Cost savings associated with an alternative payment model for integrating behavioral health in primary care

Kaile M. Ross, Emma C. Gilchrist, Stephen P. Melek, Patrick D. Gordon, Sandra L. Ruland, Benjamin F. Miller

ABSTRACT

Financially supporting and sustaining behavioral health services integrated into primary care settings remains a major barrier to widespread implementation. Sustaining Healthcare Across Integrated Primary Care Efforts (SHAPE) was a demonstration project designed to prospectively examine the cost savings associated with utilizing an alternative payment methodology to support behavioral health services in primary care practices with integrated behavioral health services. Six primary care practices in Colorado participated in this project. Each practice had at least one on-site behavioral health clinician providing integrated behavioral health services. Three practices received non-fee-for-service payments (i.e., SHAPE payment) to support provision of behavioral health services for 18 months. Three practices did not receive the SHAPE payment and served as control practices for comparison purposes. Assignment to condition was nonrandom. Patient claims data were collected for 9 months before the start of the SHAPE demonstration project (pre-period) and for 18 months during the SHAPE project (post-period) to evaluate cost savings. During the 18-month post-period, analysis of the practices’ claims data demonstrated that practices receiving the SHAPE payment generated approximately $1.08 million in net cost savings for their public payer population (i.e., Medicare, Medicaid, and Dual Eligible; N = 9,042). The cost savings were primarily achieved through reduction in downstream utilization (e.g., hospitalizations). The SHAPE demonstration project found that non-fee-for-service payments for behavioral health integrated into primary care may be associated with significant cost savings for public payers, which could have implications on future delivery and payment work in public programs (e.g., Medicaid).

Keywords

Integrated behavioral health and primary care, Alternative payment models, Finance, Primary care, Behavioral health

INTRODUCTION

Mental health has become the most costly health condition in the USA, with an estimated $201 billion spent in 2013 [1]. The health care costs resulting from mental health are largely medical costs, not specific to mental health care expenditures [2]. In particular, costs associated with patients who have a chronic illness can differ substantially when comparing patients with and without a co-occurring mental health condition or substance use disorder. For example, a patient with diabetes and no mental health diagnosis costs a health plan, on average, $811 per month, whereas when the patient with diabetes has a co-occurring serious and persistent mental illness, may cost insurers, on average, $1,775 per month [3].

Behavioral health is an umbrella term for care that addresses behavioral difficulties bearing on health, including health behaviors, mental health conditions, and substance use [4]. Behavioral health needs are insufficiently addressed in the USA, with over 60% of adults [5] and adolescents [6] with behavioral health needs not receiving treatment or services from a behavioral health clinician. Instead, approximately half of adults with poor mental health receive care solely from primary care clinicians [7]. Although an estimated 20% of primary care visits are behavioral health related [8], 67% of primary care clinicians report being unable to connect their patients to needed outpatient behavioral health clinicians [9]. Integrating behavioral health clinicians into primary care settings attempts to address this gap in care by delivering timely access to behavioral health care as part of the primary care visit [10, 11].

The movement to integrate behavioral health into primary care settings is rapidly gaining national...
traction through federal initiatives and state-based programs [12, 13]. The evidence for improved patient outcomes through integrating care has been known for quite some time [14], and multiple studies have demonstrated significant reduction in health care costs associated with integrating behavioral health into primary care [15, 16]. Yet, despite the cost savings associated with integrated models of care, financing integration efforts remains a key barrier to widespread adoption. Indeed, even exemplary integrated care practices report financial challenges as the most significant threat to sustainability [17, 18].

The historic separation of insurance benefit, payment, and delivery of behavioral health and physical health services has created financial barriers to integration [19, 20]. Many states have behavioral health “carve outs,” wherein a separate organization manages behavioral health benefits [21], further complicating the implementation of integrated behavioral health into medical settings like primary care. These constraints have led to issues such as the inability for both behavioral and physical health clinicians to receive reimbursement for the same diagnosis on the same day [17]. Uniting behavioral and physical health services in the same setting requires utilization of alternative approaches to payment to achieve financial sustainability, as the traditional fee-for-service model is insufficient for sustaining behavioral health in a primary care setting [21].

The USA is currently experiencing rapid proliferation of alternative payment models (APMs). Under the Affordable Care Act, the Centers for Medicare and Medicaid Services has been quickly increasing the percentage of APM Medicare payments, with an estimated 30% of payments being tied to APMs as of March 2016 [22]. APMs are intended to move the system and practice of health care delivery from a predominately volume-based approach (e.g., fee-for-service) to a value-based design which aims to pay clinicians for delivering high quality care that achieves better health outcomes and controls costs. Various APMs have been used with varying success over the past few decades in an attempt to contain costs and improve patient outcomes [23]; however, APMs have not been explored in the context of supporting and sustaining integrated behavioral health in primary care. Despite the widely acknowledged financial barriers to providing integrated care and need for APMs in integrated settings [20, 24], there remains little in the published literature regarding which payment models sustain behavioral health in a primary care setting. One recent article, which reviewed various APMs and evaluated their potential ability to support integrated behavioral health services in primary care, suggested that APMs that provide more flexibility in how they are utilized by the practice may provide a better fit for supporting integration of behavioral health services [25]. The aim of the current project was to begin to address the critical gap in the APM literature by prospectively evaluating the financial impact of implementing a flexible, non-fee-for-service APM payment methodology within primary care practices with integrated behavioral health. To the authors’ knowledge, this is the first project to prospectively examine an APM for integrated behavioral health services in primary care practices.

METHODS

The SHAPE program
Sustaining Healthcare Across Integrated Primary Care Efforts (SHAPE) was a demonstration project designed to examine the impact of non-fee-for-service payments provided to primary care practices to support delivery of integrated behavioral health services. SHAPE was created through the partnership of four organizations, including the Collaborative Family Healthcare Association, the Colorado Health Foundation, the University of Colorado School of Medicine, and Rocky Mountain Health Plans (a not-for-profit insurance organization). SHAPE’s primary goal was to evaluate the impact of a flexible, non-fee-for-service payment on cost of care for public payers (i.e., Medicaid and Medicare) using a pre–post data collection methodology with comparison group. The secondary aim was to examine the payment’s potential impact on screening and diagnosis of behavioral health conditions within participating practices. The Colorado Multiple Institutional Review Board approved the study protocol.

SHAPE demonstration project
In this demonstration project, primary care practices received a non-fee-for-service payment to support provision of integrated behavioral health services. The payment (i.e., SHAPE payment) amounts were calculated at the practice-level using an activity-based costing methodology [26, 27]. Utilizing this method, the practices collaborated with SHAPE research staff to identify—(i) the anticipated resource requirements for the provision of integrated behavioral health services (i.e., what screenings and interventions were necessary to meet the behavioral health needs of their patients), (ii) the cost of personnel, and (iii) related supports necessary to achieve required workflow and documentation changes. Based on the summation of these calculations, Rocky Mountain Health Plans provided a yearly lump sum payment to each practice during the 18-month demonstration phase totaling approximately $900,000 across practices receiving the payment. The practices that served as the comparison group (i.e., control group) for this demonstration project continued to operate “business as usual” and did not receive the SHAPE payment.

Practices receiving the SHAPE payment were instructed to use the payment to support integrated
behavioral health services in their practice and to support the provision of behavioral health services to patients as needed, regardless of patient insurer or patient ability to pay for services. Due to a myriad of studies already looking at clinical outcomes from integration models [16, 28], this demonstration project was designed to evaluate the impact of the SHAPE payment rather than evaluate the impact of various integrated behavioral health delivery approaches. Therefore, all practices had autonomy in delivery of integrated behavioral health services and autonomy in allocation of the SHAPE payment to support behavioral health services for their patient population. Information regarding SHAPE payment utilization/allocation within practice was not collected.

This demonstration project utilized a pre-post design. The pre-period consisted of 9 months before the start of the project. The post-period consisted of the 18 months after the start of the project, during which time the non-control practices were receiving SHAPE payments.

Practice selection
For this project, six primary care practices in Colorado with: (a) prior history of integrated behavioral health provision, (b) at least one behavioral health clinician embedded and providing behavioral health services, and (c) patients covered by Rocky Mountain Health Plans were approached about participating in SHAPE. Three practices with the highest proportion of patients with [the not-for-profit health plan] coverage were assigned to receive the SHAPE payments. This was done because Rocky Mountain Health Plans provided the SHAPE payments to the practices; the payments helped to support behavioral health services for all patients in those practices, not just patients with [the not-for-profit health plan] insurance coverage. Assigning the practices with the highest Rocky Mountain Health Plans coverage allowed for—(a) a greater number of Rocky Mountain Health Plans patients to benefit from potential improvements in behavioral health services facilitated by the SHAPE payment and (b) for Rocky Mountain Health Plans to potentially generate cost savings as a result of the payments. The other three practices with a lower proportion of patients with Rocky Mountain Health Plans coverage were assigned to participate as control practices.

Measures

Cost savings
Medical and prescription claims data were collected for all Rocky Mountain Health Plans members at the participating practices for the 9-month pre-period and the 18-month post-period. Claims data for all service types were collected (e.g., emergency department, behavioral health, dental services). The cost savings analysis included only claims data from Rocky Mountain Health Plans patients with public sector programs (i.e., Medicaid, Medicare, and those classified as Dual Eligible, enrolled in both Medicare and Medicaid).

Behavioral health screening and diagnosis
Information pertaining to depression screening and diagnosis of behavioral health conditions was extracted from all practices’ electronic medical records (EMRs). Depression screening was determined by EMR documented use of the Patient Health Questionnaire (PHQ-9) [29], a measure designed to screen for symptoms of depression. The proportion of patients screened with the PHQ-9 was determined for both the pre- and the post-periods by determining the number of patients within each practice with an EMR documented screening divided by the total number of patients in the practice. Proportion of patients diagnosed with a behavioral health condition, including depression-related disorders, anxiety-related disorders, and substance use disorders, was determined for both the pre- and post-periods. Behavioral health diagnosis information was extracted from the practices’ EMR to determine the proportion of patients with each behavioral health diagnosis type. Due to practice-level variability in EMR diagnosis documentation, diagnosis extraction was done by searching multiple EMR data files (i.e., beyond simply extracting diagnostic codes) for a variety of diagnostic terms that would indicate that the patient had been diagnosed with a depression, anxiety, or substance use related disorder. All patients with at least one EMR documented encounter/visit during the pre- or post-period were included in the analyses.

Statistical analyses

Cost savings
An actuarial firm, not affiliated with Rocky Mountain Health Plans, completed the analysis of the claims data. An actuarially adjusted historical control design was utilized to estimate the cost savings associated with implementation of the SHAPE payments. Actuarially adjusted historical control design is an approach that was initially developed for estimating the impact of disease management programs but was subsequently adopted more widely in the actuarial field for evaluating the impact of a wide variety of health care interventions [30, 31]. This approach uses longitudinal data from a control group (or historical control) to calculate an expected data trend, which is then applied to the intervention group’s baseline data to calculate an “expected” outcome (i.e., the outcome predicted based on the trend in the absence of the intervention). The actual outcome data are then compared with the “expected” outcome data to assess for
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“expected” post-period cost to determine cost savings for the public insurers (i.e., “expected” PMPM cost = actual PMPM cost − PMPM cost savings).

The PMPM “expected” costs and cost savings were calculated individually by insured member eligibility category to account for differences in payer mix across the control and SHAPE payment practices and across time. In addition, because many of the eligibility categories are somewhat age-based (e.g., Medicaid eligibility categories [adults, children, foster care, aged, and pregnant cohorts] and Medicare eligibility categories [aged and dual]), conducting the cost analysis by eligibility category aided in accounting for differences in patient age across practices. However, for ease of interpretation, PMPM and cost savings results are presented in aggregate rather than by eligibility category for Medicaid, Medicare, and Duals. Lastly, aggregate claims data were categorized by service type (e.g., inpatient facility services, emergency department service, behavioral services) to evaluate cost increases and decreases by service category from the pre- to post-period.

Behavioral health screening and diagnosis

For this analysis, the outcomes of interest were the absence or presence of a documented depression screening (yes or no) or behavioral health diagnosis (yes or no) for patient-level data. Practice-level proportions of screening and diagnoses were calculated for the pre- and post-periods.

A two-step analytical approach was used to determine how the SHAPE payment may have influenced depression screening rates and behavioral health diagnosing within the practices. In step one, a clustered linear mixed-model analysis for binary outcomes was attempted with patients nested within each practice to compare the SHAPE payment practices with control practices between the pre- and post-periods. Due to complexity of the data (i.e., a variety of EMRs and differences in documentation structures across practices), the clustered mixed-models did not converge for all outcomes; therefore, a second analytical approach was used. The second approach used generalized linear mixed models without nesting while still accounting for the nonindependent nature of the pre-post data by including each practice as a fixed covariate to account for the interrelatedness of patients within each practice. Risk ratios estimating the relative risk for screening and diagnosis in the SHAPE payment practices and control practices were calculated using a log it link function. All estimates were adjusted for the average number of patient visits throughout the study interval per clinic as an estimate of clinic capacity, patient age, ethnicity, and gender. All statistical comparisons for the screening and diagnosis data were performed in SAS 9.4 [32].

RESULTS

Practice characteristics

Six integrated primary care practices from across Colorado participated in SHAPE. Practices represented both private and public ownership models and annual patient visits ranged from 5,096 to 73,008 (see Table 1). Practices varied in number and full-time equivalent (FTE) of primary care and behavioral health clinicians. All practices had a behavioral health clinician on-site: five practices had master’s degree-level behavioral health clinicians and one had a psychologist. General patient characteristics (gender, age, race/ethnicity, and insurance type) for each practice are presented in Table 2.

In the three practices receiving the SHAPE payment, insurance coverage by Rocky Mountain Health Plans ranged from 36.3% to 50.0% with an average of 39.5%. Coverage by Rocky Mountain Health Plans in the practices that did not receive the SHAPE payment was less than 5% in total.

Cost savings

Overall, an estimated cost savings of between 3% and 5% of total health care costs for each public sector payer (Medicaid, Medicare, and Dual Eligible) was achieved across the three SHAPE payment practices for Rocky Mountain Health Plans members (N = 9,042; Table 3). The total estimated cost savings is equivalent to approximately $1.98 million during the post-period, with $1.52 million cost savings to Medicaid, $350,000 to Medicare, and $110,000 to Dual Eligible. These savings do not account for the cost of the SHAPE payments, which was approximately $900,000 in total. Net savings therefore totaled $1.08 million. Table 3 summarizes the estimated PMPM and costs saving by payer (Medicaid, Medicare, and Dual Eligible). Figure 1 demonstrates the monthly average paid costs PMPM for all public payers combined, comparing control practices with the SHAPE payment practices. The figure visually demonstrates the divergence in costs that emerged after participation in SHAPE demonstration project commenced.

The main service categories generating these savings were inpatient facility ($1.53 million), outpatient facility ($442,000), professional medical
($587,000), and emergency department services ($55,000). The main areas where costs increased included behavioral services ($60,000), Medicaid waiver services ($301,000), and dental and other services ($282,000).

Behavioral health screening and diagnosis

Patients within the practices receiving the SHAPE payment were 3.5 times more likely to have been screened for depression than in the control practices (RR 3.5, 95% CI, 3.0 to 4.2; \( p < .0001 \)). Depression was 1.5 times as likely to be diagnosed in the SHAPE payment practices over time as compared with the control practices (RR 1.5, 95% CI, 1.3 to 1.8, \( p < .0001 \)). A diagnosis of an anxiety-related condition was also about 1.3 times as likely to be given during the post-period within the SHAPE payment practices as compared to the control practices (RR 1.3, 95% CI, 1.1 to 1.6, \( p = .001 \)). Substance use disorders were the only measured behavioral health conditions that were not more frequently diagnosed within the intervention practices than the control practices during the post-period (RR 1.1, 95% CI, 0.79 to 1.3, \( p = .96 \)). The screening and diagnosis analyses controlled for patient age, ethnicity, and gender; however, uncontrolled analyses yielded similar results to the controlled analyses.

**DISCUSSION**

The results of the SHAPE demonstration project send a hopeful message about the potential utility of APMs to financially sustain the integration of behavioral health into primary care settings. Specifically, the SHAPE non-fee-for-service payments achieved approximately $1.98 million in gross cost savings among public sector payer patients in three primary care practices due to decreased downstream utilization, largely hospitalizations, leading to a net savings of $1.08 million (i.e., return on investment of $2.08 to $1.00 invested in behavioral health services).

### Table 1 | Characteristics of the practices

<table>
<thead>
<tr>
<th>ID</th>
<th>Practice type</th>
<th>Ownership</th>
<th>Location</th>
<th>Primary care clinicians ( ^a )</th>
<th>Behavioral health clinicians ( ^b )</th>
<th>Psychiatry ( ^c )</th>
<th>Annual patient visits (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SP1</td>
<td>Family practice group</td>
<td>Medical group practice</td>
<td>Urban</td>
<td>9 (6.9)</td>
<td>3 (1.0)</td>
<td>–</td>
<td>24,700</td>
</tr>
<tr>
<td>SP2</td>
<td>Federally Qualified Health Center</td>
<td>Federal</td>
<td>Rural</td>
<td>10 (7.4)</td>
<td>1 (1.0)</td>
<td>–</td>
<td>41,600</td>
</tr>
<tr>
<td>SP3</td>
<td>Family practice group</td>
<td>Physician owned</td>
<td>Rural</td>
<td>4 (4.0)</td>
<td>1 (1.0)</td>
<td>–</td>
<td>15,600</td>
</tr>
<tr>
<td>C1</td>
<td>Solo practice</td>
<td>Physician owned</td>
<td>Rural</td>
<td>1 (1.0)</td>
<td>1 (1.0)</td>
<td>–</td>
<td>3,432</td>
</tr>
<tr>
<td>C2</td>
<td>Community health + Mental health center</td>
<td>Not for profit 501c3</td>
<td>Rural</td>
<td>3 (1.2)</td>
<td>1 (0.3)</td>
<td>1 (0.4)</td>
<td>5,096</td>
</tr>
<tr>
<td>C3</td>
<td>Federally Qualified Health Center</td>
<td>Federal</td>
<td>Suburban</td>
<td>17 (15.3)</td>
<td>5 (5.0)</td>
<td>–</td>
<td>73,008</td>
</tr>
</tbody>
</table>

\( ^a \) Primary care clinicians include family medicine, internal medicine, and pediatrics; medical doctor (MD), doctor of osteopathy (DO), physician assistant (PA), and nurse practitioner (NP).

\( ^b \) Behavioral health clinicians include doctor of psychology (PsyD), licensed social worker (LCSW), licensed marriage and family therapist (LMFT), and licensed clinical professional counselor (LCPC).

\( ^c \) Psychiatry clinicians include psychiatrist (MD).

### Table 2 | Practice-level patient characteristics

<table>
<thead>
<tr>
<th>ID</th>
<th>Age (years)</th>
<th>Race/ethnicity (%)</th>
<th>Insurance/payer mix</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Female</td>
<td>≤17</td>
<td>18–44</td>
</tr>
<tr>
<td>SP1</td>
<td>54.5</td>
<td>13.6</td>
<td>37.1</td>
</tr>
<tr>
<td>SP2</td>
<td>58.0</td>
<td>31.7</td>
<td>39.1</td>
</tr>
<tr>
<td>SP3</td>
<td>49.0</td>
<td>5.0</td>
<td>26.0</td>
</tr>
<tr>
<td>C1</td>
<td>40.0</td>
<td>12.0</td>
<td>41.0</td>
</tr>
<tr>
<td>C2</td>
<td>64.0</td>
<td>11.0</td>
<td>39.0</td>
</tr>
<tr>
<td>C3</td>
<td>45.0</td>
<td>39.5</td>
<td>33.6</td>
</tr>
</tbody>
</table>

\( ^a \) SHAPE payment practice; \( ^c \) control practice.
cost savings may be encouraging to policy makers and payers interested in exploring or expanding APMs to increase access to behavioral health services in primary care while decreasing costs. Results from SHAPE reveal that alternative payments, when used flexibly by primary care practices to support ongoing integrated behavioral health efforts, have the potential to yield significant cost savings.

Although this demonstration project was not designed to examine practice-level activities that led to these cost savings, the results did show greater reach of behavioral health efforts within the SHAPE payment practices, as evidenced by higher proportions of patients being screened and diagnosed with behavioral health conditions (i.e., depression and anxiety) in comparison with control practices. A heightened ability to identify and treat behavioral health conditions among practices receiving the SHAPE payment may have ultimately led to better management of medical conditions and a reduction in medical expenditures. This hypothesis is consistent with literature that has demonstrated that provision of behavioral health services is associated with downstream medical cost savings [15, 16]. Understanding practice-level changes and activities made possible by flexible, non-fee-for-service payments is critical; future research is needed to understand the practice-level mechanisms responsible for these cost savings to replicate and scale the cost savings.

The SHAPE project has several limitations. Although the project allows for demonstration of association between the SHAPE payments and above described outcomes, it does not allow for direct causal claims as it did not employ a true experimental design (i.e., randomized controlled trial) due to the real-world nature of the demonstration project. The authors draw inferences about causality from these analyses; however, alternative explanations may be possible. In addition, assignment to the SHAPE payment condition was nonrandom and based on practice-level penetration rates of Rocky Mountain Health Plans insurance coverage which may have introduced some bias into the analysis; however, efforts to minimize bias were made by having the cost savings analysis conducted by a non-Rocky Mountain Health Plans affiliated actuarial firm. Due to non-random group assignment, small sample size, and non-standardization of integrated behavioral services delivery, it is possible that uncontrolled differences between the two groups contributed to the observed differences in outcomes between the groups. Lastly, this demonstration project was conducted with a relatively small number of practices ($n = 6$) and should be reproduced with a larger sampling of practices.

Additional studies examining APMs in integrated primary care practices are needed to fill the gaps in knowledge that the SHAPE project did not address. In particular, randomized-controlled APM studies across a larger number of primary care practices are needed.
to confirm cost-effectiveness, as well as clinical effectiveness of APMs. Testing of various APMs is needed to determine which APMs consistently demonstrate cost savings and lead to clinical improvements in integrated primary care settings. Future studies should assess how APM funds are distributed, how APMs affect clinical practice, and how those changes in clinical practice affect patient satisfaction, daily functioning, and outcome measures for specific health conditions to understand the mechanisms through which APMs generate cost savings. Evaluating the impact of APMs in integrated primary care settings is a research domain that is ripe for opportunities, given that little is known about the consequences of implementing APMs in integrated behavioral health and primary care settings.

Despite its limitations, the SHAPE project has many strengths, chief among which is having a control group against which to measure the impact of the SHAPE payments—a rarity in primary care payment research. Another strength was the use of a third-party actuarial firm for the cost savings analyses, which lessened the potential for bias in the analysis and interpretation process. Although the nonstandardization of integrated care delivery and allocation of SHAPE payment at the practice-level may be seen as a limitation, it may also be seen as a strength: practices can flexibly meet the needs of their patients without adhering to stringent mandates from payers/insurers and still achieve significant cost savings. Lastly, even though the SHAPE project included only a small number of practices and the cost analysis was limited to the public payer population, significant cost savings were found. SHAPE results should encourage further APM research and larger scale implementation in primary care settings.

CONCLUSION

The results from SHAPE are noteworthy in that it is the first known study to examine the impact of an APM for behavioral health in integrated primary care. With such a focus on controlling health care costs, and better addressing the behavioral health needs of the country, the SHAPE payment method addressed both issues at the same time—costs decrease and unfettered and timely access to behavioral health services. This study demonstrated that in integrated primary care practices, flexible payments uncoupled from fee-for-service were linked to net cost savings for public payers, a strong message to states and Medicaid programs across the country.

Integration of care is the future of health care delivery, and APMs are necessary to sustain behavioral health services in primary care. The SHAPE findings suggest that non-fee-for-service payments calculated from an activity-based costing methodology [25, 26] may be one potential solution; however, replication of the findings are needed, and broader evaluation of which APMs can be best leveraged to improve care and achieve cost saving is critical.

Acknowledgments: The authors would like to thank all the practices who participated in SHAPE as well as our funder, the Colorado Health Foundation, for their support. Additionally, the authors would like to thank Shandra M. Brown Levey, PhD and Polly Kurtz, MS, MBA for their contributions to the SHAPE project. This study was funded by the Colorado Health Foundation (grant number 4933).

Compliance with Ethical Standards

Primary Data: Findings reported have not been previously published and this manuscript is not being simultaneously submitted elsewhere. Results from this project have been presented in part at the Academy Health Conference in Boston in June 2016. The authors have full control of all primary data and agree to allow the journal to review their data if requested.

Conflict of Interest: Author Patrick Gordon is the vice president of Rocky Mountain Health Plans, the not-for-profit health plan that provided the SHAPE payments for the practices in the SHAPE demonstration project. Authors Kaile Ross, Emma Gilchrist, Stephen Melek, Sandra Ruland, and Benjamin Miller declare that they have no conflict of interest.

Ethical Approval: This study has been approved by the Colorado Multiple Institutional Review Board. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This article does not contain any studies with animals performed by any of the authors.

Informed Consent: For this type of study, formal consent is not required.

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