quality in action

Evaluating the Impact of Oncology Care Model Reporting Requirements on Biomarker Testing and Treatment

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abstract

PURPOSE The Oncology Care Model (OCM) is Medicare's first alternative payment model program for patients with cancer. As of October 2017, participating practices were required to report biomarker testing of patients with advanced non–small-cell lung cancer (aNSCLC). Our objective was to evaluate the effect of this OCM reporting requirement on quality of care.

METHODS We selected patients with aNSCLC receiving care in practices in a nationwide de-identified electronic health record-derived database. We used an adjusted difference-in-differences (DID) logistic regression model to compare changes in biomarker testing rates (EGFR, ROS1, and ALK) and receipt of biomarker-guided therapy between patients in OCM versus non-OCM practices, before and after OCM implementation.

RESULTS The analysis included 14,048 patients from 45 OCM practices (n = 8,151) and 105 non-OCM practices (n = 5,897). The overall unadjusted rates for biomarker testing and receipt of biomarker-guided therapy increased over the study period (2011-2018) in both OCM (55.5% *v* 71.6%; 89.8% *v* 94.6%, respectively) and non-OCM (55.2% *v* 69.7%; 90.1% *v* 95.2%, respectively) practices. In the adjusted DID model, the rates of biomarker testing (odds ratio [OR], 1.09 [95% CI, 0.88 to 1.34]; $P = .45$) and receipt of biomarker-guided therapy (OR, 0.87 [95% CI, 0.52 to 1.45]; $P = .58$) were similar between OCM and non-OCM practices.

CONCLUSION OCM biomarker documentation and reporting requirements did not appear to increase the proportions of patients with aNSCLC who underwent testing or who received biomarker-guided therapy in OCM versus non-OCM practices.

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INTRODUCTION

The Oncology Care Model (OCM) is a voluntary, Center for Medicare & Medicaid Innovation alternative payment model program that ties reimbursement to value of care.[1] OCM requires practices to collect and report clinical data and quality metrics. Because reporting requirements may be time consuming,[2] assessing their downstream impact on quality of care and clinical outcomes is vital to ensure policies achieve their desired effect.[3,4] As of October 2017, OCM practices were required to report molecular mutation data for predictive biomarkers for patients with advanced non–small-cell lung cancer (aNSCLC).[5] Our objective was to evaluate the effect of this OCM reporting policy on the proportion of patients who underwent biomarker testing and the rate of patients receiving biomarker-guided therapy in accordance with the test results.

METHODS

Study Population

This retrospective study used the Flatiron Health database, a nationwide longitudinal, demographically and geographically diverse database derived from de-identified electronic health record (EHR) data. The database includes patient-level structured and unstructured data, curated via technology-enabled abstraction from > 280 cancer clinics (approximately 800 sites of care) representing > 2.2 million patients with cancer in the United States available for analysis. Patients were included if they were diagnosed with nonsquamous aNSCLC (stage IIIB/IV or recurrent metastatic) between January 1, 2011, and November 30, 2018, were ≥ 65 years old at the time of diagnosis, and received ≥ 1 line of systemic therapy at a community oncology clinic. Patients were excluded if they had no structured EHR activity within 90 days of

ASSOCIATED CONTENT

Data Supplement

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diagnosis of advanced disease, because these patients were considered to have incomplete historical treatment data. Institutional review board approval with waiver of informed consent was obtained before the study was conducted. For each patient, the practice OCM status was defined at the date of advanced-disease diagnosis.

Outcome Measures

Outcomes of interest were rates of biomarker testing (EGFR, ROS1, and ALK) and rates of biomarker-guided therapy in the first-line setting, based on the presence or absence of actionable somatic mutations. Receipt of biomarker-guided first-line therapy was defined as use of a tyrosine kinase inhibitor (TKI; Data Supplement) by patients with an actionable mutation or non-TKI therapy (defined as any non-TKI therapy, including chemotherapy and/or immunotherapy) for biomarker-negative patients, based on National Comprehensive Cancer Network recommendations.[6] Patients were classified by date of advanced-cancer diagnosis into 3 periods relative to their practice OCM status: (1) preperiod (January 1, 2011 to December 31, 2015); (2) implementation washout period (January 1, 2016, to September 30, 2017); and (3) postperiod (October 1, 2017, to November 30, 2018). The implementation washout period was selected to account for the time between the start of the OCM program (July 2016) and the date when practices were first required to submit molecular mutation data for predictive biomarkers to the Centers for Medicare & Medicaid Services (October 2017).[5]

Statistical Analyses

Baseline characteristics were assessed for the overall study population, stratified by practice OCM status (OCM *v* non-OCM) using descriptive statistics. For OCM versus non-OCM sites, we estimated probabilities and unadjusted odds ratios (ORs) of biomarker testing and biomarker-guided therapy before (preperiod) and after (postperiod) OCM implementation. An adjusted difference-in-differences (DID) logistic regression model was used to compare changes in biomarker testing rates and receipt of biomarker-guided therapy between patients in OCM and non-OCM practice settings in the pre-periods and post-periods. Models were adjusted for age, year of diagnosis, sex, race and ethnicity, smoking status, and calendar time as date. All statistical comparisons used a 2-sided test with $\alpha = .05$. The analysis was conducted from December 2018 to June 2019 using R software[8] and Python software.[9]

RESULTS

Patient Baseline Characteristics

The study included 14,048 patients diagnosed across all periods with aNSCLC (OCM group, n = 8,151; non-OCM group, n = 5,897; Data Supplement) receiving care at 150 community practices (OCM, n = 45; non-OCM, n = 105), of whom 8,682 (61.8%) had evidence of testing for at least 1 biomarker of interest. Among tested patients, 8,334 (96%) had a determinate result at first test, 274 (3%) had only an unsuccessful or indeterminate test result, and 1% of patients had a determinate result at second or third test. Patients in the overall study sample were a median age of 73 years (interquartile range, 69-78 years), 50% were women, 70.3% were non-Hispanic white, and 83.6% had a history of smoking. The distribution of patient baseline characteristics was similar between OCM and non-OCM practices (Table 1).

Rates of Biomarker Testing

During the preperiod, no meaningful differences in the rates of biomarker testing were observed in the unadjusted analysis comparing OCM (55.5%) and non-OCM (55.2%) sites (OR, 1.01; 95% CI, 0.93 to 1.11). In the postperiod, there was also no meaningful difference in known biomarker testing rates between OCM (71.6%) and non-OCM sites (69.7%; OR, 1.10 [95% CI, 0.91 to 1.33]; Data Supplement). Overall testing rates increased across all practices over time, but appear to have plateaued in recent years (Fig 1A). In the DID model, the adjusted rate of biomarker testing was similar between OCM and non-OCM practices (OR, 1.09 [95% CI, 0.88 to 1.34]; $P = .45$; Fig 1A; Data Supplement).

Rates of Biomarker-Guided Therapy

Among tested patients, there were no meaningful differences in the unadjusted rates of biomarker-guided therapy use when comparing OCM (89.8%) and non-OCM (90.1%) sites during the preperiod (OR, 0.96; 95% CI, 0.79 to 1.18) and during the postperiod (OCM: 94.6%, non-OCM: 95.2%; OR, 0.89 [95% CI, 0.54 to 1.44]). In the DID model, the adjusted rate of biomarker-guided therapy was also similar between the OCM and non-OCM groups (OR, 0.87 [95% CI, 0.52 to 1.45]; $P = .58$; Fig 1B; Data Supplement).

DISCUSSION

In this nationwide network of community oncology practices, we found that OCM biomarker reporting requirements did not appear to increase the proportions of patients with aNSCLC who underwent testing or who received biomarker-guided therapy. Overall, biomarker testing rates in aNSCLC initially increased and ultimately appeared to plateau during the study period for all practices evaluated; minor improvements in testing and receipt of biomarker-guided therapy in OCM practices in the postperiod remained nonsignificant when accounting for trends in practice over time. This study adds to the emerging body of evidence evaluating the impact of the OCM, which, as of September 2019, has 175 participating practices.[1] Currently, there are limited published data evaluating the impact of the OCM on downstream outcomes of interest.[10-12] This is one of the first comparative studies to examine the specific association of OCM reporting requirements with downstream quality of care, offering

TABLE 1. Patient Baseline Characteristics

Characteristic	All (N = 14,048)	OCM (n = 8,151)	Non-OCM (n = 5,897)
Age, median (IQR), years	73 (69.0-78.0)	73.0 (69.0-78.0)	74 (69.0-78.0)
Sex			
Female	7,023 (50.0)	4,008 (49.2)	3,015 (51.1)
Male	7,024 (50.0)	4,143 (50.8)	2,881 (48.9)
Race			
Non-Hispanic white	9,822 (70.3)	5,747 (70.7)	4,075 (69.8)
Black/African American	981 (7.0)	487 (6.0)	494 (8.46)
Asian	421 (3.0)	213 (2.6)	208 (3.56)
Other race	1,303 (9.3)	833 (10.2)	470 (8.05)
Unknown	1,445 (10.3)	851 (10.5)	594 (10.2)
Region			
Midwest	2,310 (16.4)	1,192 (14.6)	1,118 (19.0)
Northeast	3,308 (23.5)	2,130 (26.1)	1,178 (20.0)
Other/missing	170 (1.2)	11 (0.1)	159 (2.7)
South	5,820 (41.4)	3,614 (44.3)	2,206 (37.4)
West	2,440 (17.4)	1,204 (14.8)	1,236 (21.0)
Smoking status			
History of smoking	11,745 (83.6)	6,898 (84.6)	4,847 (82.2)
No history of smoking	2,171 (15.5)	1,204 (14.8)	967 (16.4)
Unknown	132 (1.0)	49 (0.6)	83 (1.41)
Stage at initial diagnosis			
0	1 (0.0)	1 (0.0)	0 (0.0)
I	1,258 (9.0)	729 (8.9)	529 (9.0)
II	679 (4.8)	404 (5.0)	275 (4.7)
III	2,378 (16.9)	1,363 (16.7)	1,015 (17.2)
IV	9,331 (66.4)	5,442 (66.8)	3,889 (65.9)
Unknown	401 (2.9)	212 (2.6)	189 (3.2)
Year of advanced diagnosis			
2011	1,023 (7.3)	659 (8.1)	364 (6.2)
2012	1,452 (10.3)	886 (10.9)	566 (9.6)
2013	1,614 (11.5)	932 (11.4)	682 (11.6)
2014	1,931 (13.7)	1,116 (13.7)	815 (13.8)
2015	2,026 (14.4)	1,139 (14.0)	887 (15.0)
2016	2,224 (15.8)	1,246 (15.3)	978 (16.6)
2017	2,174 (15.5)	1,239 (15.2)	935 (15.9)
2018	1,604 (11.4)	934 (11.5)	670 (11.4)

NOTE. Data are reported as No. (%) unless otherwise indicated.
Abbreviations: IQR, interquartile range; OCM, Oncology Care Model.

additional insights into the differences between OCM and non-OCM practices.

As a value-based model, the goal of the OCM is to improve patient care while reducing costs. To track the success of the program, measure quality and costs, and understand physician treatment patterns, the OCM also requires practices to report several quality metrics and clinical data. Therefore, participating practices have needed to develop workflows and clinic infrastructure to meet reporting requirements, including biomarker data. Early analyses on core OCM measures have found that acute health care use, such as emergency department visits and intensive care unit stays, have decreased for OCM practices.[13] However, physicians have also expressed concern that the increase

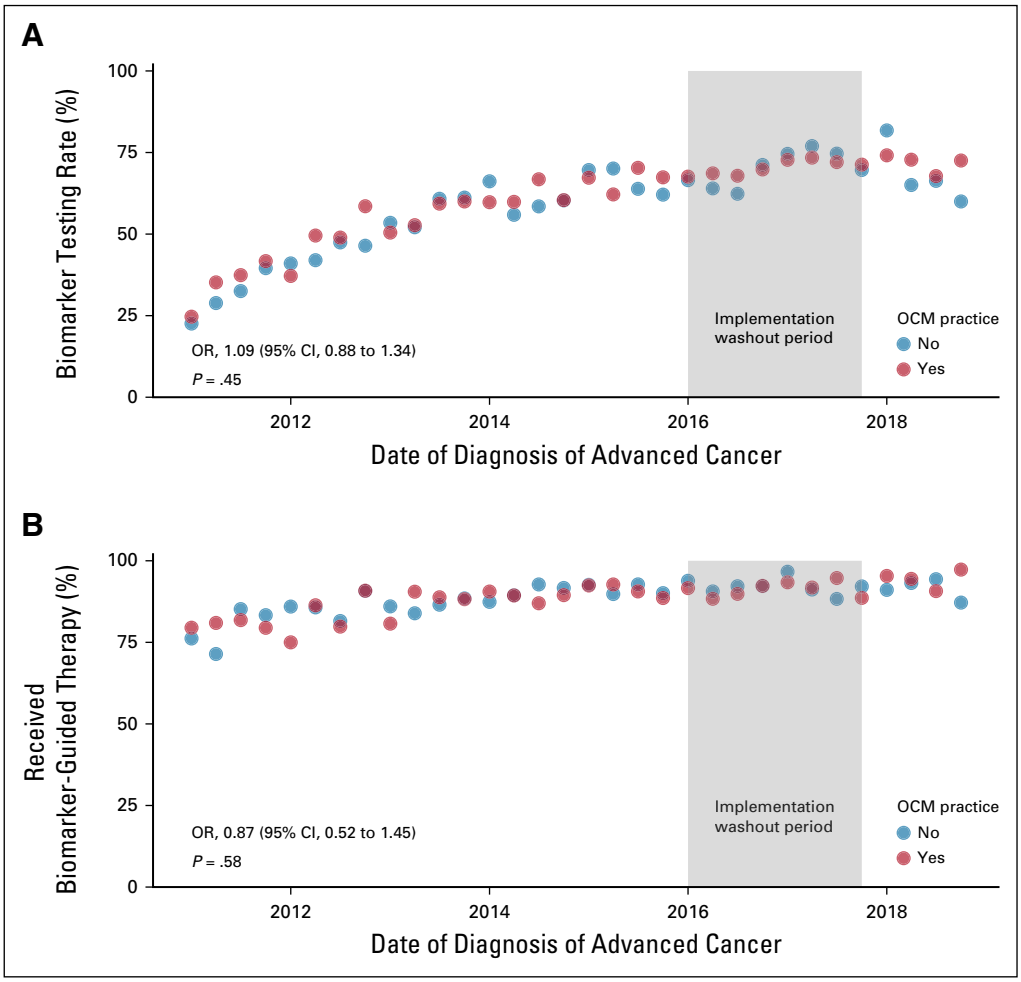

FIG 1. (A) Overall biomarker testing rates during study period. (B) Rate of biomarker-guided therapy use during study period among patients with available and documented positive or negative biomarker test results before the start of first-line therapy. OCM, Oncology Care Model; OR, odds ratio.

in documentation and reporting requirements is time consuming and may affect time with patients or staff satisfaction.[13] In part due to the burden such measurement and reporting places on community practices, several OCM reporting requirements have been modified in the past several years.[14] Our findings suggest that clinical reporting, such as the NSCLC biomarker testing requirement, may merit periodic re-examination, especially once a strong secular trend in practice has been observed.

There are some limitations to this study. First, there is potential for missing data; however, it is unlikely that there was differential missing data between OCM and non-OCM practices. Second, although most patients with an actionable mutation received a TKI in the first-line setting, we note that absolute rates of testing and of TKI use are still lower than may be expected on the basis of national guideline recommendations.[6,15] These conservative estimates may be due to the inherent limitations of our data source, because testing and treatment were ascertained only as documented in the EHR. Third, there may be clinically appropriate, real-world situations in which patients do not receive an upfront targeted therapy even with an identified actionable mutation. For example, patients whose initial test results are indeterminate due to insufficient biopsy-specimen quantity, or those with rapidly progressing cancer may receive chemotherapy before testing results are available to the treating physician.[16] Positive EGFR mutation results included all mutations, some of which may not have been sensitive to available TKIs. Clinical study drugs were masked as "non-TKI" in this analysis, and it is possible that some patients received targeted therapy on a clinical trial. Finally, this period saw the introduction of PD-L1 testing related to the use of immunotherapy; changes in practice related to these therapeutic advances were not assessed in this study but may be of future interest.

This study provides a unique perspective, essential in policy programs such as the OCM, where measuring potential improvements associated with their implementation is critical to evaluating downstream effects on patient outcomes. In a value-based care system, where accurate documentation and reporting are key to the assessment of practice patterns, quality of care, and costs, it is possible that the necessary reporting infrastructure, itself, could impact patient care. However, we did not find any differences in clinical practice patterns by OCM status, although testing and biomarker-guided therapy rates increased overall throughout the implementation periods. Evaluation of reporting requirements may provide insight into their overall utility and whether the infrastructure built to meet them could also be used to not just measure but also improve patient care.

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