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Closing the Testing Gap: Standardization of Comprehensive Biomarker Testing for Metastatic Non–Small-Cell Lung Cancer in a Large Community Oncology Practice

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abstract

PURPOSE Non–small-cell lung cancer (NSCLC), the leading cause of cancer death in the United States, accounts for 85% of all lung cancer cases. Biomarker testing is an integral part of the care of patients with NSCLC. Despite broad consensus recommendations that all patients with metastatic NSCLC (mNSCLC) undergo comprehensive biomarker testing (comprehensive genomic profiling and PD-L1), testing rates remain suboptimal.

METHODS The primary goal of this project was to apply National Comprehensive Cancer Network (NCCN) guidelines for comprehensive biomarker testing to all new patients with mNSCLC within a large community practice. Plan-Do-Study-Act methodology was used, with cycle 1 focused on provider education and the creation of a mNSCLC initial consult Note (electronic health record template/McKesson iKnowMed G2) and accompanying order set. Staging, template/order set utilization, and comprehensive biomarker testing rates were recorded while workflow processes were monitored. Cycle 2 centered on improved cancer staging, data analytic reporting, auditing, and reeducation.

RESULTS The comprehensive biomarker testing rates increased from a historic rate of 68% to 92.7% during the 1-year intervention period. The template utilization rate was 71% with complete staging (TNM stage and relevant biomarkers) documented in 40%.

CONCLUSION Implementation and standardization of comprehensive biomarker testing of patients with mNSCLC in a large multisite community-based oncology practice is feasible and results in significant improvement in comprehensive biomarker testing and reporting. Establishing reliable and measurable tracking metrics to ensure that these new processes are used and maintained can assist in scaling these processes. Efforts to scale this best practice are planned across the US Oncology Network.

INTRODUCTION

Lung cancer accounts for almost 25% of all cancer deaths in the United States, with non–small-cell lung cancer (NSCLC) representing 85% of all lung cancer diagnoses.[1] According to the 2022 State of Lung Cancer report published by the American Lung Association, the 5-year survival rate has increased from 21% in 2014 to 25% in 2018.[2] Much of this improvement has been attributed to novel targeted therapies and adoption of immunotherapies.[3] Comprehensive biomarker testing (comprehensive genomic profiling and PD-L1 testing) is recommended by the National Comprehensive Cancer Network (NCCN) for all patients with metastatic NSCLC (mNSCLC).[4]

Despite consensus and data-driven recommendations by the NCCN and others, there is variable uptake in clinical practice.[5] A 2020 International Association for the Study of Lung Cancer survey of 2,537 respondents from 102 countries suggested that <50% of patients with NSCLC received comprehensive biomarker testing.[6] These survey responses were consistent with real-world measures of testing adherence. Waterhouse et al[7] examined 3,337 patients with newly diagnosed stage IV NSCLC within the US Oncology Network (USON) from July 2016 through September 2019. Testing patterns were first examined using electronic health record (EHR) structured fields, but measurement of testing uptake proved to be difficult and inaccurate. A second cohort of 300 patients were analyzed using a manual chart review of both structured and unstructured data. In this cohort, EGFR (80%) was the most frequently tested biomarker, followed by ALK (79%), PD-L1 (72%), ROS1 (71%), and BRAF (56%). Although the proportion of tests ordered and resulted before first-line treatment increased from 2016 to 2018 for all biomarkers, only

ASSOCIATED CONTENT

Data Supplement

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one third of these patients underwent comprehensive genomic testing. On the basis of these findings, the US Oncology Network launched the MyLung initiative and reported its initial results at the 2021 ASCO Annual Meeting.[8] Results was based on a similar structured and unstructured chart review of 3,474 adult patients with mNSCLC who initiated first-line systemic therapy within USON between April 2018 and March 2020. Although most patients received biomarker testing for at least one biomarker before the initiation of therapy, only 37% of patients had comprehensive genomic profiling before treatment.

The overall goal of this quality improvement (QI) project, which was funded through a grant from Pfizer, was to implement and pilot a standardized clinical workflow that facilitated comprehensive biomarker testing in patients with mNSCLC in a large multisite community-based oncology practice that could subsequently be rolled out across other US Oncology Network practices. The project design was built on an existing quality framework by implementing a standardized EHR template and order set (Fig 1).

METHODS

The primary goal was to increase comprehensive biomarker testing rates in patients with newly diagnosed metastatic lung cancer by creating a New Patient mNSCLC EHR template and accompanying mNSCLC Order Set. The target population included patients who were (1) 18 years or older and (2) newly diagnosed with mNSCLC cancer from September 1, 2021, through August 31, 2022. The Oncology Hematology Care (OHC) Board of Directors endorsed this process improvement project with mandatory participation agreed on by all OHC physicians. The US Oncology Institutional Review Board granted a waiver for consent and exemption.

Using a Plan–Do-Study-Act methodology, cycle 1 focused on the creation of a new mNSCLC initial consult note to be used across all providers. This standardized documentation template was intended to support the provider in following NCCN testing and staging guidelines. The standardized mNSCLC template was accompanied by a new order set panel (Data Supplement [Fig A], online only). The structured order panel streamlined processes for the provider, helping to mitigate any potential oversight and make the process more intuitive and reflexive. We then produced a series of videos on NSCLC template utilization, NSCLC order set utilization, and NSCLC biomarker importance. In these videos, we demonstrated click by click directions on the new workflow, real-world scenarios in NSCLC staging, a walk-through on using the NSCLC order set, and how to order comprehensive biomarker testing. In tandem with the educational videos, we initiated mandatory 1:1 teaching sessions for each provider. During these sessions, compliance with and understanding of the educational videos were confirmed. In the first month of the project, we pushed out weekly NSCLC Quality Initiative emails highlighting the importance of the initiative and workflow, Frequently Asked Questions and tips. Following NCCN guidelines (version 2.2021), tissue testing was prioritized, with serum-based assays ordered reflexively for patients with insufficient tissue.

Cycle 2 focused on improved staging and EHR documentation to support the development and utilization of an NSCLC tracking mechanism to audit all patients with lung cancer. During cycle 1, we noted poor and inaccurate

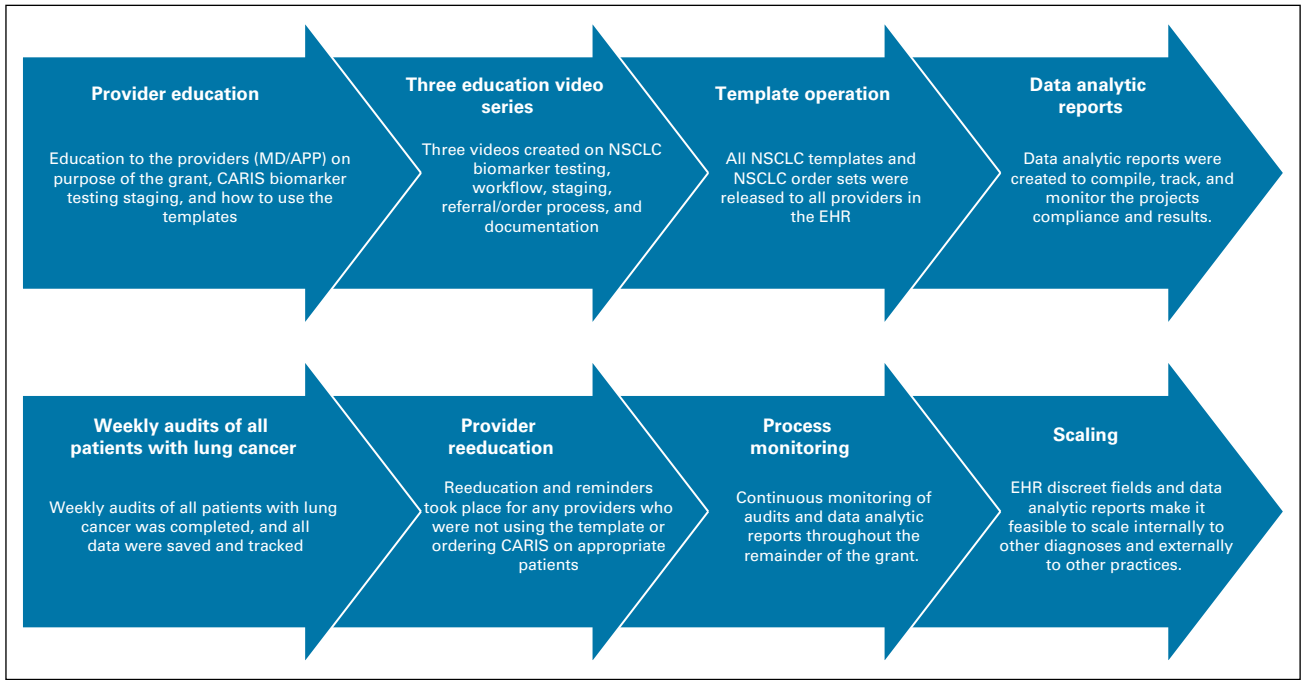

FIG 1. Study workflow. APP, advanced practice provider; EHR, electronic health record; MD, medical doctor; NSCLC, non–small-cell lung cancer.

NSCLC staging, often with charts failing to be updated with new clinical findings. Data used for the identification of possible NSCLC grant candidates came primarily from records obtained via McKesson's IKnowMed Generation 2(G2)[9] software, with some supportive data obtained from the electronic practice management software (Centricity Business and Athena IDX). Data from both systems were collected, transformed into an easily accessible format, and stored via an SQL server in an automated weekly process. A spreadsheet was generated weekly to identify patients meeting the target population parameters by using the diagnosis data from the EHR. The spreadsheet was audited by a clinical team. The spreadsheet also served as a tool to record data pertinent to the program, which was not always discreetly capturable in the EHR. The Excel data included staging, NSCLC template usage, biomarker testing orders, biomarker testing results, patient denominator exclusion, free form notes for documentation of audit reasoning, biomarker exclusion reasons, and other information helpful in facilitating the program audit workflow. Providers with gaps or missing information on patients were contacted. In these prompt reminders, we would discuss the need for biomarker testing, missing information (ie, staging), and any necessary corrections that needed made (Fig 2).

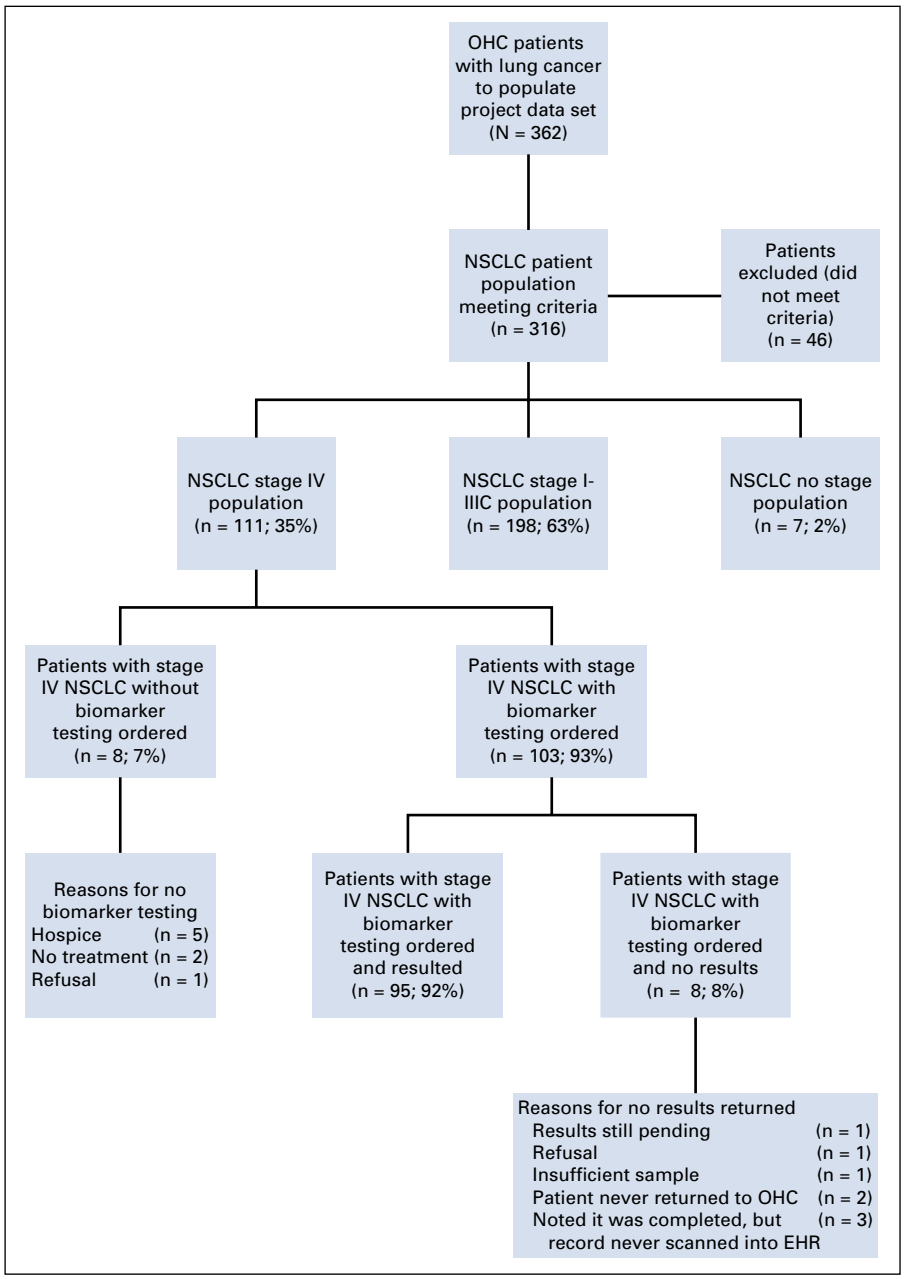

FIG 2. Flow diagram. EHR, electronic health record; NSCLC, non–small-cell lung cancer; OHC, Oncology Hematology Care.

RESULTS

Manual chart audits from the year before the project initiation suggested a baseline comprehensive biomarker testing rate of 68%. From September 1, 2021, to August 31, 2022, a total of 362 new patients with lung cancer were identified, of whom 316 met the target criteria (Fig 2). Reasons for exclusion included wrong diagnosis, SCLC, diagnosis date outside the grant window, and second-opinion visits. Of those who met the study criteria, 111 (35%) were identified as having stage IV disease. Of this mNSCLC population, 103 (93%) had orders for comprehensive biomarker testing. Eight (7%) patients did not undergo biomarker testing. The reasons for not having biomarker testing included referral to hospice care (n = 5), electing no treatment (n = 2), and refusal of testing (n = 1).

Of the 103 patients who had comprehensive biomarker testing ordered, 95 (92%) showed biomarkers results while eight (8%) patients had no results charted. In one patient, the result was still pending; another patient subsequently refused testing after the tests had been ordered; two patients did not return for follow-up; and one tissue sample was deemed insufficient (no liquid test was ordered).

The new mNSCLC template utilization rate was 71% (224 of 316 patients) with complete and accurate staging (TNM stage and relevant biomarkers) documented in 40% (44 of 111 patients) of the patients with mNSCLC.

DISCUSSION

The rate of comprehensive biomarker testing increased from our historic rate of 68% to 92.7% over the 1-year study period. Our EHR template, order sets, proposed workflow, provider education series, and audit processes provide a reproducible and scalable solution for other practices and/or malignancies. However, although the proposed auditing process is feasible for most practices, it is not optimal and can be labor intensive. Automating the chart auditing process and building structured fields for biomarkers within the EHR will be essential for the widespread scaling of these efforts. The results are encouraging despite the EHR template utilization rate of only 71%, suggesting a meaningful impact of the multifaceted provider educational process. Other educational interventions support these findings.[10-12] An unexpected barrier in the identification and tracking of patients with mNSCLC was the low rate of accurately documented staging. The observation during cycle 1 that providers too often provided poor and inaccurate NSCLC staging might suggest that our pregrant testing rate is not as accurate as the improved testing rate reported in the grant period. This does not negate the significant rate achieved but suggests an opportunity for improved staging and coding. Looking forward, we are partnering with McKesson and the US Oncology Network on an interface with our next generation sequencing venders to automatically populate discrete data fields in the EHR. This interface would allow the staging to be updated accordingly, with no results missed, and would save valuable physician time. Similarly, the EHR template and order set are in the process of being scaled to the US Oncology Network and others who are supported by the iKnowMed platform.

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