How Do Interventions That Exemplify the Joint Principles of the Patient Centered Medical Home Affect Hemoglobin A1C in Patients With Diabetes

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How Do Interventions That Exemplify the Joint Principles of the Patient Centered Medical Home Affect Hemoglobin A1C in Patients With Diabetes: A Review

Toyosi O. Morgan¹, Darcie L. Everett¹, and Anne L. Dunlop¹

Abstract

Objective: To review the impact of the Joint Principle of the Patient Centered Medical Home (PCMH) on hemoglobin A1C (HbA1C) in primary care patients with diabetes.

Methods: Systematic review of English articles using approximate terms for (1) the 7 principles of the PCMH, (2) primary care, and (3) HbA1C. We included experimental and observational studies. Three authors independently extracted data and obtained summary estimates for concepts with more than 2 high-quality studies.

Results: Forty-three studies published between 1998 and 2012 met inclusion criteria, 33 randomized and 10 controlled before–after studies. A physician-directed medical practice (principle 2) lowered HbA1C values when utilizing nursing (mean difference [MD] −0.36, 95% confidence interval [CI] −0.43 to −0.28) or pharmacy care management (MD −0.76; 95% CI −0.93 to −0.59). Whole-person orientation (principle 3) also lowered HbA1C (MD −0.72, 95% CI −0.98 to −0.45). Studies of coordinated and integrated care (principle 4) and quality and safety interventions (principle 5) did not consistently lower HbA1C when reviewed in aggregate. We did not identify high-quality studies to make conclusions for personal physician (principle 1), enhanced access (principle 6), and payment (principle 7).

Conclusion: Our review found individual interventions that reduced the HbA1C by up to 2.0% when they met the definitions set by of the Joint Principles of the PCMH. Two of the principles—physician-led team and whole-person orientation—consistently lowered the HbA1C. Other principles had limited data or made little to no impact. Based on current evidence, PCMH principles differentially influence the HbA1C, and there are opportunities for additional research.

Keywords
quality improvement, patient centered, medical home, disease management

Introduction

The joint principles of the Patient Centered Medical Home (PCMH), collated in 2007 by the American Academy of Pediatrics, American Osteopathic Association, American College of Physicians, and American Academy of Pediatrics, are the framework for structuring and evaluating primary care practice redesign.¹ ² The PCMH builds on the Chronic Care Model that guided practice reform in the 1990s. This model improved patient outcomes using registries to guide care delivery, enhancing patient management support, incorporating nonphysicians, and using technology to deliver health care.³–⁸ Integrating these concepts, the joint principles of the PCMH were defined in 2007 as having (1) a personal physician, (2) a physician-directed medical practice, (3) whole-person orientation, (4) coordinated and integrated care, (5) incorporation of quality and safety, (6) enhanced access, and (7) payment to support the PCMH.

Diabetes is a frequent target for quality improvement initiatives such as the PCMH. Diabetes and its comorbidities are a

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leading cause of death and disability in the United States. Up to 8.3% of US adults are currently diagnosed with diabetes and another 35% have prediabetes. It is a costly chronic disease estimated at about US$174 billion in 2007 alone. The PCMH practice transformations, in aggregate, decrease the cost and improve the quality of diabetes care; however, the relative impact of each of the individual principles is less clear. Studies suggest that there are differential benefits that may depend on the target condition for improvement. In a study of the PCMH principles’ impact on preventive services delivery, having a personal physician, whole-person orientation, enhanced access, and coordination with community programs were most associated with the receipt of preventive services. Within the chronic care model, team changes and care management had larger impacts on diabetes control. Given the current widespread move toward the PCMH model, there is a need to establish which specific strategies drive improvements in disease control. In this article, we review the evidence of each PCMH principle on glycemic control.

Research Design and Methods

Study Identification

Each PCMH principle was cross-referenced using a Medical Subject Heading (MeSH) search to obtain the research synonyms (Table 1). We derived our search terms from the title of the PCMH principle and or the key terms defining the principle. Using a Population, Intervention, Comparison, and Outcome (PICO) format, we combined the synonyms with population—primary care, comparison—usual care, and outcome—hemoglobin A1C (HbA1C). We searched MEDLINE, Cochrane Effective Practice and Organization of Care (EPOC) database, and scanned the reference list of all included studies.

We included studies conducted on both type 1 and 2 diabetes occurring in the pediatric or adult primary care populations. We excluded those not published in English, conducted in a specialty care setting, or without HbA1C or plasma glucose as an outcome.

Data Extraction and Analysis

Three authors independently screened the articles for full-text review. We included articles with 2-author agreement and recorded the principle, intervention, reliability of measurements, protection of the control group against contamination, and follow-up period. We used EPOC guidelines, published by the Cochrane Collaboration for systematic reviews of health care interventions to assess the quality of studies and guide data collection. These guidelines specify 7 different criteria to judge the quality of randomized controlled and controlled before–after studies.

We extracted baseline and final HbA1C means, mean change, standard deviation, and confidence intervals (CIs). Review Manager (RevMan) [Windows], Version 5.2, Copenhagen, was used to obtain a summary estimate of the intervention effect as a weighted average of the treatment effects with fixed effects. We pooled the mean difference (MD) into a summary estimate when we found more than 2 high-quality studies, given our analysis model. We used GRADE Profiler (GRADEPro) for the summary of estimates table (Table 2). The GRADE Profiler rating system uses the study design to establish the initial confidence in the estimate, which is then adjusted based on the strength of association, dose response, risk of bias, inconsistency, indirectness, imprecision, and publication bias to derive a high, moderate, or low confidence in the estimate.

Results

Forty-three studies published between 1998 and 2012 (median 2008; interquartile range 2005-2010) met the inclusion criteria (Figure 1). In all, 33 were randomized and 10 were controlled before–after. The median (interquartile range) follow-up was 12 (6.5-14.25) months, and the average baseline HbA1C was 8.52%.

Principle 1: Personal Physician

We found only observational studies without comparison groups for this principle. In Hueston et al., a minimum of 2 visits to the same physician over a 3-year period lowered HbA1C. Team continuity was 45% similarity with the same resident physician lowered HbA1C. Team continuity was similar to individual continuity.

Principle 2: Physician-Directed Medical Practice

This principle identified studies that used nurses or pharmacists to incorporate care management by (1) triaging patients based on glycemic control, (2) developing collaborative plans, (3) providing education and self-management training, (4) reviewing medications, and (5) modifying patient management.

2. A Nursing. Four studies of a nurse care manager collectively lowered the HbA1C significantly more than controls (MD −0.36, 95% CI −0.43 to −0.28) from an average baseline of 8.31 (Figure 2). One study included a community health worker with the nurse care manager but had no impact on the HbA1C.

2. B Pharmacists. Four studies of pharmacist care management collectively reduced the HbA1C when compared to the control intervention (MD −0.76, 95% CI −0.93 to −0.59) from a baseline of 9.81 (Figure 3). Jameson et al had no impact on the HbA1C from a baseline of at least 9 and was excluded from the analysis because it reported skewed data.

Principle 3: Whole-Person Orientation

The studies we retrieved for whole-person orientation were of physician-led interventions addressing lifestyle modification...
| Principle #1 | Personal physician | Each patient has an ongoing relationship with a personal physician trained to provide first contact, continuous, and comprehensive care |
| Principle #2 | Physician-directed medical practice | The personal physician leads a team of individuals at the practice level who collectively take responsibility for the ongoing care of patients |
| Principle #3 | Whole-person orientation | The personal physician is responsible for providing for all the patient’s health care needs or taking responsibility for appropriately arranging care with other qualified professionals. This includes care for all stages of life, acute care, chronic care, preventive services, and end-of-life care |
| Principle #4 | Coordinated and integrated care | Care is coordinated and/or integrated across all elements of the complex health care system (eg, subspecialty care, hospitals, home health agencies, and nursing homes) and the patient’s community (eg, family, public, and private community based services). Care is facilitated by registries, information technology, health information exchange, and other means to assure that patients get the indicated care when and where they need and want it in a culturally and linguistically appropriate manner |
| Principle #5 | Quality and safety are hallmarks | Quality and safety are hallmarks of the medical home. Practices advocate for their patients to support the attainment of optimal, patient-centered outcomes that are defined by a care planning process driven by a compassionate, robust partnership between physicians, patients, and the patient’s family. Evidence-based medicine and clinical decision-support tools guide decision making. Physicians in the practice accept accountability for continuous quality improvement through voluntary engagement in performance measurement and improvement. Patients actively participate in decision making, and feedback is sought to ensure patients’ expectations are being met. Information technology is utilized appropriately to support optimal patient care, performance measurement, patient education, and enhanced communication. Practices go through a voluntary recognition process by an appropriate nongovernmental entity to demonstrate that they have the capabilities to provide patient centered services consistent with the medical home model. Patients and families participate in quality improvement activities at the practice level |
| Principle #6 | Enhanced access to care | Enhanced access to care is available through systems such as open scheduling, expanded hours and new options for communication between patients, their personal physician, and practice staff |
using behavior theory to enhance patients’ self-efficacy, goal setting, nutrition, physical activity, and psychological wellness. Five such studies collectively lowered the HbA1C significantly compared to controls (MD $-0.72$, 95% CI $-0.98$ to $-0.45$) from an average baseline of 9.02 (Figure 4). Naik et al found reductions in the HbA1C but did not report enough data to be included in the analysis.

In Rocco et al, physicians and patients using a care plan to set goals lowered the HbA1C by 0.35 points, but the baseline HbA1C was not reported.

In Glasgow et al, an internet-based self-managed lifestyle program with or without social contact did not reduce the HbA1C.

**Principle 4: Coordinated and Integrated Care**

We identified two major concepts and an additional study during the review for this term.

4.A Care coordination with information technology. Here, four studies used technology enhancements to supplement the care coordination provided by a nurse care manager through telemedicine portals. In Shea et al, nurse care managers used video conferencing and reduced the HbA1C (MD $-0.18$, 95% CI $-0.17$ to $-0.19$) from a baseline of 7.35. In Stone et al, patients transmitted their blood glucose to trigger care management contact and this reduced the HbA1C (MD $-0.9$, 95% CI $-0.64$ to $-1.16$) from a baseline of 9.6. Two smaller studies, one using e-mail and another automated telephone contact, had no impact on the HbA1C.

4.B Depression integration. Diabetes and depression are well-established comorbid conditions. Two studies provided cognitive behavioral therapy (CBT) and none reduced the HbA1C.

In Ismail et al combined CBT with motivational enhancement therapy and reduced the HbA1C (MD $-0.45$, 95% CI $-0.12$ to $-0.79$) from a baseline of 9.6. Ismail et al combined CBT with motivational enhancement therapy and reduced the HbA1C (MD $-0.45$, 95% CI $-0.12$ to $-0.79$) from a baseline of 9.6.

4.C Embedded care manager. One study, Davidson et al, examined the integration of an embedded nurse care manger in the primary care practice compared to referring patients to a care manager independent of the practice. Both models reduced the HbA1C by 2.0 points from an average baseline HbA1C of 10.

**Principle 5: Quality and Safety**

In this category, we identified multiple subconcepts.

5.A Electronic delivery of blood glucose self-monitoring to physicians. Five studies assessed self-monitoring of blood glucose...
Table 2. Summary of Findings for the Joint Principles of the Patient Centered Medical Home impact on Hemoglobin A1C.

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Control</th>
<th>PCMH Principles</th>
<th>No of Participants (Studies)</th>
<th>Quality of the Evidence (GRADE)</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impact of personal physician on change in A1C (PCMH 1)</td>
<td>Not estimable</td>
<td>Not estimable</td>
<td>0 (0)</td>
<td>Not estimable</td>
<td>No high-quality studies identified.</td>
</tr>
<tr>
<td>Impact of nurse care management on change in A1C (PCMH 2.A)</td>
<td>The mean impact of the control intervention (PCMH 2.A) was —0.37 points</td>
<td>The mean impact of nurse care management on change in A1C (PCMH 2.A) in the intervention groups was 0.36 lower than control (0.43-0.28 lower)</td>
<td>7174 (5 studies*)</td>
<td>High^b,c</td>
<td>Meta-analysis Dorr et al,17 Aubert et al,23 Mousques et al,24 and Krein et al25 Review Gary et al26</td>
</tr>
<tr>
<td>Impact of pharmacist care management on change in A1C (PCMH 2.B)</td>
<td>The mean impact of the control intervention (PCMH 2.B) was —0.42 points</td>
<td>The mean impact of pharmacist care management on change in A1C (PCMH 2.B) in the intervention groups was 0.76 lower than control (0.93-0.59 lower)</td>
<td>972 (5 studies*)</td>
<td>High^b,c</td>
<td>Meta-analysis Johnson et al,27 Choe et al,28 Neto et al,29 and Salvo et al30 Review Jameson and Baty31</td>
</tr>
<tr>
<td>Impact of whole-person orientation on change in A1C (PCMH 3)</td>
<td>The mean impact of the control intervention (PCMH 3) —0.4 points</td>
<td>The mean impact of whole-person orientation on change in A1C (PCMH 3) in the intervention groups was 0.72 lower than control (0.98-0.45 lower)</td>
<td>983 (8 studies*)</td>
<td>High^a</td>
<td>Meta-analysis Song et al,32 Hornsten et al,33 Kirsh et al,34 Schillinger et al,35 and Polonsky et al36 Review Naik et al,37 Glasgow et al,38 and Rocco et al39 Review McCarrier et al,40 Piette et al,41 Shea et al,42 and Stone et al43</td>
</tr>
<tr>
<td>Impact of care coordination with information technology on change in A1C (PCMH 4.A)</td>
<td>See comment^d</td>
<td>See comment^d</td>
<td>1841 (4 studies)</td>
<td>High^c,e</td>
<td>Review McCarter et al,40 Piette et al,41 Shea et al,42 and Stone et al43</td>
</tr>
<tr>
<td>Impact of depression integration on change in A1C (PCMH 4.B)</td>
<td>See comment^d</td>
<td>See comment^d</td>
<td>1631 (6 studies)</td>
<td>Moderate^f,g</td>
<td>Review Katon et al,44 Piette et al,45 Pouwer et al,46 Snoek et al,47 Bogner and de Vries,48 and Ismail et al49</td>
</tr>
<tr>
<td>Impact of care manager integrated into primary care office (PCMH 4.C)</td>
<td>Single study identified</td>
<td>Single study identified</td>
<td>545 (1 study)</td>
<td>See comment^b</td>
<td>Review Davidson et al50</td>
</tr>
</tbody>
</table>

(continued)
### Table 2. (continued)

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Assumed Risk</th>
<th>Corresponding Risk</th>
<th>No of Participants (Studies)</th>
<th>Quality of the Evidence (GRADE)</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impact of clinical decision support for use of clinical practice guidelines on A1C (PCMH 5.B) Follow-up: mean 21 months</td>
<td>See comment(^d)</td>
<td>See comment(^d)</td>
<td>10287 (7 studies(^a))</td>
<td>Moderate(^f)</td>
<td>Review O'Connor et al, 2011,(^{56}) Guldberg et al,(^{57}) Maclean et al,(^{58}) Weitzman et al,(^{59}) Benjamin et al,(^{60}) Ziener et al,(^{61}) and Holbrook et al(^{62})</td>
</tr>
<tr>
<td>Impact of use of electronic medical records on change in A1C (PCMH 5.C) Follow-up: mean 48 months</td>
<td>Single study identified</td>
<td>Single study identified</td>
<td>2556 (1 study)</td>
<td>See comment(^b)</td>
<td>Review O'Connor et al(^{63})</td>
</tr>
<tr>
<td>Impact of enhanced access on change in A1C (PCMH 6)—not measured</td>
<td>Not estimable</td>
<td>Not estimable</td>
<td>–</td>
<td>Not estimable</td>
<td>No high-quality studies identified</td>
</tr>
<tr>
<td>Impact of payment on change in A1C (PCMH 7)—not measured</td>
<td>Not estimable</td>
<td>Not estimable</td>
<td>–</td>
<td>Not estimable</td>
<td>No high-quality studies identified</td>
</tr>
</tbody>
</table>

Abbreviations: CI, Confidence interval; PCMH, Patient Centered Medical Home.

1. The basis for the assumed risk (e.g., the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

2. GRADE Working Group grades of evidence: high quality: further research is very unlikely to change our confidence in the estimate of effect. Moderate quality: further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. Low quality: further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. Very low quality: we are very uncertain about the estimate.

\(^a\)50% RCT.

\(^b\)Observational study design introduced risk.

\(^c\)At least 2 studies had a RR > 2.

\(^d\)Data not pooled due to heterogeneity.

\(^e\)Two studies had SD close to or encompassing 0.

\(^f\)Differing estimates of effect.

\(^g\)Wide confidence intervals noted.
Records identified through database searching (n = 1389)

Additional records identified through other sources (n = 100)

Records after duplicates removed (n = 832)

Records excluded [non-relevant to study search criteria] (n = 591)

Records screened (n = 832)

Full-text articles assessed for eligibility (n = 241)

Full-text articles excluded, with reasons (n = 198)

1. Study Design (n = 53)
2. No (Relevant) Intervention (n = 81)
3. Not Primary Care (n = 7)
4. No (Relevant) Outcome, Only process outcome, No A1C reported (n = 20)
5. Clinical Trial Registration (n = 17)
6. Multicomponent Intervention (n = 14)
7. Other review article, not English (n = 6)

Studies included in qualitative synthesis (n = 43)

Studies included in quantitative synthesis (meta-analysis) (n = 13)

Figure 1. Review study identification, selection, and exclusion.

Figure 2. Impact of nurse care management on change in A1C (Patient Centered Medical Home [PCMH] 2.A).
(SMBG) feedback delivered electronically to the Physician’s office. Of these, two studies delivered results to the clinic with automated responses generated for abnormal values, while one simply delivered the results. None reduced the HbA1C.

Augstein et al and Lim et al combined SMBG with personalized decision support using the patient’s diet and physical activity and lowered the HbA1C by 0.5 (baseline of 7) and 0.4 (baseline of 7.8), respectively.

5.B Clinical decision support. In two studies where physicians received point-of-care recommendations and population feedback, neither lowered the HbA1C. When both patients and physicians received these data, 1 study reduced the HbA1C by 0.2 points while another did not. In O’Connor et al and Benjamin et al, collaborative adoption of clinical decision support (CDS) with workflow changes reduced the HbA1C by 0.26 points from a baseline of 8.5 and 0.9 points from a baseline of 9.30, respectively. In Ziemer et al, the availability of CDS reduced HbA1C only when a provider received individualized feedback about its use.

5.C Electronic medical documentation. In O’Connor et al, there was no effect of using an electronic version of the medical record on the HbA1C.

Principle 6: Enhanced Access
We found no high-quality studies for this principle. In 2 descriptive studies, patient–provider electronic messaging users were notably younger and had better control of their HbA1C. Augstein et al and Lim et al combined SMBG with personalized decision support using the patient’s diet and physical activity and lowered the HbA1C by 0.5 (baseline of 7) and 0.4 (baseline of 7.8), respectively.

Principle 7: Payment
We found no high-quality studies for this principle. In Kloos et al, in addition to standard fee-for-service, a €25 payment to physicians to identify patients at risk, provide structured patient education, and strengthen patient self-management skills reduced the HbA1C by 0.55 points over 9 years.

Methodological Considerations
Three groups of studies were from the same trial, and only the most relevant study from each group was included in the analysis. Of the 33 randomized trials, 5 were cluster randomized of which only Hornsten et al was included in the meta-analysis for PCMH 3. We included Hornsten et al, given that the authors analyzed their data using...
hierarchical analysis of variance to account for clustering. We conducted sensitivity analysis by excluding the study and obtained similar results.

Naik et al did not include a standard deviation for the difference in the mean change for the intervention and control, which precluded it from a meta-analysis using the mean difference.\textsuperscript{37} We conducted a final mean analysis as sensitivity analysis, which did not change the estimate significantly. We used the final mean analysis approach (where the baseline means were similar) to obtain our pooled estimates for all the meta-analysis and obtained similar results. Five studies did not have similar baseline HbA1C between the intervention and the control groups and could not be included in the final mean analysis.\textsuperscript{17,34,36,37,42}

We excluded one study that had a single control and intervention site.\textsuperscript{85} One study was prone to contamination because the same provider implemented the intervention and the control activities.\textsuperscript{54} One did not report baseline HbA1C.\textsuperscript{39} All but 2 of the trials had >80\% patient follow-up rates.\textsuperscript{25,58} The statistical heterogeneity describing the percentage of variation across the studies that were pooled had an I\textsuperscript{2} range from 33 to 84 (Figures 2–4).

Discussion

We conducted this review to understand the relative value of individual PCMH practice improvement strategies on the HbA1C of diabetic patients.

Two PCMH principles improved the HbA1C: physician-directed medical care with nursing or pharmacist care management (principle 2) and whole-person orientation with lifestyle modification support (principle 3). Both principles emphasize a team approach to patient care with the inclusion of the patient as a member of the health care team. They also highlight the value of the expanded roles and skills of both physicians and nonphysician team members.

The review for coordinated and integrated care (principle 4) and quality and safety (principle 5) each had more than five robust studies researching their impact; however, variability in the way these concepts were implemented limited the collective interpretation of results. Nevertheless, we noted the importance of personalization. When personalization was combined with information technology (principle 4.A), electronic reporting of patients’ self-monitored blood glucose (principle 5), or the adoption of CDS tools (principle 5) by health professionals, the studies reported lowered HbA1Cs.

Several concepts were identified, which require further research to determine their direct effect on health outcomes. Although not supported by rigorous studies, a personal physician (principle 1) seems associated with lower HbA1C, an effect that may extend to a team of physicians.\textsuperscript{68,69} Enhanced access (principle 6) and payment (principle 7) may also improve diabetes outcomes.\textsuperscript{16,18,20}

The impact of these interventions on the HbA1C ranged from a 0.18\% to a 2\% reduction and none of the studies reviewed worsened the HbA1C. This is important because a 1\% reduction in HbA1C levels has been associated with a 37\% decrease in the risk of microvascular complications and a 21\% reduction in death, making the PCMH a key component in attaining optimal patient outcomes.\textsuperscript{86}

A major limitation of this study is the omission of some potentially relevant studies. To operationalize the PCMH principles, we stayed true to the concept definitions. This undoubtedly limited our search results but was important because current PCMH efforts build on the principles.\textsuperscript{87–90} Another limitation is the heterogeneity of the studies, which was seen with the different approaches to implementing the PCMH concepts, baseline HbA1C, length of follow-up, and study size. We performed subgroup analysis to address this, collating the studies that appeared to measure the same concepts. A third limitation is the possible regression to the mean effect with most studies having a baseline HbA1C higher than 8\%.\textsuperscript{16}

Despite these limitations, our findings are consistent with studies that have examined the effects of health care delivery changes in diabetes outcomes. In the review by Renders et al, interventions that expanded nursing roles or involved patients, improved outcomes.\textsuperscript{18} Estimates of the effects of team change interventions by Shojania et al ranged from 0.3\% to 0.8\%, which is similar to our findings for principle 2.\textsuperscript{16} Similarly, Ferrante et al described the relational PCMH principles of a personal physician and whole-person orientation as having a stronger correlation with the delivery of preventive services.\textsuperscript{15} These relational principles are core to primary care and reflect the 1994 IOM definition of primary care as providing integrated care and addressing a large majority of personal health care needs while developing partnership with patients.

Various evaluations show that the PCMH practice transformation process improves glycemic control in diabetic patients, and our review suggests that the PCMH principles of physician-directed team care (principle 2) and whole-person orientation (principle 3) are most influential.

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