

# Reducing Long-Term Cost by Transforming Primary Care: Evidence From Geisinger’s Medical Home Model

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**A**t this time of national focus on the need to simultaneously improve quality and reduce cost, novel solutions are needed. The fragmented healthcare delivery system further adds to the challenge.<sup>1</sup> The key stakeholders—physicians, patients, health insurers, and hospital administrators, as well as the federal government—now recognize the need for healthcare redesign to increase the quality of care while containing the cost of care.<sup>2</sup> In particular, reorienting the current healthcare delivery system to one in which greater emphasis is given to more effective primary care is likely to be an important solution to the problem.<sup>3-5</sup>

Recently, patient-centered medical homes (PCMHs) have gained attention as a way to re-engineer the care-delivery process. In the broadest sense of the term, PCMHs refer to “provision of comprehensive primary care services that facilitates communication and shared decision-making between the patient, his/her primary care providers, other providers, and the patient’s family.”<sup>2</sup> There is early but growing evidence that PCMHs have the potential to improve care for individuals, improve health of populations, and slow the growth in costs of healthcare by reviving primary care and bringing the patient and family to the center of the care-delivery system<sup>6-10</sup> (ie, achieving the “triple aim”).<sup>5,11</sup>

The ultimate goal of PCMHs is to improve patient outcomes via re-designed primary care. The preventive aspect of primary care enhances the value proposition of PCMHs as a long-term intervention. Such an emphasis on primary care, therefore, implies that PCMHs may have the desirable effect of reducing cost of care. The early experiences of the PCMH demonstrations strongly suggest this.<sup>12</sup> In this study, we explicitly explore this possibility by evaluating the effect of ProvenHealth Navigator (PHN), an advanced model of PCMHs developed and implemented by Geisinger Health System (Geisinger), since 2006 on cost of care.

## BACKGROUND

PHN consists of the following 5 core program components: (1) patient-centered primary care, (2) integrated population management, (3) medical “neighborhood”<sup>13</sup> (ie, alignment of key community partners, such as home health agencies, skilled nursing facilities, outpatient/ancillary services, hospital facilities, and community pharmacies), (4) comprehensive quality improvement, and

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**Objectives:** To estimate cost savings associated with ProvenHealth Navigator (PHN), which is an advanced model of patient-centered medical homes (PCMHs) developed by Geisinger Health System, and determine whether those savings increase over time.

**Study Design:** A retrospective claims data analysis of 43 primary care clinics that were converted into PHN sites between 2006 and 2010. The study population included Geisinger Health Plan’s Medicare Advantage plan enrollees who were 65 years or older treated in these clinics (26,303 unique members).

**Methods:** Two patient-level multivariate regression models (with and without interaction effects between prescription drug coverage and PHN exposure) with member fixed effects were used to estimate the effect of members’ exposure to PHN on per-member per-month total cost, controlling for member risk, seasonality, yearly trend, and a set of baseline clinic characteristics.

**Results:** In both models, a longer period of PHN exposure was significantly associated with a lower total cost. The total cumulative cost savings over the study period was 7.1% (95% confidence interval [CI] 2.6-11.6) using the model with the prescription drug coverage interaction effects and 4.3% (95% CI 0.4-8.3) using the model without the interaction effects. Corresponding return on investment was 1.7 (95% CI 0.3-3.0) and 1.0 (95% CI -0.1 to 2.0), respectively.

**Conclusions:** Our finding suggests that PCMHs can lead to significant and sustainable cost savings over time.

(*Am J Manag Care.* 2012;18(3):149-155)

For author information and disclosures, see end of text.



### Take-Away Points

■ Geisinger Health Systems has implemented its own version of patient-centered medical homes called ProvenHealth Navigator (PHN) since 2006. Our results demonstrate that the longer the member has been exposed to PHN sites, the lower the cost of care. The return on investment (ROI) has not yet significantly exceeded the break-even point. However, because the magnitude of savings from PHN depends on the length of members' exposure to PHN, it remains to be seen whether the cumulative ROI can eventually exceed the break-even point.

■ Cost savings are achievable by redesigning primary care, but it takes time to reap the benefits.

(5) value-based reimbursement redesign that includes a quality, outcome-based pay-for-performance program. More detailed descriptions of how the PHN intervention was designed and implemented are published elsewhere.<sup>6,10,14</sup>

PHN is designed to move resources further “upstream” in the primary care setting to reduce “downstream” costs from the highest acuity settings. In this system, primary care is considered upstream in the sense that it serves as the starting point in the chain of care delivery. In general, care becomes more expensive as patients move downstream to specialty and inpatient care. Therefore, successful upstream efforts are expected to result in reductions of inpatient care–related costs due to fewer uncontrolled exacerbations of chronic diseases and more effective care transitions that prevent hospital readmissions and unnecessary duplication of services.

A PHN site refers to one of the primary care clinics that has been designated as such by Geisinger and has undergone significant changes in its management and operations in accordance with the PHN practice redesign. PHN was implemented in several phases over the 5-year period from late 2006 through 2010. At its core, the PHN intervention can potentially reduce cost over time while improving quality via:

- Prevention: redesigned primary care using automation to leverage resources and enhance reliability for early detection and interventions prior to exacerbations and complications
- Chronic disease optimization: redesigned primary care using a high-touch, high-technology approach to manage emerging exacerbations and to minimize complications
- Comprehensive care management: health-plan–trained, practice-embedded “concentrated care–RNs” who serve as nurse case managers focused on proactive identification and management of the more medically complex patients

## METHODS

This analysis focuses on individual members' exposure to PHN by measuring how long a member has been exposed to a PHN site and examining whether a prolonged exposure to

PHN is associated with a lower cost of care over time. It is expected that the longer the patient has been exposed to a PHN site, the greater the cost savings.

As shown in the **Figure**, a number of primary care clinics in the Geisinger Health Plan (GHP) provider network were selected and converted to PHN sites during each phase of the intervention. As a result, primary care clinics became PHN

sites at different times. We exploit this variation in time of PHN conversion to estimate the effect of PHN exposure on total cost. The figure also shows the trends in average per-member per-month (PMPM) total cost among clinics in each PHN implementation phase. For baseline clinic characteristics in each phase, see **eAppendices A and B**, available at [www.ajmc.com](http://www.ajmc.com).

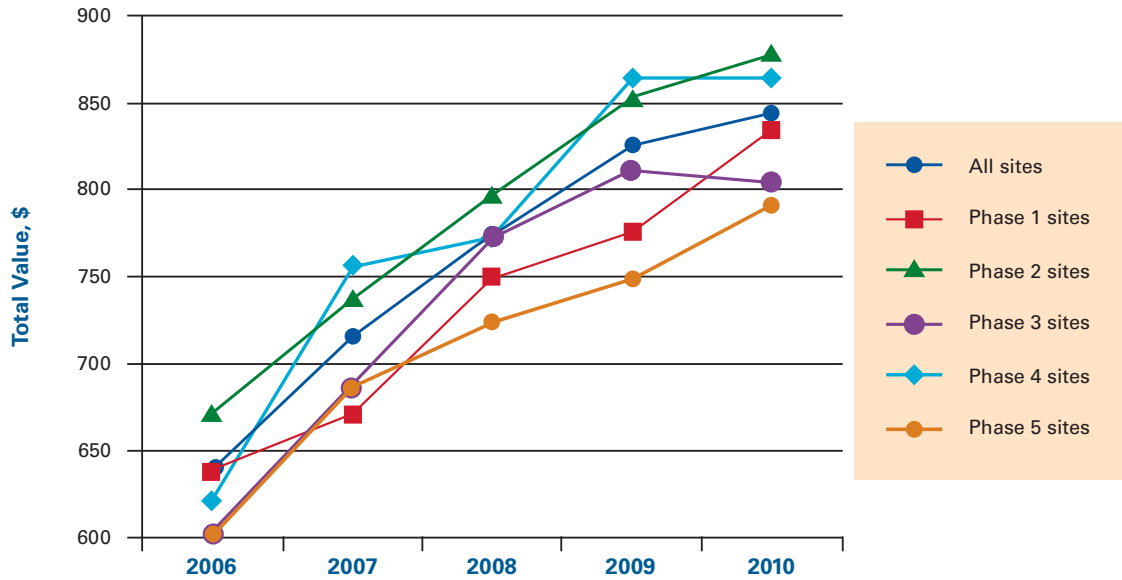
Our data originated from GHP's claims database covering the period between January 1, 2006, and December 31, 2010. The unit of observation was member-month (ie, there was a unique record for each member for each month during which the patient was a GHP member). If the member did not have any claims for that month, claim amounts were recorded as \$0. Our sample was restricted to GHP's Medicare Advantage plan members who were at least 65 years of age during the study period (because PHN had focused primarily on the Medicare population during this time) and enrolled in 43 primary care clinics that eventually became PHN sites by the end of 2010 (37 with physicians employed by Geisinger and 6 non-Geisinger primary care practices). About 30% of all patients treated by practices with Geisinger-employed physicians are covered by GHP.

Two measures of PHN exposure were developed: First, a member-level PHN exposure measure was calculated as the number of months a member had been enrolled in a PHN clinic as of a given time. This exposure measure was then broken into 5 categories (0, 1-6 months, 7-12 months, 13-24 months, and >24 months) in order to capture any non-linear relationship between the cost of care and PHN exposure. Second, a clinic-level PHN exposure measure was also calculated as the number of months in which the clinic had been a PHN site as of a given period since its PHN conversion on the phase start date as shown in Figure 1.

The clinic-level PHN exposure variable is intended to capture the degree to which there might have been learning at clinics over time in accordance with PHN's rapid-cycle innovation principle.<sup>14</sup> This is in recognition of PHN's being a dynamic program that has undergone continuous modifications over time while maintaining its core components. As such, it is difficult to determine exactly at what point the



■ **Figure.** Trends in Average PMPM Total Cost by PHN Implementation Phase



| Phase | Start Date | No. of PHN Sites (Cumulative) | Members in PHN (Cumulative) |
|-------|------------|-------------------------------|-----------------------------|
| 1     | Nov 2006   | 3                             | 15%                         |
| 2     | Nov 2007   | 13                            | 54%                         |
| 3     | Aug 2008   | 25                            | 92%                         |
| 4     | Jan 2010   | 36                            | 93%                         |
| 5     | Oct 2010   | 43                            | 100%                        |

PHN indicates ProvenHealth Navigator; PMPM, per member per month.

PHN sites transitioned from practice transformation and re-design to fully functioning PHN sites. Nevertheless, we hypothesize that the longer a clinic has been designated a PHN site, the greater its impact on cost of care.

In addition to the member-level and clinic-level PHN exposure variables as described above, the covariates included age and hierarchical condition categories (HCC) risk score to capture each member's case mix along with year-indicator variables to capture the temporal trend in total cost over time as well as month-indicator variables to capture seasonality. Other covariates included a set of baseline clinic characteristics as of 2005 (ie, percentage of male patients and average patient age in 2005, along with average total cost, HCC score, and number of inpatient admissions and readmissions in 2005). These variables were intended to capture any underlying differences among different clinics which may be correlated with each member's total cost during the study period.

The main outcome measure was the total cost of care, defined as the total allowed amount (plan payment to providers plus copayments) for a given member in a given month

(per-member-per-month [PMPM]) which included payments for inpatient and outpatient facility and professional services, as well as prescription drugs. Less than 2% of the total member-month observations in our sample had 0-value total cost, because capitation payments for certain services, such as behavioral health, were reflected in the total cost calculations.

Because there are multiple observations for each member, a member fixed-effects model was used to account for these repeated measures as well as to remove any unobserved and time-invariant member characteristics that could have biased our estimates. In this model, we exploit the within-member variation in the total cost and the PHN exposure variable over time. Thus, each member acts as his or her comparison. In other words, the question that our model seeks to answer may be stated as the following: relative to his or her own cost at 0 PHN exposure, what is each member's expected total cost at 1 to 6 months, 7 to 12 months, 13 to 24 months, and greater than 24 months, of exposure?

Moreover, because members' total costs vary depending on whether they have prescription drug coverage or not, a binary



■ **Table 1. Descriptive Statistics**

| Descriptive Statistics (Interquartile Range in Parentheses)   |                |                      |              |                  |
|---|----------------|----------------------|--------------|------------------|
| Member Characteristics (26,303 members; 1,053,445 member-month observations)  |                |                      |              |                  |
| PMPM total cost (mean) (\$)   |                |                      |              | 800 (48-437)     |
| Median member age (years)   |                |                      |              | 76 (71-81)       |
| % male  |                |                      |              | 42               |
| Median HCC risk score   |                |                      |              | 0.85 (0.53-1.44) |
| % member-month covered by Rx benefit  |                |                      |              | 67%              |
| PHN Exposure  | % Member-Month | Mean Total Cost (\$) | Mean Age (y) | % Rx Coverage    |
| 0 mo  | 49%            | 709                  | 76           | 59%              |
| 1-6 mo  | 12%            | 787                  | 75           | 72%              |
| 7-12 mo   | 11%            | 797                  | 76           | 73%              |
| 13-24 mo  | 16%            | 823                  | 76           | 76%              |
| >24 mo  | 12%            | 847                  | 77           | 74%              |
| Clinic Characteristics (43 clinics)   |                |                      |              |                  |
| Median clinic-level PHN exposure as of 2010 (mo)  |                |                      |              | 26 (15-35)       |
| Median percent of male members in 2005  |                |                      |              | 43 (41-45)       |
| Median average member age in 2005   |                |                      |              | 75 (75-76)       |
| Median average PMPM total cost in 2005 (\$)   |                |                      |              | 680 (600-816)    |
| Median average HCC risk score in 2005   |                |                      |              | 1.04 (1-1.09)    |
| Median No. admissions per 1000 members in 2005  |                |                      |              | 248 (206-305)    |
| Median No. readmissions per 1000 members in 2005  |                |                      |              | 39 (25-31)       |
| HCC indicates hierarchical condition categories; PHN, ProvenHealth Navigator; PMPM, per member per month; Rx, prescription. |                |                      |              |                  |

indicator variable for prescription drug coverage status during each month was also included as a covariate. Because of the fixed effects model used in this analysis, our estimate of the drug coverage effect relied on variation in the prescription drug coverage variable due to the change in each member's drug coverage status over time. About 32% of the members picked up the drug coverage and dropped it at some point, or vice versa.

We hypothesized that the effect of PHN on total cost may differ depending on whether a member has prescription drug coverage in each period (ie, an interaction effect between prescription coverage and PHN exposure). For instance, a case manager might find out whether his or her members have drug coverage or not, and if they have coverage, the case manager might encourage them to become more adherent to their drug therapy and therefore incur greater total cost. As such, we estimated 2 models: one with and another without the interaction effects. These 2 models might yield different estimates of total cost savings attributable to PHN, because in the model with interaction effects, the estimates depend both on the level of each member's PHN exposure and the proportion of members who have drug coverage in each period. In the

model without the interaction effects, the estimates depend only on the PHN exposure level.

Using the parameter estimates obtained from the fixed-effects model, we calculated the expected total cost if none of the members had any PHN exposure (ie, member as well as clinic-level PHN exposure of 0 months) and compared them against the total costs given the actual levels of PHN exposure for each member in each given period (ie, the "observed" cost). This allowed us to estimate the effect of the PHN exposure on cost in terms of percent savings (see eAppendices A and B for the full regression model parameter estimates). The mean percent savings and the standard errors used to construct the 95% confidence intervals (CIs) were obtained via bootstrap method with 200 replications.

As a sensitivity check, we also obtained a number of alternative estimates using different sample definitions. In particular, we obtained estimates with a restricted sample consisting of only those who did not switch their primary care clinics during the study period (about 80% of the full sample size). This allowed us to control for any clustering effects due to similarities among members enrolled in same clinics<sup>15</sup> by including member-clinic fixed effects in our regression model.



■ **Table 2.** Selected Regression Coefficient Estimates<sup>a</sup>

| Total PMPM Allowed Cost (\$)         |  |   |
|--------------------------------------|--|---|
| Key Covariates                       | Coefficient (\$) (95% CI)                    | Coefficient (\$) (95% CI)                 |
|                                      | Without Rx Coverage Interaction <sup>b</sup> | With Rx Coverage Interaction <sup>c</sup> |
| PHN exposure: 1-6 mo                 | -24.08 <sup>d</sup> (-46.95 to -1.22)        | -38.11 <sup>d</sup> (-76.62 to 0.40)      |
| PHN exposure: 7-12 mo                | -20.58 (-50.01 to 8.84)                      | -37.13 <sup>d</sup> (-81.08 to 6.81)      |
| PHN exposure: 13-24 mo               | -33.51 (-75.51 to 8.48)                      | -62.35 (-113.81 to -10.9)                 |
| PHN exposure: >24 mo                 | -59.70 <sup>d</sup> (-126.50 to 7.09)        | -108.3 <sup>f</sup> (-183.32 to -33.28)   |
| Rx coverage                          | 176.83 <sup>e</sup> (153.04-200.62)          | 164.75 <sup>f</sup> (139.25-190.26)       |
| Rx coverage X PHN exposure: 1-6 mo   |  | 18.48 (-23.57 to 60.54)                   |
| Rx coverage X PHN exposure: 7-12 mo  |  | 21.53 (-22.34 to 65.40)                   |
| Rx coverage X PHN exposure: 13-24 mo |  | 37.13 <sup>d</sup> (-1.56 to 75.83)       |
| Rx coverage X PHN exposure: >24 mo   |  | 63.35 <sup>f</sup> (18.78-107.91)         |
| Clinic-level PHN exposure            | -0.29 (-2.45 to 1.87)                        | -0.30 (-2.45 to 1.86)                     |
| Adjusted R <sup>2</sup>              | 0.11   | 0.11                                      |

CI indicates confidence interval; HCC, hierarchical condition categories; PHN, ProvenHealth Navigator; PMPM, per member per month; Rx, prescription.

<sup>a</sup>Also includes member age, HCC risk score, baseline clinic characteristics in 2005, as well as indicator variables for each of the calendar years and claim months. For full regression output, see eAppendices A and B, available at [www.ajmc.com](http://www.ajmc.com).

<sup>b</sup>Assumes that PHN effect is independent of drug coverage.

<sup>c</sup>Assumes that PHN effect depends on whether the member has drug coverage.

<sup>d</sup>P < .1.

<sup>e</sup>P < .05.

<sup>f</sup>P < .01.

The resulting estimates (available upon request) were similar to the reported estimates shown below.

## RESULTS

As shown in **Table 1**, the final sample consisted of 26,303 members over the 5-year period, corresponding to 1,053,445 member-month observations in 43 primary care clinics that were designated as PHN sites at different points in time between 2006 and 2010. The median age of the members was 76 years, and 42% were male. Slightly less than half of the member-month observations fell in the 0 member-level PHN exposure category; about 12% fell in the highest category of greater than 24 months of PHN exposure. Table 1 also indicates that greater PHN exposure is associated with higher total cost and age, as well as greater proportion of member-months with prescription coverage. This suggests that the effect of PHN exposure on total cost is confounded by member age and presence of prescription drug coverage benefit.

On average, GHP members in our sample maintained their membership for about 40 months out of the maximum possible 60 months, suggesting a stable enrollment pattern. About 20% of the members in our sample switched from a non-PHN site to a PHN site during our study period, while only about 1% switched from a PHN site to a non-PHN site.

**Table 2** shows the regression coefficients and their corresponding 95% CIs for the key covariates in the 2 models

(with and without the interaction effects between drug coverage and PHN exposure). In both models, the coefficients on the PHN exposure variables are consistently negative and get increasingly larger as the length of exposure increases, suggesting that longer PHN exposure is consistently associated with lower total cost. However, in contrast, the coefficient estimates on the interaction terms between drug coverage and PHN exposure are consistently positive, suggesting that there is a significant interaction between them.

**Table 3** shows the estimated percent savings and the corresponding bootstrapped 95% CIs as obtained from the regression model parameter estimates shown in Table 2. Table 3 clearly supports the hypothesis that a longer exposure to PHN is associated with lower total cost and therefore greater savings, regardless of whether the interaction effects were included in the model. The largest and statistically most significant percent saving was achieved in the highest category of PHN exposure (>24 months) in both models.

Overall, the estimated total cumulative savings to Geisinger attributable to PHN from its inception in November 2007 through December 2010 is 7.1% using the model that includes the interaction effects and 4.3% using the model that does not include the interaction effects, both of which are statistically significant (ie, greater than 0). However, there is no statistically significant difference between these 2 estimates, as indicated by the large overlapping CIs around these estimates (the overlap in the intervals ranges from 2.6% to 8.3%).





■ **Table 3.** Estimated Savings (%) by PHN Exposure Category

| PHN Exposure (Mo) | Without Rx Coverage Interaction <sup>a</sup> |                                 |                                | With Rx Coverage Interaction <sup>b</sup> |                                 |                             |
|-------------------|--|---------------------------------|--------------------------------|---|---------------------------------|-----------------------------|
|                   | Expected Cost (\$) <sup>c</sup>              | Observed Cost (\$) <sup>d</sup> | % Difference (95% CI)          | Expected Cost (\$) <sup>b</sup>           | Observed Cost (\$) <sup>b</sup> | % Difference (95% CI)       |
| 1-6               | 825  | 800                             | 3.0 (-0.8 to 6.8)              | 839                                       | 800                             | 4.6 (-1.1 to 10.3)          |
| 7-12              | 874  | 850                             | 2.8 (-1.4 to 6.9)              | 890                                       | 850                             | 4.5 (-1 to 9.9)             |
| 13-24             | 945  | 904                             | 4.3 <sup>e</sup> (-0.1 to 8.6) | 974                                       | 904                             | 7.1 <sup>g</sup> (2-12.3)   |
| >24               | 1024   | 955                             | 6.7 <sup>f</sup> (1.2-12.1)    | 1072                                      | 955                             | 10.8 <sup>g</sup> (4.7-17)  |
| <b>Overall</b>    | 921  | 881                             | 4.3 <sup>f</sup> (0.4-8.3)     | 949                                       | 881                             | 7.1 <sup>g</sup> (2.6-11.6) |

CI indicates confidence interval; PHN, ProvenHealth Navigator; Rx, prescription.  
<sup>a</sup>Assumes that PHN effect is independent of drug coverage.  
<sup>b</sup>Assumes that PHN effect depends on whether the member has drug coverage.  
<sup>c</sup>Indicates regression-adjusted average total cost with all members assigned to 0 PHN exposure.  
<sup>d</sup>Indicates regression-adjusted average total cost at observed levels of PHN exposure.  
<sup>e</sup>*P* < .1.  
<sup>f</sup>*P* < .05.  
<sup>g</sup>*P* < .01.

**Table 4** shows the return on investment (ROI) of the PHN intervention to Geisinger. Geisinger has invested considerable resources to support the PHN initiative over the years by hiring and training case managers to assist in patient care and administrative staff to provide data support, as well as by providing incentive payments and bonuses to the participating clinics and physicians. The return to Geisinger is the estimated cost savings as shown in Table 3. ROI is calculated by dividing the estimated total dollar savings by the actual dollar amounts invested in implementing PHN. Thus, an ROI figure greater/less than 1 suggests that the returns from PHN were greater/less than the investment. ROI of 1, therefore, indicates a break-even point.

Table 4 suggests that, because of the large 95% CIs around our estimates, we cannot conclude that the ROI has exceeded the break-even point at any point during the first 4 years of the PHN implementation. Nevertheless, the point estimate of ROI in each year shows a consistent upward trend. To the extent that higher returns from PHN depend on the length of members' exposure to PHN, as shown in Table 3, it remains

to be seen whether the cumulative ROI can eventually exceed the break-even point.

## DISCUSSION

In this analysis, we have shown that over time, PCMHs as embodied in Geisinger's PHN initiative can reduce cost by providing patients improved care coordination, enhanced access to primary care providers, and more effective and efficient disease and case management. There may indeed be downstream benefits of PCMHs which manifest themselves at the individual level only after a considerable length of exposure. While the ROI estimates did not reach statistical significance during this study period, the results still suggest that as more members get longer exposure to PHN, the accrued savings to GHP will likely increase beyond the level shown in this analysis, and the net savings as demonstrated by ROI may eventually achieve statistical significance. As such, in order to be able to detect any measurable success of PCMHs in terms of significant and sustainable cost savings, a

■ **Table 4.** Estimated ROI by Year

| Year             | ROI (95% CI)                                 |   |
|------------------|--|---|
|                  | Without Rx Coverage Interaction <sup>a</sup> | With Rx Coverage Interaction <sup>b</sup> |
| 2007             | 0.7 (-0.2 to 1.6)                            | 1.1 (-0.2 to 2.4)                         |
| 2008             | 0.6 (-0.2 to 1.4)                            | 1.0 (-0.1 to 2.1)                         |
| 2009             | 1.1 (-0.1 to 2.2)                            | 1.8 (0.3-3.3)                             |
| 2010             | 1.2 (0.0-2.4)                                | 2.1 (0.6-3.5)                             |
| <b>All Years</b> | 1.0 (-0.1 to 2.0)                            | 1.7 (0.3-3.0)                             |

CI indicates confidence interval; ROI, return on investment; Rx, prescription.  
<sup>a</sup>Indicates that Rx coverage and PHN exposure variables were included as independent covariates only without the interaction effects.  
<sup>b</sup>Refers to inclusion of interaction effects between these 2 variables in our regression model.



continued investment in PCMHs as well as patience is likely to be necessary.

Our findings are consistent with the “prevention hypothesis” of PCMHs—that the enhanced primary care delivered by PCMHs reduces the likelihood of exacerbation of chronic conditions or allows more efficient management of these exacerbations and thus reduces future inpatient admissions and readmissions. While we were unable to directly confirm this hypothesis in our study, the previous studies<sup>6,10</sup> have shown that PHN produces significant reductions in hospitalization and certain adverse outcomes. Furthermore, we have found an interaction effect between drug coverage and PHN exposure which suggests that, when a member obtains drug coverage, PHN exposure is associated with higher total cost. This is consistent with the hypothesis that prescription drugs may be complements to other healthcare services in producing improved patient outcomes, rather than substitutes.

There may have been changes other than drug coverage in the benefit design (eg, changes in participating provider network) that may have impacted each member's total costs over time. Unfortunately, our claims data do not include detailed information on each member's benefit design other than the drug coverage status. This problem, however, is somewhat mitigated by the fact that our sample includes only the Medicare Advantage enrollees of a single managed care organization.

This study further supports the case for PCMHs as a key component in developing a new and comprehensive system of care aimed at achieving the “triple aim.”<sup>5,11</sup> Future studies will examine whether PHN has led to significant improvements in patient and provider satisfaction, a critical aspect of the quality of care rendered within this redesigned primary care system.

### Acknowledgments

We acknowledge Earl Steinberg, MD, MPP, Jason Roy, PhD, and Walter Stewart, PhD, for their valuable comments and suggestions. We also acknowledge Richard Bitting, BBA, and Alison Star, MBA, for facilitating acquisition of the data used for this study.

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**Funding Source:** There was no external funding for this report.

**Author Disclosures:** All authors (DDM, JG, TRG, JNL, NBD, JT, DED, FJB, GDS) report employment with Geisinger, which offers consulting services to other organizations for medical home implementations. Dr Bloom also re-

ports receiving lecture fees from Merck for patient-centered medical home topics.

**Authorship Information:** Concept and design (DDM, JG, TRG, NBD, JT, DED, FJB, GDS); acquisition of data (DDM, NBD); analysis and interpretation of data (DDM, JG, TRG, JNL, NBD, GDS); drafting of the manuscript (DDM, JG, TRG, JNL, JT, DED, GDS); critical revision of the manuscript for important intellectual content (DDM, JG, TRG, JNL, JT, DED, FJB, GDS); statistical analysis (DDM); provision of study materials or patients (FJB); administrative, technical, or logistic support (JT, DED, FJB); and supervision (JG, DED, FJB).

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