (such as code sets for defining avoidable inpatient and ED use, uniform standards for risk-adjustment and handling of outliers in cost and utilization reporting). PCMH evaluations suffer inherently from sample size needed to assess impacts on clinical and economic outcomes while accounting for cluster effect; and our ability to pool data across interventions to examine such effects will be dependent upon adoption of uniform standards.	We agree with your concerns and have further highlighted the need for standard nomenclature and methodologies. The second paragraph of the Limitations of the Review Process section now reads: "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." In addition, the subsection of the Discussion titled "Most Important PCMH Components" now includes the following sentences: "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)."

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer 6	General	The cautions reported about not finding concrete evidence for improved patient outcomes or reduced overall costs are important. A recent study by Solberg reaches much the same conclusions. However, without sufficient payment changes that support key variables such as increased care management and reduced panel size for PCPs, it will remain difficult to find significant changes in these key outcomes. It is probable that the "Dose" of the intervention needed to impact such outcomes is greater than current studies have provided.	You bring up an important point concerning the need for information on payment reform. We note in the section on “Limitations of the Review Process” that the lack of information on financial systems into which PCMH is being implemented is a significant limitation of the current literature on PCMH. The second paragraph of the Limitations of the Review Process now reads: “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.” Thank you for raising the important point about future studies needing to address the “dose” of the intervention. We agree and have added this to the “Research Gaps” section (under “Most Important PCMH Components”).
Peer Reviewer 6	General (Clarity/Usability)	Yes, although I would be happier of there were a mention of the issue I have raised above.	Thank you for the comment. Please see our above response to your concerns.
Peer Reviewer 6	Introduction	The introduction is concise, well stated and accurate.	Thank you for the comment.
Peer Reviewer 6	Methods	Yes, the methods are appropriate. My only criticism is that without effective economic support to create the changes suggested in the PCMH, the degree of changes in practices will be small and may, therefore, be ineffective. It is as if we were studying a drug intervention with homeopathic doses of a potentially effective drug. Future studies will only be more useful if the "dose" of the intervention is sizable.	Thank you for raising the important point about future studies needing to address the “dose” of the intervention. We agree and have added this to the “Research Gaps” section (under “Most Important PCMH Components”).
Peer Reviewer 6	Results	Yes, on all of these factors. The details are appropriate and the key messages are repeated usefully in every section.	Thank you for the comment.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer 6	Discussion	Yes, the implications are clear as are the need for focused future research. My only issue is that we may be testing an ineffective degree of change in practices to expect to see differences in cost and quality outcomes.	Thank you for raising the important point about future studies needing to address the "dose" of the intervention. We agree and have added this to the "Research Gaps" section (under "Most Important PCMH Components").
Peer Reviewer 7	General	**Though the idea of a critical review of Medical Home literature through the lens of health services research is admirable, it may well not yet be valid, due to the still-developing state of the science.** I appreciate very much the authors' effort to take a critical look at the Medical Home model of care. It is very important to make every effort to examine the effectiveness of the model and its component parts by looking at what literature there is to support or refute the model. As the concept has evolved over two decades, the Medical Home model has undergone evaluation to an increasingly rigorous degree. However, the operationalization of Medical Home processes, outcomes and measurements for research purposes and funding for research related to the Medical Home is still in its very early stages, with most projects five years old or less. In fact, the first AHRQ-funded conference on developing a policy-relevant research agenda for the Medical Home occurred less than three years ago, and it is likely that projects informed by this conference are not yet even completed.	We appreciate your concern and believe that the horizon scan is a very important part of this report for the reasons that you mention. We have attempted to address the concern that the evidence base is being developed, and to clarify that we are not saying PCMH does not work. See, e.g., the first paragraph of the Discussion, where we have added the sentence "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 considered preliminary."
Peer Reviewer 7	General (Clarity/Usability)	Please see my comments in the Discussion/Conclusion section above.	Thank you for the comment.
Peer Reviewer 7	Introduction	The rationale for the report is well outlined.	Thank you for the comment.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer 7	Methods	Please also see my comments in the "results" section below that have methodological implications especially for revision. **The review's search strategy fails to include important literature that is critical to evaluating the effects of Medical Home interventions.** The review's search strategy is quite specific to variations on the term "medical home" and as such misses many studies that either examined the effects of important activities that are part of the medical home concept, or done before the term was widely used. While used in the child health literature as far back as 1967, the term has been used widely in child health only since the late 1990s and in the adult literature since about 2005. A review of the evidence for the medical home in children with special health care needs (Homer et al, Pediatrics 2008; 122:e922-e937) took a different approach, identifying 33 articles in the child health literature from 1986-2006 that involved evaluation of eight major and more than 20 minor activities on outcomes. Outcomes primarily involved quality of care, organized according to the STEEEP quality domains from the Institute of Medicine, with some studies also evaluating quality of life, health status, and cost outcomes. The review concluded that the evidence in children as of 2006 provided "moderate support for the hypothesis that medical homes provide improved health-related outcomes for children with special health care needs. " Few of these studies were included in the AHRQ review.	We appreciate your raising this concern. We agree that there is a very broad literature on the impact of individual components of the PCMH model and single-condition disease management programs that have a number of aspects similar to PCMH. We believe that these studies provide important information on the care of patients with chronic illness. However, the goal of the present review was to examine studies of programs/interventions that address multiple chronic illnesses. We address this issue in the Introduction (Scope of Review section) and Discussion. We took an approach that attempted to both capture key articles addressing the medical home (KQ1 articles with comparison groups at least 6 months in duration). We have revised the Methods to clarify that the term medical home and other terms for this concept were utilized in our search. The detailed search strategy is given in Appendix A. The Homer article is now cited both in the Methods chapter and in the Discussion (under "Findings in Relationship to What is Already Known"). We point out that interventions that improve access to primary care improve health outcomes and lower costs.
Peer Reviewer 7	Methods	More recently, an article by Cooley et al., "Improved Outcomes Associated with Medical Home Implementation in Pediatric Primary Care" (Pediatrics 2009; 124:358-364) that showed significant improvements in ED and inpatient utilization in a multi-state, multi-payer demonstration was not mentioned in the AHRQ review. It is unclear why this was not included.	While we agree that the Cooley article provides important cross-sectional information concerning the medical home, it does not meet inclusion criteria for this review. It is not a test of an intervention that can be evaluated for whether it meets the criteria of the PCMH. Rather, it is based on a cross-sectional survey of whether the current organization of practices meets the standards of the PCMH. As a result, it could not be evaluated as part of KQs 2-3. In addition, there is not a true set of control clinics or patients, an additional requirement for inclusion in our KQ 1 analyses.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer 7	Results	**The review includes a disproportionate number of adult studies, and incorrectly combines literature on older adults with that on children with special health care needs.** The principles of the Medical Home were articulated in pediatrics as early as 1967, with an increasing amount of investigation occurring from the mid-1980s through the present time. Nonetheless, the studies cited in this review are more than 80% adult-only studies done since 2000. This ignores the accumulated experience of child health services researchers without adequate explanation. Additionally, the care of older adults is markedly different from that of children with special health care needs in many respects. Assessment of medical homes serving children and adolescents must take into account the ways in which developmental trajectory, dependent relationships, differential epidemiology and changing demographics affect possible outcomes (Stille et al., Academic Pediatrics 2010; 10: 211-217). Thus, there is no intrinsic reason to believe that medical homes serving children with special health care needs can be compared directly to medical homes serving adults. Simply aggregating studies designed specifically for children with studies for older adults has little to no face validity. These analyses should be separate. In fact, the scant number of child-focused studies in the review suggest that when taken separately, Medical Homes for children are effective. In Tables 7 through 13, 10 of the 13 childfocused findings actually support the effectiveness of medical homes. Two findings (both from the same study) are equivocal and only 1 is negative.	We appreciate your raising this concern. We agree that there is a very broad literature on the impact of individual components of the PCMH model and single-condition disease management programs that have a number of aspects similar to PCMH. We believe that these studied provide important information on the care of patients with chronic illness. However, the goal of the present review was to examine studies of programs/interventions that address multiple chronic illnesses. We have addressed this concern as follows: - In the Introduction and Discussion, we re-emphasize the literature showing benefits on single conditions - We cite the article by Stille et al. in the Discussion (“Missing Outcomes” section) and call for evaluations to be tailored carefully to the population studies - We conducted subgroup analysis for adults versus children and incorporated these findings into the revised report. These analyses led to a change in conclusions for economic outcomes. - Although formal subgroup analyses were possible for only selected outcomes, we now note that child and adult outcomes were generally congruent. Further, these effects are generally positive, except for clinical and economic outcomes, where the extant data are insufficient.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer 7	Results	**The review, while focusing correctly on studies involving patients with more than one condition, inadvertently excludes important evidence from studies focusing on Medical Home interventions for patients with one or a few discrete conditions. It also excludes studies examining one or a few elements of the Medical Home that are important to evaluate its utility.** 475 of the 588 excluded articles were excluded because they "did not meet the PCMH definition". The authors are correct in their emphasis on studies that include large proportions of patients in a population. However, given the inherent difficulty in measuring outcomes in groups of patients with heterogeneous health care needs and the relative ease of measuring outcomes in patients with discrete conditions (e.g. asthma, diabetes, depression), much of the important literature describes evaluations of interventions for patients with discrete conditions. Examples include several excluded studies by Katon et al. (adult depression), Lorig et al. (adult diabetes), and several pediatric investigators in the area of asthma care. The critical issue with these studies is whether the interventions that show promise are generalizable to patients with other conditions; many are very likely generalizable. Additionally, it appears that many studies that did not meet the definition of the PCMH did examine critical components of the Medical Home model (for example, Klitzner et al., J Pediatr 2010; 156: 1006- 1010, care coordination for children with complex needs). With no incentives for large-scale Medical Home change in either the existing health care delivery system or the existing payment system, smallscale studies evaluating certain components of the Medical Home are the norm at the present time. We agree completely that the evidence for larger-scale studies is lacking, but funding for these studies as well as funding for large-scale practice change currently does not exist.	We appreciate your raising this concern. We agree that there is a very broad literature on the impact of individual components of the PCMH model and single-condition disease management programs that have a number of aspects similar to PCMH. We believe that these studies provide important information on the care of patients with chronic illness. However, the goal of the present review was to examine studies of programs/interventions that address multiple chronic illnesses. We have addressed this issue in the Introduction ("Scope of Review" section) and have added further clarification in the Methods. Finally, we have added additional emphasis in the Discussion (see "Findings in Relationship to What is Already Known") that medical home- type interventions which are focused on selected chronic conditions are well established in children and adults to improve outcomes.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer 7	Discussion	**The review's conclusion, while perhaps scientifically accurate, could easily be construed by policymakers as concluding that the Medical Home model has no benefit.** During this time of scarce Federal and state resources, federal and state policymakers, insurers, and health care providers at under great pressure to support only those health care activities that are "evidence based". Many will turn to brief summaries from respected agencies such as AHRQ, emphasizing the critical need for precision in this review. In its conclusion (p. 67), the review seems to unintentionally oversimplify the data presented: "There is little to no evidence of improved clinical outcomes or reduced economic burden." This statement, even if technically correct, is misleading , as policymakers could easily interpret "little to no evidence" to mean that the Medical Home concept is ineffective**.** This misleading and potentially harmful statement must be modified.	Thank you for raising this important point. We agree that we are not saying PCMH does not work. We have revised our conclusion for KQ1 (see Discussion) and added a caution that these findings should be considered preliminary given the current state of the science.
Peer Reviewer 9	General	Overall, the report is well done and the topic is very timely.	Thank you for the comment.
Peer Reviewer 9	General (Clarity/Usability)	The report is well structured and organized. Main points are clearly communicated. The discussion of the limitations of existing studies and recommendations on PCMH study designs should be useful to researchers currently working on PCMH evaluations and should help toward improving the quality of future PCMH studies. The report also will be informative to policymakers. The PMCH model has been touted as a way to "bend the cost curve"; however, as this report demonstrates, few studies exist to support this hypothesis and of those that do show some cost savings, many are of poor quality and limited generalizability. This unbiased, empirical report should be useful in tempering some of this initial enthusiasm. Because a number of PCMH studies that have come out since the literature review for this report was conducted, and because of the large number of studies currently underway, I would encourage AHRQ to update this evidence report in two years.	Thank you for the comment.
Peer Reviewer 9	Introduction	Background section was well done. It is concise while raising the key points.	Thank you for the comment.
Peer Reviewer 9	Introduction	Specific comments: - ES-1, line 42-48: also mention role of states and Medicare in supporting PCMH programs	Thank you. We have added a mention of Medicare to the Executive Summary and main report.
Peer Reviewer 9	Introduction	- p. 6, line 49: delete extra "evaluation"	Thank you, we have corrected this typographical error in the final report.
Peer Reviewer 9	Methods	Methods and inclusion/exclusion criteria are well-explained, justifiable, and appropriate.	Thank you for the comment.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer 9	Methods	Specific comments: - p. 10, line 38-47: p. 8 (line 16-17) states that uncontrolled pre-post studies were included but p. 10 suggests that studies with no comparator were excluded. Please clarify whether pre-post studies with no comparison group were included.	Thank you for asking this question. In the sections you mention, we have clarified that pre-post studies were considered only for KQs 2-3.
Peer Reviewer 9	Methods	- p. 17, line 25: Can you elaborate on the reasons for excluding the 4255 abstracts, as you do in line 36-47?	Reasons for exclusion are not recorded when studies are excluded base on review of the title and abstract. These studies are judged by two reviewers to have no relevance to any study question.
Peer Reviewer 9	Methods	p. 17, line 38: Unclear what you mean by "not original data".	We have clarified that “Not original data” articles refers to “editorials, letters, etc.” that do not contain original research data.
Peer Reviewer 9	Results	Amount of detail is appropriate. Study characteristics are clearly described. I appreciated that the details were repeated each time the study was referenced, as the reader may forget or may read only certain sections. Key results are explicit and applicable.	Thank you for the comment.
Peer Reviewer 9	Results	To my knowledge, no studies that were available at the time the literature review was conducted was overlooked. The report should note, however, that a number of studies have come out since then that may address some of the gaps in evidence or alter the findings of this report. This is especially true for this topic, given the rapidly increasing number of PCMH programs.	Thank you for raising this important point. The PubMed literature searches were rerun on December 6, 2011. We have included 1 additional study relevant to KQs 2-3. We agree that key information is continuing to come out about PCMH and have attempted to address this issue as part of the horizon scan (KQ4); we identified 1 new citation for this question.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer 9	Results	The list of ongoing studies (KQ 4) is incomplete. For example, CMS currently has two PCMH demonstrations underway (MAPCP and FQHC APCP) and a third in development (CPCI). No information about these demos are included, even though all three have an evaluation component. Likewise, several states that have PCMH pilots with evaluations are not mentioned but should be (e.g., NY's Adirondack Region Medical Home Pilot, PA's Chronic Care Initiative, VT's BluePrint for Health). **(See line 62 below for information on these studies)**	Thank you. We reviewed the available CMS information in our initial review. The CMS demonstration projects initially did not meet our inclusion criteria because there was no specified plan for comparison with non-PCMH care. On review of the websites suggested in another comment, below, we have found the required detail for the MAPCP project and now include this in the horizon scan (KQ4). However, we could not find any text describing the FQHC APCP that specified a comparison group for evaluation. We recognize that this is a limitation of our review and the grey literature available to us. We have further expanded on this limitation in the KQ4 section and specifically note the FQHC APCP demonstration.
Peer Reviewer 9	Results	I suggest adding information about how each study "scored" on the SOE domains (risk of bias, consistency, directness, precision). This could be added to Appendix G.	Strength of evidence pertains to bodies of evidence, rated across all relevant studies. Therefore, SOE domains are not applicable to individual studies. The quality assessment tool (Appendix D) and summary quality scores (Results and Appendices G-I) are used to evaluate individual studies.
Peer Reviewer 9	Results	Specific comments: - p. 22, line 27: What coordination of care measure was used in this study? Bice and Boxerman's COC Index?	We have clarified in the table and associated text that coordination of care was measured using select questions from the “Components of Primary Care Index”.
Peer Reviewer 9	Results	- p. 24, line 9/10: Provide additional details on how self-reported coordination of care was measured in the AAFP NDP study.	See immediately preceding comments. We clarified in the table and associated text that coordination of care was measured using items from the “Components of Primary Care Index.”
Peer Reviewer 9	Results	- p. 40, line 13-14: Incomplete sentence	Thank you. We have revised to: “Based on the literature about disease management, reduced use of resources may result from prevention of disease exacerbations. This possibility is reflected by the result that inpatient admissions….”
Peer Reviewer 9	Results	- Appendix G: Add information about the predominant limitations of each study.	Thank you for this suggestion. Major limitations of each study have been added to the appendices.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer 9	Results	- p. 59, Table 22: Table 22 was easier to understand after having read the previous sections; however, it was difficult to understand when included in the Executive Summary (p. ES-12, Table ES 2) without this context. I had a number of questions when I first reviewed in the Executive Summary: - Did all the studies measure a concept the same way? For example, did the seven studies that examined patient experience measure it in the same way? If not, how do these different measurement methods affect the reported magnitude of the effect? - How were "small" and "moderate" SOEs defined? - How were the ESs derived? - Is the number of subjects listed in column 1 the number of patients or practices? - When measuring effect size, was each study weighted equally or were studies with larger sample sizes given greater weight? I would recommend either not including this table in the Executive Summary or providing more context in the narrative to be able to better understand it.	We have added additional context to the Executive Summary and table footnotes to aid interpretation, including a reminder to the reader about the meaning of strength of evidence. Studies did not use the same instrument to measure the concept. Details about measurement are contained in the Results section of the body of the report, but were judged to be too finely grained for the Executive Summary. SOE was defined as described in the Methods (see Strength of Body of Evidence). Effects sizes were calculated using standard statistical methods. We have added details on ES calculation in the Methods section (see Data Synthesis). Column 1 shows the number of studies (patients in parentheses) as described in the column header. Effect sizes were calculated for each study individually. With the exception of rates of inpatient admissions and emergency department visits, summary estimates were not calculated. Thus, weighting is not relevant to the effect size calculation.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer 9	Results	- Appendix J: Add information about CMS demos and PA, VT, and NY's PCMH pilots that are underway. Information about CMS's PCMH demos is available on the following websites. As project officer for the CMS evaluations, I also would be happy to provide additional details if needed: - MAPCP: https://www.cms.gov/DemoProjectsEvalRpts/MD/ItemDetail.asp?ItemID=CMS1230016 - FQHC APCP: http://www.fqhcmedicalhome.com/ and http://www.cms.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=3&sortOrder=descending&itemID=CMS1230557&intNumPerPage=10 - CPCi: http://innovation.cms.gov/initiatives/cpci/	Thank you. We reviewed the available CMS information in our initial review. The CMS demonstration projects initially did not meet our inclusion criteria because there was no specified plan for comparison with non-PCMH care. On review of the websites suggested in another comment, below, we have found the required detail for the MAPCP project and now include this in the horizon scan (KQ4). However, we could not find this for the FQHC APCP, the CPCi, or the VT and NY pilot initiatives. Please note, the PA PCMH project was captured during our search of the Commonwealth database and is included in the table. We recognize that there may be several ongoing PCMH demonstration projects that will provide useful information on its effectiveness, but do not meet our specified criteria. This is a significant limitation of the grey literature available to us. We have further expanded on this limitation in the KQ4 section.
Peer Reviewer 9	Discussion	The report's major findings are clearly stated and limitations and research gaps are well described.	Thank you for the comment.
Peer Reviewer 10	General	I appreciate the study team's attempt to conduct a meaningful examination of the medical home model. As noted by the authors, it was a challenge. I find issues associated with the approach taken by the team and the report conclusions (see below). The definition, the target populations, and the key questions are clearly stated. Because of the variability in medical home definitions, it was appropriate to utilize the AHRQ definition, which expands the tenets of primary care.	Thank you for the comment.
Peer Reviewer 10	General	I suggest rewording KQ1 "what are the effects of the PCMH on patient and staff experiences...economic outcomes"? The wording connotes an intervention like applying silver sulfadiazine cream to a burn, consistent with the authors' description on page 65 of a discrete intervention. Regarding medical home, there are many permutations to the concept/model. This study is looking at what happens to patient care in a construct defined by AHRQ. It can't begin to address all the possible constructs and PCMH-related outcomes.	We appreciate the concern. Once the initial key questions are approved by AHRQ, we are not permitted to change it.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer 10	General (Clarity/Usability)	Clarity and Usability: The report is generally well structured and organized. It importantly identifies gaps and limitations of the evidence base. It outlines some areas for additional studies and research. More specificity regarding measures and outcomes at the various levels may be helpful. One area that wasn't mentioned is the need to measure the PCMH at the community level. There also should be a call for studies that address the unique characteristics of children and child-relevant outcome measures, including measures of system integration. For specific suggestions, see policy statement on research and policy related to the family-centered medical home from the Academic Pediatric Association. Stille C, et al. Academic Pediatrics 2010; 10:211-7	Thank you for recommending the paper by Stille. We now cite this paper in the Discussion (see "Missing Outcomes" section) and have revised the text to include: "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. For example, developmental outcomes, effects on family, school performance and school absences may be particularly important in pediatric studies."
Peer Reviewer 10	Introduction	For the child health community, family-centered care is cornerstone of the medical home model.	We agree with your comment.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer 10	Methods	The identified clinical outcomes may have been appropriate for the adult population but aren't the most sensitive measures for children. Looking only at these outcomes doesn't adequately capture the child experience. It's not surprising that there were no pediatric studies associated with the 3 identified clinical outcomes. For CSHCN, most common conditions fall under the category of mental and behavioral health. Thus, functional and developmental outcomes are more relevant for children as is utilization of community services. Because optimal child health's not only dependent on the health system, the degree of system integration is a more meaningful measure. A measure that may be applied to both populations would be adherence to therapy (p.29, line 25). Another potential measure would be receipt of preventive services.	The most common reasons for exclusion were: studies not meeting the functional definition of PCMH, or not addressing a general population or children with special health care needs. Receipt of preventive services was an eligible outcome; treatment adherence is an intermediate outcome and was not eligible in this report. We have reviewed the articles considered but excluded from our report. None were excluded because outcomes were limited to mental or behavioral health. However, if the study focused on a single condition (e.g., childhood depression), it would have been excluded as not meeting our requirements for the eligible population. We agree that behavioral and developmental health outcomes for children are important. In fact, these issues are central to well-child care and also constitute a large proportion of other visits in the pediatric setting. However, measuring the impact of interventions on these outcomes is difficult because of the long period of followup needed. Instead, studies focus on the process of care, as described by the reviewer. The impact of the medical home on these processes of care would be captured in this review (e.g., patient/family experience, staff experience, improved processes of care for referral and followup, and economic outcomes). These measures would also capture the impact of medical home on other important pediatric conditions, such as asthma. Our search strategy was designed to be inclusive, but focused on evidence of sufficient quality to understand the impact of the medical home.

Commentator & Affiliation	Section	Comment	Response
Peer Reviewer 10	Results	The predominance of adult focused studies negates benefits observed in the very few studies focused on children (p.43). One study that was overlooked: Cooley, WC, et al Pediatrics 2009; 124;358-364 I understand that the publication may not have been captured because of the words "pediatric primary care" in the title. However, this is an important study that should have been reviewed. KQ4 - there is a cohort of pediatric practices that have implemented the medical home model over the past several years in Pennsylvania. There is a great amount of registry data and family experiences associated with the EPIC-IC medical home initiative. www.pamedicalhome.org. Contacts: Molly Gatto and Renee Turchi MD	While we agree that the Cooley article provides important cross-sectional information concerning the medical home, it does not meet the inclusion criteria for this review. It is not a test of an intervention that can be evaluated for whether it meets the criteria of the PCMH. Rather, it is based on a cross-sectional survey aimed at determining whether the current organization of practices meets standards of the PCMH. As a result, it could not be evaluated as part of KQs 2-3. Moreover, there is not a true set of control clinics or patients, an additional requirement for inclusion in KQ1 analyses. The Pennsylvania demonstration project is included in KQ4. Access to the EPIC-IC dashboard is restricted to registered medical home practices. We did not identify a summary publication on the referenced website that gives outcomes.
Peer Reviewer 10	Discussion	The marked imbalance in studies of adult populations versus child populations highlights the funding gap in child related research. This is a point that should be included in the discussion.	We revised the results to consistently contrast the number of studies in adults versus children. In the Discussion, we placed additional emphasis on the finding that most studies were conducted in older adults.
Peer Reviewer 10	Discussion	The authors' conclusion that "there is little to no evidence of improved clinical outcomes..." contradicts what's stated on page 34, line 49 that "there is insufficient evidence to determine the impact of PCMH implementation on clinical outcomes." Further, the examined studies were confined to the adult population so in essence, nothing can be said about outcomes for children.	We have revised our conclusion for KQ1 (see Discussion), and added a caution that these findings should be considered preliminary given the current state of the science. We have also added additional emphasis that most evidence is derived from studies of older adults.

Commentator & Affiliation	Section	Comment	Response
Benard Dreyer, MD Academic Pediatric Association	General	The APA has carefully reviewed the AHRQ Draft Evidence Report entitled, "Closing the Quality Gap Series: Revisiting the State of the Science—The Patient-Centered Medical Home." Undoubtedly, this report when it is released in final will be highly influential in determining the future of medical homes in the United States. Consequently, the final draft of the report must be written with the utmost precision and care, especially as it relates to our most vulnerable populations. In this critique, the APA has identified substantial concerns related to the review of evidence in the AHRQ draft report concerning medical homes for children. While the attention of AHRQ to the issue of medical home effectiveness is much appreciated, the APA has concluded that the draft report needs to be modified as follows: 1. Delete/modify "There is little to no evidence of improved clinical outcomes or reduced economic burden." 2. Disaggregate PCMH evidence for children and adults, and present results separately. 3. Include the work of Homer et al. (Pediatrics 2008; 122: e922-37) (and the key studies reviewed there) and Cooley et al. (Pediatrics 2009; 124: 358-64) in the review. (Comment continued on next page)	1. We have revised our conclusion for KQ1 (see Discussion), and added a caution that these findings should be considered preliminary given the current state of the science. 2. In the Results section, we have conducted subgroup analysis to contrast any differences in findings for adult populations vs. children and adolescents. 3a. We appreciate the suggestions of additional articles to review. We examined titles in the Homer article to determine if there were any that were missed in other searches done for the review. No additional eligible articles were identified. As noted in the abstract to the Homer article, the studies Homer reviewed did not test the entire medical home model, an inclusion criteria for the present EPC review. 3b. While we agree that the Cooley article provides important cross-sectional information concerning the medical home, it does not meet the inclusion criteria for this review. It is not a test of an intervention that can be evaluated for whether it meets the criteria of the PCMH. Rather, it is based on a cross-sectional survey aimed at determining whether the current organization of practices meets standards of the PCMH. As a result, it could not be evaluated as part of KQs 2-3. Moreover, there is not a true set of control clinics or patients, an additional requirement for inclusion in KQ1 analyses. (Response continued on next page)

Commentator & Affiliation	Section	Comment	Response
Benard Dreyer, MD Academic Pediatric Association	General	4. Revise the review criteria to include studies with one or a few discrete conditions, as well as studies examining one or a few key elements of the medical home. 5. Identify where investments in design and measurement of PCMH process and outcomes should be made to clearly assess the benefits and limitations of PCMH.	4. We thank the APA for discussing the issues of whether studies of single disease should be included. The decision was made not to include such studies because the definition of the PCMH upon which the report is based emphasizes that PCMH involves broad reorganization of the delivery of primary care, as opposed to reorganizing care for a specific disease. Further, previous systematic reviews have examined aspects of the management of individual conditions. Such studies are important, but beyond the scope of the present review. 5. We agree that it is important that additional work be done in the area of measuring the PCMH model. We have called for this in the "Research Gaps" section of the Discussion.

Commentator & Affiliation	Section	Comment	Response
Benard Dreyer, MD Academic Pediatric Association	Methods	***The review's search strategy fails to include important literature that is critical to evaluating the effects of medical home interventions.*** The pediatric medical home concept evolved over a 40-year period, informed by an increasingly rich body of research that has accumulated since 1980. The draft review, however, relies primarily (>80%) on studies done on adults within the last decade, excluding the child-related research that was formative in developing the medical home construct and ignoring the accumulated experience of child health services. The review's search strategy is limited to variations on the term "medical home" and, as such, misses studies that either examined important components of the medical home concept or were conducted before the term was widely used. While the term "medical home" has been used in the child health literature as far back as 1967, it only became widely accepted in child health in the late 1990s and in the adult literature since about 2005. A review of the evidence for the medical home in children with special health care needs (Homer et al, Pediatrics 2008; 122: e922-e937) took a different approach, identifying 33 articles in the child health literature from 1986-2006 that evaluated the impact of eight major and more than 20 minor activities on outcomes, including improved health outcomes in randomized controlled trials involving asthma care. Outcomes primarily involved quality of care, organized according to the STEEEP (safe, timely, effective, efficient, equitable, patient-centered) quality domains from the Institute of Medicine, with some studies also evaluating quality of life, health status, and cost outcomes. The review concluded that there was "moderate support for the hypothesis that medical homes provide improved health-related outcomes for children with special health care needs." Few of these studies were included in the AHRQ review.	We appreciate your raising this concern. We agree that there is a very broad literature on the impact of individual components of the PCMH model and single-condition disease management programs that have a number of aspects similar to PCMH. We believe that these studies provide important information on the care of patients with chronic illness. However, the goal of the present review was to examine studies of programs/interventions that address multiple chronic illnesses. We have addressed this issue in the Introduction (Scope of Review section) and Discussion. We took an approach that attempted to capture key articles addressing the medical home (KQ1 articles with comparison groups at least 6 months in duration). We have revised the Methods to clarify that the term medical home and other terms for this concept were utilized in our search. The detailed search strategy is given in Appendix A. The Homer article is cited in the Methods and Discussion (Findings In Relationship To What Is Already Known section). We point out that interventions which improve access to primary care improve health outcomes and lower costs.

Commentator & Affiliation	Section	Comment	Response
Benard Dreyer, MD Academic Pediatric Association	Methods	A more recent article by Cooley et al., "Improved Outcomes Associated with Medical Home Implementation in Pediatric Primary Care" (Pediatrics 2009; 124: 358-364), that showed significant improvements in ED and inpatient utilization in a multi-state, multi-payer demonstration, was not included in the AHRQ review.	While we agree that the Cooley article provides important cross-sectional information concerning the medical home, it does not meet the inclusion criteria for this review. It is not a test of an intervention that can be evaluated for whether it meets the criteria of the PCMH. Rather, it is based on a cross-sectional survey aimed at determining whether the current organization of practices meets standards of the PCMH. As a result, it could not be evaluated as part of KQs 2-3. Moreover, there is not a true set of control clinics or patients, an additional requirement for inclusion in KQ1 analyses.
Benard Dreyer, MD Academic Pediatric Association	Results	***The review does not explicitly separate services designed for children with special health care needs from those designed to serve older adults.*** There is no intrinsic reason to 2 believe that medical homes serving children with special health care needs will have similar outcomes to medical homes serving adults. The primary goal of child health services is maximization of child health, defined by the child's potential over the course of a lifetime. Therefore, assessment of medical homes serving children and adolescents must take into account the ways in which developmental trajectory, dependent relationships, differential epidemiology and changing demographics affect possible outcomes (Stille et al., Academic Pediatrics 2010; 10: 211-217). Patient-centered care should be tailored to the population served. Simply aggregating studies designed specifically for children with studies for older adults seems invalid on its face. These analyses should be separate.	We appreciate your raising this concern. We agree that there is a very broad literature on the impact of individual components of the PCMH model and single-condition disease management programs that have a number of aspects similar to PCMH. We believe that these studies provide important information on the care of patients with chronic illness. However, the goal of the present review was to examine studies of programs/interventions that address multiple chronic illnesses. We have addressed this concern as follows: -In the Introduction and Discussion, we re-emphasize the literature showing benefits on single conditions -We cite the article by Stille et al. in the Discussion (Missing Outcomes section) and call for evaluations to be tailored carefully to the population studies -We conducted subgroup analysis for adults versus children and incorporated these findings into the report. These analyses led to a change in conclusions for economic outcomes.

Commentator & Affiliation	Section	Comment	Response
Benard Dreyer, MD Academic Pediatric Association	Results	***Separately examining the cited studies related to children with special health care needs highlights weaknesses in the review methodology and likely yields different conclusions.*** Review of the child-focused process and outcome studies in Tables 7-13 (pp. 27-42) leads to two conclusions. First, the paucity of child-focused studies raises serious doubts about the validity of the analysis conducted for this report, which must rest its credibility on the existence of adequately large bodies of evidence. Table 7 has only 2 child-focused findings, Table 8 has 1, Table 9 has 0, Table 10 has 1, Table 11 has 1, Table 12 has 6, and Table 13 has 2. These few findings reflect only 4 separate studies. Second, 10 of the 13 child-focused findings actually support the effectiveness of medical homes. Two findings (both from the same study) are equivocal and only 1 is negative. If any conclusion can be drawn from these studies, it is one that confirms previous reviews in the pediatric literature supporting medical homes for children.	We revised our approach to examine studies in aggregate, across patient populations, then for adults compared to children. In most instances, there were too few studies in children for formal qualitative or quantitative comparisons. However, results for children and adults were generally concordant. We have revised the results to draw these contrasts where possible, including meta-analyses of these subgroups for select economic outcomes. Our conclusions now emphasize the relative paucity of studies in children.
Benard Dreyer, MD Academic Pediatric Association	Results	***The review, while appropriately focused on studies involving patients with multiple conditions, excludes important evidence from studies of medical home interventions for patients with one or a few discrete conditions, as well as studies examining one or a few key elements of the medical home.*** The PCMH case definition utilized in this evidence review excludes many studies examining key elements of the medical home - 475 of the 588 excluded articles were excluded because they "did not meet the [authors'] PCMH definition." The draft correctly places emphasis on studies that include large proportions of patients in a population. However, this has a limiting effect by excluding in the AHRQ review studies by Katon et al. (adult depression), Lorig et al. (adult diabetes), and several pediatric investigators in the area of asthma care. It also appears that many studies that did not meet the PCMH definition used in this review did examine critical components of the medical home model (e.g., Klitzner et al., J Pediatr 2010; 156: 1006-10). With few incentives for large-scale medical home change in either the existing health care delivery system or the existing payment system, small-scale studies evaluating certain components of the medical home have been the norm. The lack of evidence from large-scale studies is largely due to a lack of funding for these studies, and funding for large-scale practice change currently does not exist.	We appreciate your raising this concern. We agree that there is a very broad literature on the impact of individual components of the PCMH model and single-condition disease management programs that have a number of aspects similar to PCMH. We believe that these studies provide important information on the care of patients with chronic illness. However, the goal of the present review was to examine studies of programs/interventions that address multiple chronic illnesses. We have addressed this issue in the Introduction ("Scope of Review" section) and have added further clarification in the Methods. Finally, we have added additional emphasis in the Discussion that medical home-type interventions which are focused on selected chronic conditions are well established in children and adults to improve outcomes.

Commentator & Affiliation	Section	Comment	Response
Benard Dreyer, MD Academic Pediatric Association	Discussion	The draft report by AHRQ is a worthy preliminary attempt at summarizing the current literature. With respect to its treatment of medical homes for children, however, there are important issues that must be addressed prior to releasing the final report. The nation is in a sensitive period of economic instability and a period of rapid flux in the health care system. During this time, federal and state policymakers, insurers, and health care providers will be called upon to make far-reaching decisions using whatever information is rapidly available to them in easily digestible form. Many will inevitably turn to brief summaries and second-hand descriptions of reports that bear a seal of approval from respected agencies such as AHRQ. Being precise is therefore critical. Avoiding overstating or understating the definitive conclusiveness of findings is essential to prevent unintended consequences. The patient-centered medical home (PCMH) model has been in a constant state of evolution and has increased in complexity over time. Moreover, PCMH core principles have been understood as a general approach to the provision of care and/or a management process, not a specific and clearly defined treatment intervention with specific and clearly defined outcomes. In this context, broad statements about the effectiveness of medical homes are at best fraught with difficulty and, at worst, highly premature. In its conclusion (on p. 67), however, the report includes a summary statement that dangerously oversimplifies and universalizes existing data: “There is little to no evidence of improved clinical outcomes or reduced economic burden.” This statement is incorrect and misleading, implying that “little to no evidence” exists across populations and that “little to no evidence” means evidence of little to no effectiveness. **This potentially harmful statement must be deleted or modified to avoid misinterpretation**.	Thank you for raising this important point. We agree that we are not saying PCMH does not work. We have revised our conclusion for KQ1 (see Discussion) and have added a caution that these findings should be considered preliminary given the current state of the science.
Public Reviewer #2 National Center for Medical Home Implementation	General	We would first like to strongly emphasize that the National Center fully supports the comments and suggested modifications submitted by the Academic Pediatric Association (APA) in regard to this report. In addition to the valid concerns expressed by the APA, the National Center is especially concerned that some of the information included in the review of available evidence-based research is premature and therefore may result in a situation where readers, researchers and others may be at risk of arriving at false conclusions with unintended consequences, as further described below.	Thank you for the comment.

Commentator & Affiliation	Section	Comment	Response
Public Reviewer #2 National Center for Medical Home Implementation	Methods	**The key elements that comprise the medical home need to be evaluated as an approach to comprehensive care delivery, rather than as a treatment intervention.** While the use of a treatment effectiveness model to evaluate medical home outcomes is flawed, we also have some concerns about how studies referenced in this review may have determined the presence of a medical home. At this point in the evolution of the medical home as a conceptualization that applies to the entire US health system, the primary task is to identify truly comparable definitions of that which is medical home and to then utilize methods and measures that have matured over time to capture outcomes. To the degree that various recognition program measures may have been used to cull articles for the review, we are concerned that evidence is not yet available that these program-specific measures accurately detect all of the actual operational functionalities that might make a medical home effective.	We appreciate the concerns of the National Center for Medical Home Implementation. We agree that there is a lack of agreement concerning the definition of PCMH. As a result, we utilized the definition provided by AHRQ as a basis for operationalizing the definition for the purposes of this review. We have attempted to reiterate this in the Introduction. We note that the lack of agreement on terminology and definitions is a limitation of both the review process and evidence base. Further, we encourage the use of common nomenclature in future evaluations of PCMH.
Public Reviewer #2 National Center for Medical Home Implementation	Results	Further, the consideration of developmental, social-emotional, functional, and family outcomes are not likely to be given importance in adult care as they would and have been in pediatric care. In a recent review of 12 successful *family-centered* medical home settings that took part in national medical home learning collaboratives in 2004–2006, one focus has been on characterizing what distinguishes a pediatric medical home from an adult medical home. While the data review process related to the aforementioned review has only recently begun, one of the characteristics that is frequently repeated is the importance of families to the process of delivering high quality care for children.	We agree that important outcomes may differ for pediatric and adult populations. We searched for and included social-emotional and functional outcomes. We did not include developmental outcomes, but review of the included pediatric studies did not show any developmental outcomes reported. We have revised the Discussion (Missing Outcomes section) to cite the article by Stille et al., and to call for evaluations to be tailored carefully to the population studies.
Public Reviewer #2 National Center for Medical Home Implementation	Results	Finally, it is possible that meta-analysis may not be an appropriate evaluation strategy for this review due to the fact that the history of medical home is so different in pediatrics and the clinical conditions addressed are not comparable to adult patient populations. A meta-analysis is only as strong as the articles it chooses to include and exclude, which in this case biases the analysis against understanding how the medical home impacts children and their families.	We conducted additional qualitative and quantitative analyses to evaluate results in adult and pediatric populations separately. These findings have been included in the Results sections

Commentator & Affiliation	Section	Comment	Response
Public Reviewer #2 National Center for Medical Home Implementation	Results	**Some evidence presented in the report shows a lack of a consistent or substantial effect on healthcare utilization costs.** As stated previously, most of the evidence presented in the report is based upon adult literature, with a particular emphasis on inclusion of studies that focus on older adults. In fact, the two pediatric studies (Domino and Martin) cited in Table 12 show a decrease in emergency department and hospital utilization. The total cost of patients who utilized services was decreased in medical home participants, and the total costs per member per month increased presumably reflecting the increase in access to services. This only reflects a small fraction of the cost of illness. When children are sick there is school loss and work loss. This can have both an immediate negative economic consequence on the family (loss of income, loss of job promotion, loss of job) and long term impact on the family (poor school performance poor job performance loss of job).	We appreciate this concern. We conducted subgroup analyses to compare effects in adults and pediatric populations. This led to a change in conclusions regarding economic outcomes – there is insufficient evidence for effects in children and adolescents. Further, we added a comment about the need for outcome evaluations that are tailored to the population, noting the importance of school loss and school performance.
Public Reviewer #2 National Center for Medical Home Implementation	Discussion	**The conclusions made in this report may make it more difficult to sustain the medical home.** While the pediatric community has been working with the medical home model and its implementation through quality improvement for two decades, its attractions have only more recently become apparent to the health care system as a whole and to the research community (and its funders). Although the foundational principles of the medical home have endured and not changed greatly in 15 years, the structures and processes for medical home implementation have improved steadily. Because quality improvement is one of those foundational principles, the medical home model has been subjected to “small tests of change” based on observation and data in many practice settings. To date, there are not any known individual practices or practice networks that have made significant advances in their evolution to provide care within a patient and family centered d down the road to the medical home that would agree to rolling back the changes in practice that have resulted. While practice settings that currently implement the medical home may not be swayed by the conclusions of this report, there are great risks that policy makers and payers will be influenced, resulting in an environment in which sustaining the medical home will become increasingly difficult.	We appreciate this concern. We agree that it is important for practices and organizations to work continually to improve the care provided to individual patients. The goal of this review is not to call into question the decisions of individual practices. Rather, it is to review the current evidence concerning PCMH implementation published in the peer-reviewed literature and conduct a horizon scan of what forthcoming studies can be expected. Based on the horizon scan, we expect that the peer-reviewed evidence base concerning PCMH will continue to expand rapidly. We have revised our conclusion for KQ1 (see Discussion), and added a caution that these findings should be considered preliminary given the current state of the science.

Commentator & Affiliation	Section	Comment	Response
Public Reviewer #2 National Center for Medical Home Implementation	Discussion	Finally, as stated by the APA in their comments, we believe that this report will influence the implementation of the medical home across the country for both adult and child populations. Because of the critical importance for every child and youth—especially those with special health care needs—to have access to a medical home, we strongly believe the above comments need to be appropriately addressed in the final report.	Thank you for the comment.