original contributions

Utilization of Clinical Pathways Can Reduce Drug Spend Within the Oncology Care Model

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QUESTION ASKED: Can a community oncology practice use evidence-based clinical pathways in the absence of a prior authorization process to reduce drug spend and maximize Oncology Care Model (OCM) episodic cost savings?

SUMMARY ANSWER: The practice's adherence to evidence pathways increased from 69% to 81%, and drug spend was reduced by 13.5% relative to the OCM median.

WHAT WE DID: Cancer Care Specialists of Illinois (CCSI) used value-based clinical pathways for OCM-attributed patients. All treatment plans were submitted to the pathway vendor in real time for clinical pathway adherence measurement. Analysis was conducted before implementation and on an ongoing daily and weekly basis to identify cases in which higher cost drugs or regimens were ordered. A clinical data governance committee met biweekly to review clinical pathway performance metrics and drug utilization. Drug spend data were compiled from a combination of Centers for Medicare and Medicaid Services feedback reports, quarterly data reports, Medicare claims data, and reconciliation reports specific to the evaluation period.

WHAT WE FOUND: From quarter 1 of 2017 to quarter 1 of 2019, the median drug spend increased less rapidly for CCSI (18.6%) compared with OCM (34.4%). Furthermore, the percent difference in drug spend for CCSI relative to OCM decreased from 13.5% to 0.1% ($P < .001$). Additional analyses found that, over a 15-month period (October 2017 through December 2019), CCSI achieved an increase in pathway adherence from 69% to 81%.

BIAS, CONFOUNDING FACTORS, DRAWBACKS: It is difficult to isolate the specific impact of value-based clinical pathways from other potential confounding influences. The act of convening the practice's clinicians to discuss missed opportunities, as well as the institution of formulary changes to align with the pathways, likely had an impact as well. In addition, CCSI had higher-than-median chemotherapy spending at baseline, a fact that may have made reductions easier to achieve than if CCSI started at or below median.

REAL-LIFE IMPLICATIONS: The misguided perception that drug prices are outside oncologists' control has led many OCM participants to focus their efforts on other areas, such as reducing preventable emergency department visits and hospital admissions. In this article, we demonstrate that reduction in drug spend is indeed possible using value-based clinical pathways. It is worth noting that this reduction occurred in the absence of any prior authorization. This fact suggests that prior authorization may not be necessary within more aligned payment models, in which physicians share in the value created.

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Accepted on January 20, 2020 and published at ascopubs.org/journal/op on March 20, 2020: DOI https://doi.org/10.1200/JOP.19.00753

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abstract

PURPOSE Reducing drug spend is one of the greatest challenges for practices participating in the Oncology Care Model (OCM). Evidence-based clinical pathways have the potential to decrease drug spend while maintaining clinical outcomes consistent with published evidence. The goal of this study was to determine whether voluntary use of clinical pathways by a practice can maximize OCM episodic cost savings.

METHODS AND MATERIALS A community oncology practice used evidence-based clinical pathways for OCM-attributed patients. All treatment plans were submitted to the pathway vendor in real time for clinical pathway adherence measurement. Analysis was conducted before implementation and on an ongoing daily and weekly basis to identify cases in which higher cost drugs or regimens were ordered. A clinical data governance committee met biweekly to review clinical pathway performance metrics and drug utilization.

RESULTS From quarter 1 of 2017 to quarter 1 of 2019, the median drug spend increased less rapidly for Cancer Care Specialists of Illinois (CCSI; 18.6%) compared with OCM (34.4%). Furthermore, the percent difference in drug spend for CCSI relative to OCM decreased from 13.5% to 0.1% ($P < .001$). Each quarter, there was approximately a 1.7% decrease (95% CI, 1.0% to 2.4%) in drug spend for CCSI relative to OCM. Additional analyses found that, over a 15-month period (October 2017 through December 2019), CCSI achieved an increase in pathway adherence from 69% to 81%.

CONCLUSION Reduction in drug spend is possible within a value-based care model, using evidence-based clinical pathways.

JCO Oncol Pract 16:e456-e463. © 2020 by American Society of Clinical Oncology

INTRODUCTION

The oncologist today exists in a world of dramatic innovation and increasing clinical complexity driven by genomics and immuno-oncology. Although these innovations have led to improved outcomes for patients, they have come with spiraling costs that threaten patients' access to care. Cancer care represents 12% of all costs for Medicare populations, is increasing annually at 8%-10%, and is predicted to reach $240 billion by 2023.[1] Cancer drugs are the largest driver of the increase in costs.[2]

As an effort to slow the rate of increase in health care costs, the Centers for Medicare and Medicaid Services (CMS) created the Center for Medicare and Medicaid Innovation (CMMI) to "find new ways to pay for and deliver care that can lower costs and improve care."[3] The Oncology Care Model (OCM) is one such model CMMI has developed for cancer care. Episode based, the OCM targets chemotherapy and related care for a 6-month period that is triggered by the administration of chemotherapy.[4] The program combines fee-for-service payments for evaluation and treatment with monthly payments for enhanced oncology services and performance-based payments.[5,6] Enhanced oncology services can include such things as extended clinic hours to allow walk-in visits for the purposes of emergency department avoidance, as well as care management and navigation services. To receive performance-based payments, a practice must achieve lower spending per treatment episode than target prices established by CMMI.

One of the greatest challenges in OCM is the management of drug spend, which accounts for > 50% of episode costs within OCM (Center for Medicare and Medicaid Innovation, unpublished government

Author affiliations and support information (if applicable) appear at the end of this article.

Accepted on January 20, 2020 and published at ascopubs.org/journal/op on March 20, 2020: DOI https://doi.org/10.1200/JOP.19.00753

reports, August 2017-August 2019) The chances of financial success within the model dramatically increase when practices can effectively manage drug spend. Clinical pathways, proposed as an essential tool in the movement to value-based payment models,[8] have been shown in oncology to decrease costs while maintaining outcomes consistent with published evidence.[9-11] Value-based clinical pathways have been adopted by third-party payers as a part of the prior authorization process to successfully decrease the rate of increase of oncology drug spend (New Century Health [NCH] proprietary data). We embarked on this study to determine whether evidence-based clinical pathways could be used by a community oncology practice in the absence of a prior authorization process to reduce drug spend and maximize OCM episodic cost savings.

METHODS AND MATERIALS

NCH, a developer of value-based clinical pathways, brings a history of successfully controlling drug spend and taking risk on behalf of commercial payors in oncology. NCH's preferred clinical pathway algorithms are developed by first performing a detailed review of the medical literature to identify the realm of treatment regimens for each clinical scenario. These treatment alternatives are evaluated, with the greatest weight given to efficacy and clinical effectiveness, followed by toxicity. Treatment cost is only considered as a final step. Emphasis is placed on the level of evidence supporting each of the alternatives. Finally, all pathways are reviewed and approved by an independent scientific review board composed of oncologists from community and academic practices—many of whom will use the resultant clinical pathways—as well as a patient advocate.

An OCM participant, Cancer Care Specialists of Illinois (CCSI) is a community-based oncology private practice spread throughout rural Illinois, with 14 medical oncologists, 4 mid-level providers, 6 radiation oncologists, and 1 urologic oncologist. CCSI engaged NCH in a clinically and financially aligned relationship to provide support and resources to help the practice maximize its OCM episodic cost savings.

Starting in January 2017, NCH began to engage and ramp up activities with CCSI. More specifically, NCH held periodic meetings and educational sessions with CCSI. In addition, CCSI was provided access to NCH's pathways as a resource. In October 2017, NCH's pathway program was officially launched at CCSI for OCM-attributed patients. The practice initially wished to integrate NCH pathways into their electronic medical record (EMR), which was determined to be technically feasible. However, the practice shared their EMR with a local hospital. The hospital approval process for the integration, as well as the cost to the practice by the EMR vendor to perform the integration, proved prohibitive to the practice. Therefore, NCH care pathways were instead embedded in all CCSI physician computers for rapid access and as a reference for decision making (Fig 1). All treatment plans were submitted in real time to NCH for clinical pathway adherence measurement. Analysis was conducted before implementation and on an ongoing daily and weekly basis to identify cases in which higher cost drugs or regimens had been ordered. A joint CCSI/NCH clinical data governance committee met biweekly to review clinical pathway performance metrics and drug utilization. The goal was to encourage treatment choices favoring both efficacy and value.

Data Source and Analysis

Drug spend data were compiled from a combination of CMS feedback reports, quarterly data reports, Medicare claims data, and reconciliation reports specific to the evaluation period. CMMI provides OCM participants quarterly feedback on program performance. The source for these reports includes Medicare Parts A, B, and D claims. Using these data, CMMI determines the patient population for all participants and provides each practice median expenditure and utilization values for that practice as well as an overall value for all OCM participating practices. Finally, to account for the impact of disease variance, all expenditures are calculated on a per-beneficiary per-month basis and are risk adjusted based on the practice's average CMS Hierarchical Condition Category risk score compared with the OCM population average score. Values are determined from a 4-quarter average, with the represented quarter being the midpoint of the period.[7]

During the study period (from quarter 1 of 2017 to quarter 1 of 2019), the drug spend values for CCSI and OCM were compared by calculating a percent difference score (median drug spend per patient for CCSI – median drug spend per patient for OCM/median drug spend per patient for OCM) for each quarter. On the basis of 9 quarters of data, a time series data set was generated, and a linear regression analysis was performed to examine whether there was a decrease in the percent difference scores during the study period.[12] All statistical tests were considered significant at $P < .05$, and a 95% CI was calculated for the regression coefficient.

RESULTS

As shown in Figure 2A, median drug spend per patient increased less rapidly for CCSI compared with OCM across the study period. For CCSI, the median drug spend increased by 18.6%, from $2,661 in quarter 1 of 2017 to $3,156 in quarter 1 of 2019. However, for OCM, the median drug spend increased by 34.4%, from $2,345 in quarter 1 of 2017 to $3,151 in quarter 1 of 2019.

As shown in Figure 2B, the percent difference in drug spend for CCSI relative to OCM decreased from 13.5% in quarter 1 of 2017 to 0.1% in quarter 1 of 2019. This decrease was found to be statistically significant ($P < .001$). In

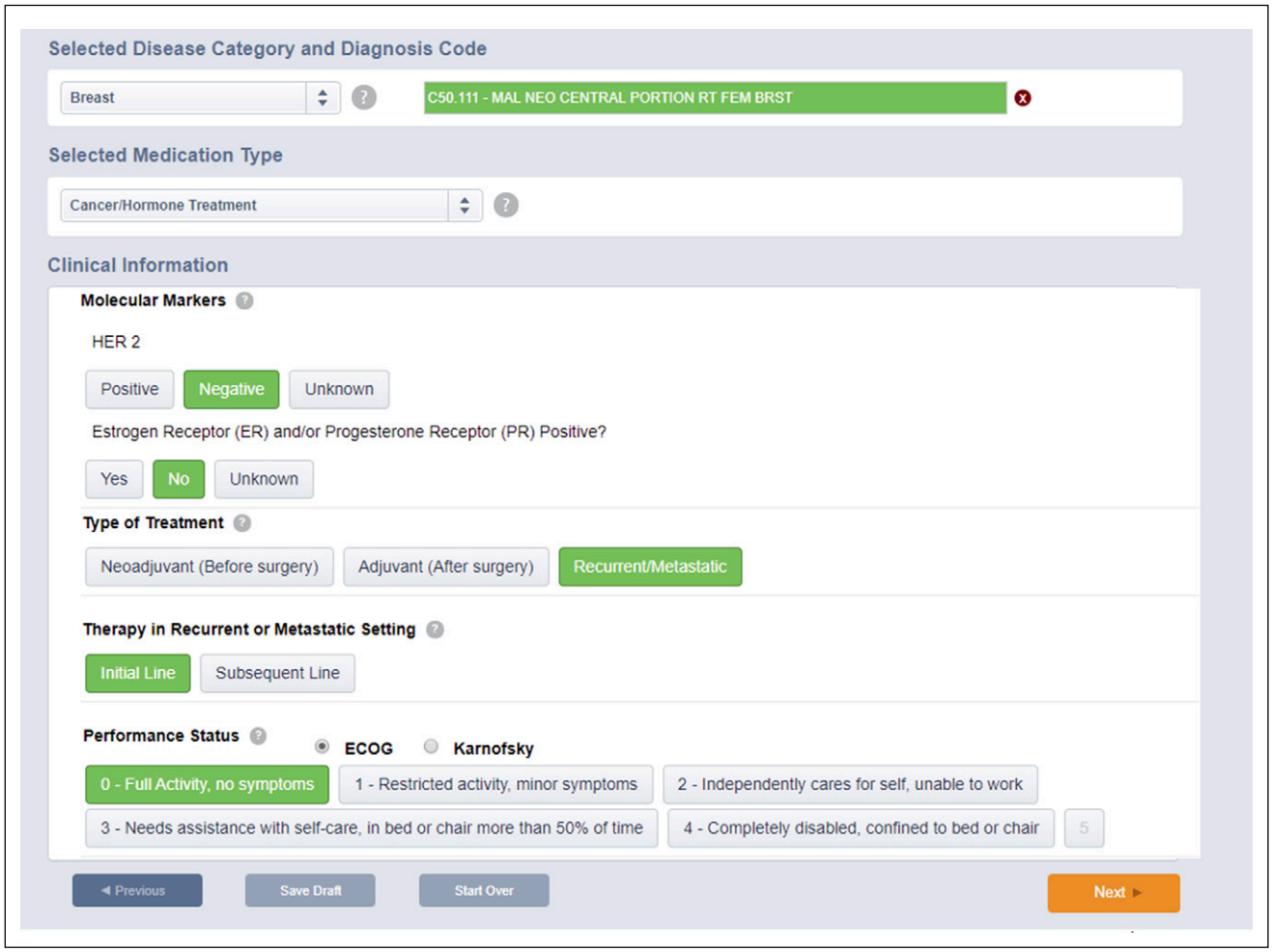

FIG 1. Clinical decision support for value-based oncology therapy. Example of a clinical pathway with treatment options for first-line therapy of triple-negative breast cancer. Pathway choices are marked with a green check box. ECOG, Eastern Cooperative Oncology Group; IV, intravenous.

each quarter, there was approximately a 1.7% decrease (95% CI, 1.0% to 2.4%) in median drug spend for CCSI relative to OCM.

Additional analyses were conducted on the 15-month period from October 2017 through December 2018. The time period covered episodes occurring within OCM performance periods 3, 4, and 5. Performance periods are defined by CMS as 6-month periods during which a cohort of episodes terminates and is reconciled together. OCM median drug spend from quarter 1 of 2017 was taken as a baseline. By quarter 1 of 2019, CCSI had decreased its drug spend relative to the OCM median by 13.5% (Fig 2), which is equivalent to approximately $250,000 saved per medical oncologist over the 15-month period.

The reduction in drug spend contributed to a reduction in total cost of care by 5% as compared with the OCM median. Post analysis also revealed an increase in pathway adherence from a baseline of 69% to 81% at the end of the measurement period. Results are summarized in Figure 3.

DISCUSSION

Since the launch of OCM in July of 2015, oncology practices have worked to efficiently manage the treatment episodes for which they are accountable by eliminating waste and creating value. For the most part, they have concentrated on the use of care coordination to reduce preventable emergency department visits, inpatient hospitalizations, and inpatient postacute care.[13] Little attention has been devoted to reducing drug spend, which accounts for > 50% of the total cost of episodes. This is a result of a perception that drug prices are outside the control of the oncologist. This perception fails to account for the documented success value-based clinical pathways have had in reducing drug spend with no change in clinical outcomes.[9-11] Value-based clinical pathways, in which value is a defined equation encompassing efficacy, toxicity, and cost, are closely aligned with the intention of value-based care models, such as OCM, that look at decreasing cost without compromising the quality of care. Given the high percentage of the total episode cost that drug spend

PATHWAY	REGIMEN NAME	EMETOGENIC RISK	NEUTROPENIC RISK	COST ESTIMATE FOR 90 DAYS
✓	CARBOPLATIN	Moderate	Low	$146.14
✓	CARBOPLATIN + GEMCITABINE	Moderate	Low	$535.46
✓	CISPLATIN	High	Low	$1,788.06
✓	DOCETAXEL	Low	Intermediate	$891.89
✓	GEMCITABINE	Low	Low	$562.42
✓	PACLITAXEL	Low	Intermediate	$220.91
	CAPECITABINE	Minimal	Low	$3,275.10
	CAPECITABINE + DOCETAXEL	Low	Low	$2,705.30
	CYCLOPHOSPHAMIDE (IV)	Moderate	Low	
	CYCLOPHOSPHAMIDE (IV) + METHOTREXATE + FLUOROURACIL (CMF)	High	Low	$3,439.07
	CYCLOPHOSPHAMIDE (ORAL)	High	Low	$1,316.46
	CYCLOPHOSPHAMIDE (ORAL) + METHOTREXATE + FLUOROURACIL (CMF)	High	Intermediate	$2,600.81
	DOXORUBICIN	High	Low	$1,818.40
	DOXORUBICIN + CYCLOPHOSPHAMIDE (AC)	High	Intermediate	$3,553.72
	DOXORUBICIN HCL LIPOSOME (DOXIL/LIPODOX)	Low	Low	$15,949.23
	EPIRUBICIN	High	Low	$2,087.85
	EPIRUBICIN + CYCLOPHOSPHAMIDE (EC)	High	Low	$3,719.89
	ERIBULIN	Low	Low	$25,000.42
	GEMCITABINE + PACLITAXEL (GT)	Low	Low	$701.35
	IXABEPILONE	Low	Low	$27,630.55
	OLAPARIB	Moderate	Low	$41,659.34
	PACLITAXEL + BEVACIZUMAB	Low	Low	$35,795.70
	PACLITAXEL PROTEIN BOUND	Low	Low	$24,702.99
	TRIPTORELIN PAMOATE	Minimal	Low	$797.34
	VINORELBINE	Minimal	Low	$721.72

FIG 1. (Continued).

accounts for, small improvements in utilization can result in larger savings than a decrease in hospitalizations, which account for < 20% of the spend.[1]

Two options for first-line treatment of patients with metastatic squamous non–small-cell lung cancer provide an example of how small changes in regimen selection can significantly reduce drug costs without sacrificing clinical efficacy. In October 2018, the US Food and Drug Administration approved pembrolizumab in combination with carboplatin and either paclitaxel or nanoparticle albumin–bound (nab) paclitaxel (Abraxane; Celgene, Summit, NJ) for patients with non–small-cell lung cancer. The Keynote-407 study concluded that the treatment effects of paclitaxel or nab-paclitaxel were similar among the patients who received those drugs.[14] However, the cost of paclitaxel is approximately 1% of nab-paclitaxel ($70 *v* $6,700 for a 21-day supply).[15] Therefore, paclitaxel is incorporated in the preferred value-based pathway. In 2019, CCSI's utilization of these 2 regimens showed that 10 patients were treated with carboplatin, paclitaxel, and pembrolizumab and 1 patient was treated with carboplatin, nab-paclitaxel, and pembrolizumab. This difference in utilization was a result of our clinical pathways as well as provider discussion and education.

In this article, we demonstrate that a reduction in drug spend is possible within a value-based care model, through the use of value-based clinical pathways. The inverse correlation of the reduction of drug spend with an increase in clinical pathway adherence scores lends support to a causative effect of the pathways and is consistent with the medical literature.[9-11] It is noteworthy that the 13.5% reduction in spend versus the OCM median occurred in the absence of any prior authorization; it is comparable to drug-spend reductions that NCH has seen when using its pathways as part of a prior authorization program in Medicare Advantage plans. This suggests that with more

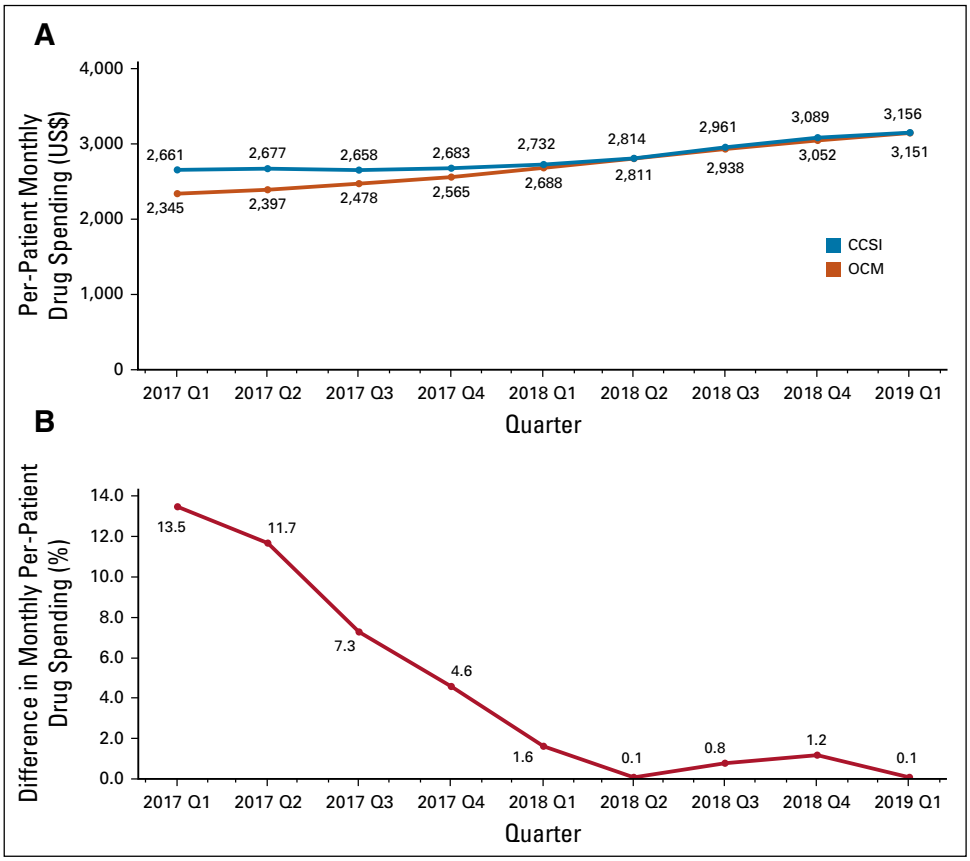

FIG 2. (A) Median per-patient per-month drug spend (risk-adjusted 4-quarter average) for Cancer Care Specialists of Illinois (CCSI) compared with the median of all Oncology Care Model (OCM) participating practices. (B) Percent difference in per-patient per-month drug spend for CCSI relative to OCM median. Q, quarter.

aligned payment models, in which physicians share in the value created, prior authorization may not be necessary.

This is not to say that clinical oversight of a pathway program is not required. Important factors contributing to the increase in clinical pathway adherence and reduction in drug spend include real-time identification of high-cost drugs and regimens that are off clinical pathway, with electronic notification of the provider, as well as rapid desktop access to a catalog of higher value clinical pathway alternative therapies.

Another aspect that cannot be disregarded is the willingness on the part of the physicians to look at their prescribing

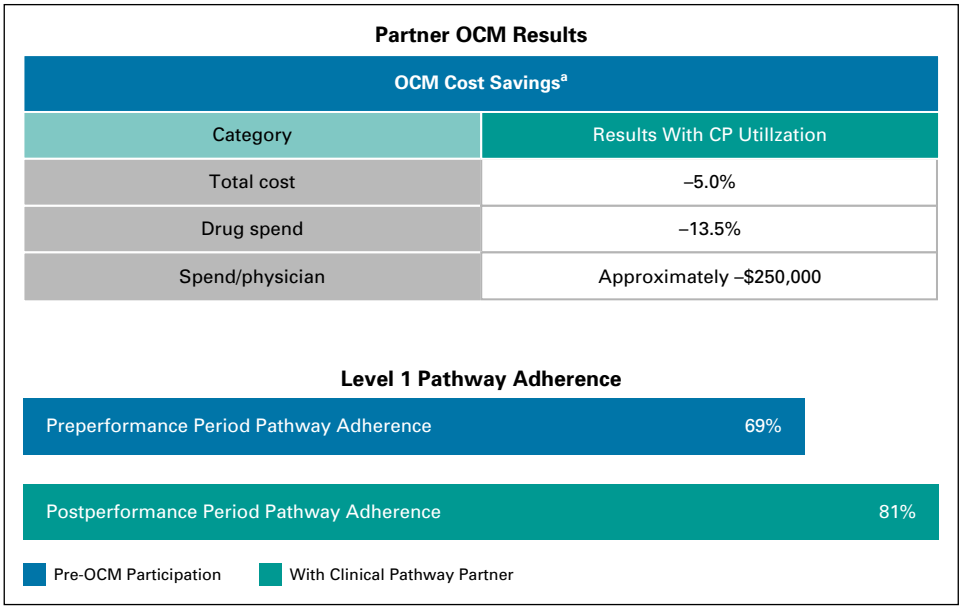

FIG 3. Case study: Clinical pathway (CP) partner helped Oncology Care Model (OCM) practice reduce costs and drug spend from median. ([a]) Total cost and drug spend decreased compared to OCM median over 15-month period.

behavior and agree to implement change. This qualitative aspect is imperative for the implementation of outcome-based clinical pathways to be successful. Certainly, this takes time. We have found that a ramp-up period needs to be provided for physicians to become accustomed to the new considerations that pathways present. Given the time that physicians already devote to EMRs, an attempt was made to minimize disruptions to workflow through the use of a 2-click tool, which allows oncologists to quickly access pathways with 2 mouse clicks. Although there is a time trade-off to first check pathways before prescribing a treatment, the payoff is the ability to quickly prescribe outcomes-based regimens that ultimately will lower total cost without detracting from quality. In addition, individual accountability is necessary to ensure that each physician is contributing to the success of the group. In our case study described here, this was achieved through the biweekly clinical governance meetings. Through the meetings, cases were identified and discussed as a group to ensure alternatives had been considered. Over time, this evolved into a streamlined discussion in which proactive questions were made about off-pathway decisions. Having aligned incentives, which in this case meant working toward a performance-based payment in OCM, also helped physicians hold one another accountable. This type of peer influence and shared sense of accountability, in addition to the educational opportunities provided by these meetings, was most certainly a contributing factor to the results achieved.

Another perhaps controversial subject related to accountability is the introduction of pathway adherence metrics in models such as OCM. In the case outlined in this article, we did not hold physicians to a pathway adherence metric. We merely suggested a target rate. Indeed, the increase in pathway adherence was done on their own—a significant increase from 69% to 81% over the study period. However, with the advent of 2-sided risk models, where practices and risk partners both assume significant financial risk, reasonable adherence metrics would need to be considered. Such metrics could consider the evolving standard of care, as well as novel therapies that may not be labeled as top-level pathways.

We recognize several important limitations to this study. In any quasi-experimental study with before and after analysis, results are subject to potential confounding influences that may be confused with treatment effect. In the current study, one cannot separate out the impact of climbing the learning curve of the OCM model from the effect of clinical pathways. The act of simply bringing the clinicians together to discuss missed opportunities, as well as the institution of formulary changes to align with the pathways, likely had an impact as well. Finally, the fact that CCSI had higher-than-median chemotherapy spending at baseline may have made it easier to come down to the median drug spend. However, analysis of additional oncology practices using NCH pathways will be required to determine whether pathways are more effective in practices with higher versus lower drug spend. Although segregating out the contribution of each of these factors is difficult, we have shown that reduction of drug spend using clinical pathways to optimize chemotherapy utilization is possible and can increase the chances of a practice's success within the OCM model.

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PRIOR PRESENTATION

Presented in part at the 2019 ASCO Quality Care Symposium, San Diego, CA, September 6-7, 2019.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST AND DATA AVAILABILITY STATEMENT

Disclosures provided by the authors and data availability statement (if applicable) are available with this article at DOI https://doi.org/10.1200/JOP.19.00753.

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Conception and design: Andrew Hertler, Sang Chau, Rani Khetarpal, Ed Bassin, Jeff Dang, Vijay Damarla, James Wade
Provision of study materials or patients: James Wade
Collection and assembly of data: Andrew Hertler, Sang Chau, Ed Bassin, Daniel Koppel, Vijay Damarla, James Wade
Data analysis and interpretation: All authors
Manuscript writing: All authors
Final approval of manuscript: All authors
Accountable for all aspects of the work: All authors

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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Open Payments is a public database containing information reported by companies about payments made to US-licensed physicians (Open Payments).

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Consulting or Advisory Role: New Century Health

No other potential conflicts of interest were reported.