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Effect of a pragmatic, cluster-randomized controlled trial on patient experience with care: The Transforming Outcomes for Patients through Medical home Evaluation and reDesign (TOPMED) study

David A. Dorr, MD, MS¹, Tracy Anastas, BA¹, Katrina Ramsey, MS¹, Jesse Wagner, MA¹, Bhavaya Sachdeva, MPH¹, LeAnn Michaels, BS¹, and Lyle Fagnan, MD¹

¹Oregon Health and Science University, 3181 SW Sam Jackson Park Road, Portland, OR 97239

Abstract

Background—Health reform programs like the Patient-Centered Medical Home (PCMH) are intended to improve the Triple Aim. Previous studies on PCMHs have shown mixed effects, but High Value Elements (HVEs) are expected to improve the Triple Aim.

Objective—To understand whether focusing on high value elements (HVEs) would improve patient experience with care.

Methods—Eight clinics were cluster-randomized in a year-long trial. Both arms received practice facilitation, IT-based reporting, and financial incentives. Intervention practices were encouraged to choose HVEs for QI goals. To assess patient experience, 1,597 Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys were sent pre- and post-trial to a stratified random sample of patients. Difference in difference multivariate analysis was used to compare patient responses from intervention and control practices, adjusting for confounders.

Results—The response rate was 43% (n=686). Non-respondent analysis showed no difference between arms, although differences were seen by risk status and age. The overall difference in difference was 2.8%, favoring the intervention. The intervention performed better in 9 of 11 composites. The intervention performed significantly better in *Follow-up on test results* (p=.091) and *Patients' rating of the provider* (p=.091), while the control performed better in *Access to care* (p=.093). Both arms also had decreases, including 4 of 11 composites for the intervention, and 8 of 11 for the control.

Discussion—Practices that targeted HVEs showed significantly more improvement in patient experience of care. However, contemporaneous trends may have affected results, leading to declines in patient experience in both arms.

Keywords

CAHPS; patient centered care; primary care; quality improvement

Corresponding author: David Dorr, MD, MS, Department of Medical Informatics & Clinical Epidemiology, Oregon Health and Science University, Mail code: MDYMICE, 3181 SW Sam Jackson Park Road, Portland, OR 97239, Fax: 503-346-6815 (include "David Dorr" on coversheet), Phone: 503-418-2387, dorr@ohsu.edu.

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Introduction

Patients with chronic illness account for over 80% of health care expenditures,¹ but outcomes for patients with chronic illness continue to be poor. For instance, both age- and sex-adjusted mortality rates for diabetes or chronic kidney disease, and the individual burden of living with chronic illness continue to increase.^{2, 3} These patients need comprehensive, coordinated, patient-centered care;^{3, 4} however, primary care clinics are incented to provide episodic, fee-for-service care. This disconnect – the need for continuous care in a system promoting episodic care – is expected to reduce patient experience of care.

Chronic illness control requires a partnership between patients and clinical teams. Behavior, lifestyle, and social determinants of health, such as race and socio-economic status, affect a patient's ability to gain access to care and manage their chronic illness.⁵ The possible complexity, risk and benefit ratios, and burden of medical treatment require that patient preferences and values be elicited and treatment decisions be shared by patients and providers.⁶ Better chronic illness outcomes, including improved health, reduced costs, and improved satisfaction, come when patients receive significant self-monitoring support, proactive planning, and patient-centered education.⁷ Measurement of these factors in primary care includes a number of patient reported outcomes, including patient's experience of care.⁸ The most common validated survey for patient experience of care is the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey; for primary care, a clinician and group (CG-CAHPS) survey asks patients to report these experiences across 11 composite categories. Historically and in general, primary care has a wide variability in CG-CAHPS scores.⁹

Health reform is intended to address these issues by changing the way care is supported through incentives, infrastructure support, and technical assistance to improve the triple aim of health care: improving patient experience of care, health of populations, and reducing cost. In primary care, the Patient-Centered Medical Home (PCMH) is the most common reform model, having more than 10,000 primary care clinics accredited; to achieve certification, they must show that they performed certain services for their patients, including improved access, care management, population management, and quality improvement.¹⁰ While the PCMH model is one attempt to improve care for patients with chronic conditions in the US, other models such as the Innovative Care for Chronic Conditions, created by the World Health Organization (WHO) in 2002, have similar goals. This model overlaps with relevant PCMH principles, such as building integrated healthcare to coordinate across different settings, using healthcare personnel effectively to provide team-based care, and placing patients at the center of care.¹¹

Although intended to improve the triple aim, health reform efforts to date have had mixed success, especially in patient experience of care and cost. While efforts at Geisinger Health System, GroupHealth, and Intermountain Healthcare have been successful,^{12–14} other models, such as the National Demonstration Project, the Southeast Pennsylvania PCMH initiative, and others have not shown improvements.^{15, 16} Similarly, in one study, patient experience of care survey results demonstrated a positive association between PCMH status

and improved access to care, but not with other domains such as experience with office staff or follow-up on test results.¹⁷ Finally, a 2012 evaluation of 11 Medicare coordinated care demonstrations identified six key features of programs successfully decreasing hospital admissions (care coordinators having face-to-face contact with patients, care coordinators managing transitions of care, using patient education to affect behavior change, care coordinators communicating often with physicians, medication management, and physician engagement).¹⁸

We initiated the Transforming Outcomes for Patients through Medical home Evaluation and reDesign (TOPMED) trial to better understand how to replicate the common components of trials that appear to improve patient outcomes and support transformation more effectively in smaller systems and individual clinics. Intervention clinics received focused encouragement, including being asked to work on high value elements (HVEs) which have been shown to improve patient outcomes and costs in the previous trials. Although the derivation of these HVEs is described elsewhere,¹⁹ we largely determined these elements through a literature review and focus groups with experts and patients to find measures most likely to improve patient experience and reduce poor outcomes that were related to the broad PCMH attributes of *accountability, access, coordination and integration, comprehensive care, continuity, and patient and family experience*. For instance, in Oregon's PCMH model the care coordination measure is "Assigns individual responsibility for care coordination and tells each patient or family the name of the team member responsible for coordinating his or her care," while the HVE for care coordination is "Care coordination outreach reaches 25% of high risk patients." One of the outcomes for this trial that other similar studies have not analyzed explicitly through a focus on specific components of PCMH standards and HVEs was patient experience of care, measured by the CG-CAHPS survey with specific questions for PCMHs added.

The purpose of this paper is to investigate whether focusing on HVEs will improve patients' experience with care, especially in areas related to HVEs. We hypothesized that both intervention and control clinics will see improvements in patient experience because both received quality improvement (QI) encouragement; however, we predict that there will be a greater improvement in the intervention clinics due to their focus on HVEs.

Methods

Overview

We completed a pragmatic cluster randomized controlled trial in primary care clinics across the state of Oregon. The Oregon Health and Science University's Institutional Review Board approved this study. The trial protocol, created and reported according to CONSORT guidelines (Appendix 1), is published elsewhere;²⁰ briefly, all practices were stratified into matched pairs, then randomized by computer into two groups. All practices received IT-based milestone reporting, financial incentives based on self-selected QI goals, and quality improvement guidance from a practice facilitator (PF). PFs have been demonstrated to provide a framework for practices to identify leadership, build relationships internally and externally, and monitor and evaluate QI progress and are associated with completing more quality improvement projects.^{21,22} The TOPMED PF met with all practices monthly to

identify areas for improvement and monitor progress on previously set goals. Intervention clinics were directed to select their quality improvement goals from a list of 12 HVEs, which our team identified from the literature and stakeholder and patient focus groups as likely to reduce cost and utilization and improve patient outcomes. Control clinics selected goals related to PCMH measures. Each arm received an equal amount of touches from the PF and on average each clinic made 7.75 QI goals over the year. The current paper will discuss changes in patient experience of care from before and after the trial. Patient experience had been demonstrated to be crucial in driving system transformation and is associated with improvements in patient engagement and adherence and clinical processes and outcomes.²³ HVEs relate directly to CAHPS composites and working on them may improve those respective composites. For instance, the HVEs of *Advance directive utilization*, *Education and self-management resources*, and *Care plan utilization* may influence the CAHPS composite of *Providers support you in taking care of your own health*.

Setting

The study took place in eight primary care clinics that were engaged in PCMH health reform located in 5 different counties in Oregon; over 500 practices in Oregon and 10,000 nationwide are engaged in PCMH-related redesign. The practices were diverse in terms of size (3 to 20 providers), location (urban versus rural), and population. Implementation of the TOPMED trial occurred between May 2013 and May 2014.

Sampling, Recruitment, and Administration

The practices were recruited by the Oregon Rural Practice-based Research Network (ORPRN). Eligibility included an implemented EHR, willingness to participate in QI efforts, and a practice panel that contained adult patients. Once enrolled, practices were stratified by size, location, and ownership (health system versus independent), and paired clinics were randomized by a computer to either intervention or control.

Patients selected to receive pre- or post-surveys had visited the respective practice within the last year, spoke English, and were aged 18 years or older. EHR data was queried to randomly select 100 patients per clinic per time period (1,600 total surveys sent); we estimated 80% power to detect a 10% difference with base score of 50% and a 50% response rate. Due to differences in clinic population, patients determined by a modified Charlson Comorbidity Risk score to be high risk (2 or more chronic illnesses) were oversampled at 50% of total sample, while average risk patients (0–1 illnesses) constituted the remaining 50%.

Pre-trial survey data was collected between May 2013 and September 2013, and post-trial data was collected between May 2014 and September 2014. Surveys were initially mailed in May, and phone call reminders were made in mid-June to encourage additional responses. Samples for pre- and post-surveys were different. In August, surveys were re-mailed to participants who had not responded. Included with the surveys was an information sheet, which invited them to participate and explained the study, and an optional sheet to complete to be entered into a gift card drawing. Patients were excluded if they died, were too ill, did

not receive care from the provider on their survey within the last year, did not speak English, or their survey was returned undeliverable.

Measurement of Patient Experience

Patient experience of care was measured with the validated 2007 Consumer Assessment of Healthcare Providers and System (CAHPS) Clinician & Group Survey (CG-CAHPS), which asks patients to rate their experiences with doctors and staff. It is a commonly used patient survey that has been tested for reliability, construct validity, and criterion validity at a practice- and patient-level.^{24,25} It contains 44 questions about experience of care, grouped into 11 composite scores, with additional demographic questions. These composites, such as getting care quickly, courteous office staff, and getting needed care, have been found to be associated with global ratings of patient satisfaction with healthcare.²⁶ The composites each have between one and six component questions, which are mainly four-point ordinal ratings (Never to Always and Poor to Excellent) with some yes/no questions, and one 0–10 point overall rating of the provider.

Analysis

The main outcome of interest was the difference between control and intervention clinics in the change between pre-study and post-study patient satisfaction, or the "difference in differences." Patient satisfaction was calculated as the percentage of all responses across a composite that fell in the best (or "top-box") category, for example rating of four on a four-point scale. For each of the 11 composite scores, we fit a population-averaged linear probability model with response as the unit of analysis and a generalized estimating equation (GEE) approach to account for similarity between responses from the same person. Because randomization occurred at the clinic level, we could not simultaneously model intervention and use GEE for correlation between responses from the same clinic; instead, we fit clinic and pre-post indicator variables along with their interactions and used them to calculate overall intervention differences in differences adjusted for age, minority, and risk status as defined by the modified Charlson score. The statistician performing analyses was blinded to intervention and control groups.

Analysis was performed to see if achieving certain HVEs was associated with 5 related composite scores. Correlations between these HVEs over time and change in these 5 composite scores were calculated. We consider p-values less than .10 and .05 as marginally and highly significant to acknowledge the large intracluster and between time variation, which reduced our power across several composites. Additionally, other studies utilizing patient surveys have included both these levels in their results and discussions.^{27, 28} Furthermore, absolute value percentage changes more than 5% and 10%, representing a number needed to treat from 1 in 10 to 1 in 20, are considered moderate and major trends, respectively.

Results

A total of 1,597 CAHPS surveys were sent, 795 (49.8%) for the pre-trial and 802 (50.2%) for the post-trial. 178 surveys were excluded (11.1%), and detailed statistics are found in

Figure 1. Our analysis included 163 (45.0%) eligible pre-trial surveys for the intervention group and 170 (45.6%) for the control group; there were 178 (52.0%) eligible post-trial surveys for the intervention group and 175 (51.2%) in the control. Respondent and non-respondent bias analysis (Appendix 2) shows that a higher percent of low risk patients responded in the pre-trial, and a higher percentage of high risk patients responded in the post-trial, which also affected age distribution. The survey analysis used interaction terms to account for these effects.

Table 1 shows there were no significant differences among respondents in the pre-post periods in either arm for age, sex, self-rating of physical and emotional health, or who helped to fill out the survey (average difference 0.3%). The pre-period had fewer high risk patients in the control group (43.7%) than the intervention (49.1%), but both arms were evenly represented during the post period with 58% high risk respondents in both groups. Table 2 shows the differences between clinics and their matching criteria: location, size, and relative percentages of high risk patients; the matching reduced cluster differences but substantial differences remained.

Table 3 and Figure 2 present the adjusted CAHPS results, which account for the demographic and risk differences between respondents. The adjusted patient experience of care results show that pre-trial values are mostly similar between the intervention and control groups. Differences between groups include the control performing better in *Patient's rating of the provider* (70.6% intervention vs. 80.4% Control) and *Providers support you in taking care of your own health* (42.4 % vs. 50.8%), while the intervention performed better in *Getting timely appointments, care, and information* (57.9 % vs. 50.4%) and *Access to care* (42.1% vs. 56.1%). None of the differences were statistically significant at the $p < .10$ level.

The results for CAHPS scores are mixed. The difference-in-difference results show an average difference of 2.8% with the intervention performing better than the control, and 3 of the 11 composites have major differences between the intervention and control. Over time the intervention performed better than the control in *Follow-up on test results* with a slight 0.8% increase, and the control decreased significantly by 12.8% (difference in difference 13.5%, $p = .091$). Similarly for *Patient's rating of the provider*, the intervention had a small 1.5% increase, while the control decreased significantly by 10.3% (11.8%, $p = .091$). However, the control was better in *Access to care* with the intervention decreasing significantly by 13.2%, and the control showing a small 0.6% increase (−13.2%, $p = .093$). Additionally, there was a moderate difference favoring the intervention for *Providers support you in taking care of your own health* with the intervention increasing by 2.9% and the control decreasing by 4.5% (7.4%, $p = .27$).

For pre-post changes, the intervention and control performed similarly for 3 composites, which might be explained by contemporaneous trends. For *Getting timely appointments, care, and information*, the intervention had a moderate decrease of 7.9%, and the control had a major decrease of 11.3% (3.3%, $p = .55$). Additionally, the intervention and control had moderate decreases, 5.3% and 6.2% respectively, for *How well providers (or doctors) communicated with patients* (−5.3%, $p = .90$). Both intervention and control increased

moderately, 5.3% and 6.6% respectively for *Providers pay attention to your mental or emotional health* (1.3%, $p=.838$).

In the study, HVEs are intended to help clinics improve cost and utilization; patient experience of care elements more related to these outcomes might improve more in the intervention clinic. Our pre-analysis grouping of the patient experience of care measures identified *Providers support you in taking care of your own health* (D-I-D +7.4%); *Providers pay attention to your mental or emotional health* (+1.3%); and *How well providers (or doctors) communicate with patients* (+0.9%) as highly related to HVEs, and *Follow-up on Test Results* (+13.5%); *Attention to Care from Other Providers* (−4.4%); and *Providers discuss medication decisions* (+3.9%); as somewhat related. Of these six, two demonstrated strong improvement, and two showed improvement for intervention versus control, providing moderate support for the hypothesis. However, none of these differences were statistically significant, and correlations between number of HVEs obtained and patient experience of care were non-significant.

Conclusion

Our cluster randomized controlled trial compared the outcomes of patients' experience of care when their primary care practices were incented to achieve HVEs (intervention) versus standard quality improvements (control), showed that we were partially successful in that the difference in difference for patient experience was more positive (and sometimes declined less) in intervention clinics. Two composites improved marginally significantly more ($p<.10$) in the intervention than the control, while one composite improved more in the control. However, there was an overall reduction in patient experience in several categories, so the intervention might be described as worsening less in these composites versus control.

An overall decline in patient experience of care may have several sources, including contemporaneous factors. First, during the time period of the study, Medicaid expansion occurred in Oregon as did a major failure in Oregon's Health Insurance Exchange, leading to significant frustrations and a relative decrease in access across the state. A contemporaneous survey for CAHPS showed a decrease in access scores for primary care clinics in Oregon from 85% to 50%,²⁹ which is similar to the post-period's 49.5% for intervention and 56.8% for controls. Additionally, research in New York, comparing CAHPS results from PCMH recognized clinics and non-PCMH clinics, showed that *Access to care* scored lower in PCMH clinics than non-PCMH clinics.³⁰ It is feasible that PCMH recognition might require additional clinic resources, thereby decreasing patients' perceived access to care. Finally, the CAHPS survey focuses heavily on providers, rather than the care team, thus the team-based aspects of the HVEs and QI efforts may have worsened scores inadvertently.

Working on HVEs for QI may have had positive and negative impacts on patient experience. For instance, *Providers support you in taking care of your own health* relates to the *Education and self-management resources* HVE, and patients responded more positively in the intervention. Contrarily, some of the HVEs and some of the CAHPS composites don't have a strong theoretical relationship, including *Clinical Information Exchange* (HVE) and

How well providers (or doctors) communicated with patients (CAHPS); many patients may not have a better experience with these HVEs improving.

Limitations of this study include the low number of clusters, selection bias, inability to adjust for respondent bias and mean reversion, and the lack of strong correlation of the CAHPS survey with the intent of the study. The low numbers of clusters means that individual cluster variation might drive outcomes more than the intervention; for instance, if a single cluster transforms its efforts, it could tip results towards intervention or control with no effect from the study itself. We adjusted for this variation conservatively, leading to large differences with marginal p-values. Both selection and respondent bias also were evident; although we created a randomized stratified sample of patients, those motivated to respond in the pre- and post-periods were different. Although we statistically attempt to account for these differences, some bias may remain.³¹ We also show that the majority of composites were better in the intervention than control over time, but the actual number of HVEs achieved did not directly impact the patient experience score.

In the setting of decreased satisfaction with care, we saw a more positive response from patients in their experience of care when clinics were encouraged to achieve HVEs, such as intensive care planning, care coordination, and self-management support. Other PCMH trials have shown mixed effect on patient experience outcomes, but the TOPMED trial demonstrated that focusing on HVEs can improve patient experience or at least act as a protective factor against outside influences. The TOPMED design, including HVEs, may help inform future practice transformation efforts to present specific transformation options in conjunction with practice facilitation if improved patient experience is desired.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
Response rate for CAHPS Surveys

Figure 2.
Difference in difference of adjusted CAHPS results

TABLE 1

Characteristics of respondents (n=686)

Characteristic	Control (n=345)		Intervention (n=341)		P
	Pre	Post	Pre	Post	
Female	57	59.9	61.5	61.2	0.83
High risk (based on score 2)	43.7	58.8	49.1	58.1	0.014*
Age					0.264
18 to 24	6.7	4.3	5.8	7.3	
25 to 34	7.3	5.5	11.5	8.5	
35 to 44	9.7	14.7	7.1	10.3	
45 to 54	28.5	20.2	17.9	24.2	
55 to 64	21.2	25.8	29.5	26.7	
65 to 74	26.7	29.4	28.2	23	
Minority race/ethnicity	13	11.3	9.2	12.4	0.737
Education					0.677
8th grade or less	8.5	7.5	8.3	7.9	
Some high school, but did not graduate	17.7	23	29.5	21.8	
High school graduate or GED	38.4	35.4	32.1	35.8	
Some college or 2-year degree	12.2	12.4	9.6	15.8	
4-year college graduate	23.2	21.7	20.5	18.8	
Self-rated overall health					0.325
Excellent	12.2	6.8	5.8	9.8	
Very good	22	27.8	32.9	29.9	
Good	36	33.3	31	34.8	
Fair	23.8	24.7	25.2	17.1	
Poor	6.1	7.4	5.2	8.5	
Self-rated mental/emotional health					0.455
Excellent	18.8	16	19.2	18.2	
Very good	24.8	34.4	38.5	34.5	
Good	31.5	30.7	21.8	29.1	
Fair	20	14.7	14.7	13.3	

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Characteristic	Control (n=345)		Intervention (n=341)		P
	Pre	Post	Pre	Post	
Poor	4.8	4.3	5.8	4.8	
Someone helped complete the questionnaire	14.2	7.5	9.8	10.6	0.274

*
p<.05

TABLE 2

Characteristics of practices (n=8)

Organization	Location	Total Number of Patients	Percentage of High Risk Patients	Number of High Risk Patients	Matched and randomized group *
Multiclinic Group	Urban	14,119	8%	1,130	1 (C)
Single Clinic	Urban	11,603	18%	2,113	1 (I)
Academic Medical Center	Urban	13,040	21%	2,738	2 (C)
Academic Medical Center	Urban	13,125	16%	2,100	2 (I)
Small Health System	Rural	10,282	9%	915	3 (C)
Small Health System	Rural	7,257	8%	601	3 (I)
Small Health System	Rural	1,200	30%	358	4 (C)
Small Health System	Rural	13,321	3.2%	426	4 (I)

* I = Intervention; C=Contro

TABLE 3

Adjusted CAHPS results[†]

	Control				Intervention				Difference in differences	p		
	Pre		Post		Pre		Post					
	Score	(95% CI)	Score	(95% CI)	Difference	(95% CI)	Score	(95% CI)				
Getting timely appointments, care, and information	50.4	(45.0–55.8)	39.1	(33.6–44.7)	–11.3**	57.9	(52.4–63.4)	50	(44.5–55.4)	–7.9**	3.3	0.55
How well providers (or doctors) communicate with patients	80.3	(75.7–85.0)	74.1	(68.8–79.4)	–6.2*	80.7	(76.6–84.7)	75.4	(70.8–79.9)	–5.3*	0.9	0.834
Follow-up on test results	71.5	(63.7–79.3)	58.8	(50.7–66.9)	–12.7**	69.4	(61.1–77.7)	70.2	(62.4–77.9)	0.8	13.5*	0.091
Helpful, courteous, and respectful office staff	77.7	(72.3–83.2)	70.8	(64.7–76.8)	–7*	76.7	(70.6–82.7)	72.2	(66.1–78.3)	–4.4	2.5	0.657
Patients' rating of the provider (or doctor)	80.4	(74.1–86.6)	70	(62.9–77.1)	–10.3**	70.6	(63.2–78.1)	72.1	(65.0–79.2)	1.5	11.8*	0.091
Providers pay attention to your mental or emotional health	49.9	(43.7–56.1)	55.2	(48.9–61.5)	5.3	46.2	(39.7–52.7)	52.8	(46.6–59.0)	6.6	1.3	0.838
Providers support you in taking care of your own health	50.8	(44.2–57.5)	46.4	(39.3–53.5)	–4.5	42.3	(35.4–49.2)	45.2	(39.2–51.2)	2.9	7.4	0.273
Providers discuss medication decisions	66.1	(59.3–73.0)	57.9	(50.5–65.2)	–8.3	60.8	(53.1–68.6)	56.5	(49.7–63.3)	–4.4	3.9	0.598
Information about care and appointments	75.5	(70.6–80.5)	73.8	(68.8–78.8)	–1.7	69.8	(64.1–75.6)	71.8	(66.3–77.2)	1.9	3.7	0.489
Attention to care from other providers	77.4	(72.0–82.7)	80.7	(75.9–85.6)	3.4	75.8	(70.0–81.7)	74.8	(69.7–79.8)	–1.1	–4.4	0.412
Access to care	56.1	(48.3–64.0)	56.8	(50.1–63.4)	0.6	62.1	(53.7–70.4)	49.5	(41.6–57.3)	12.6**	–13.2*	0.093

* P < .10

** P < .05

[†] Adjusted for difference between demographics and risk of respondents