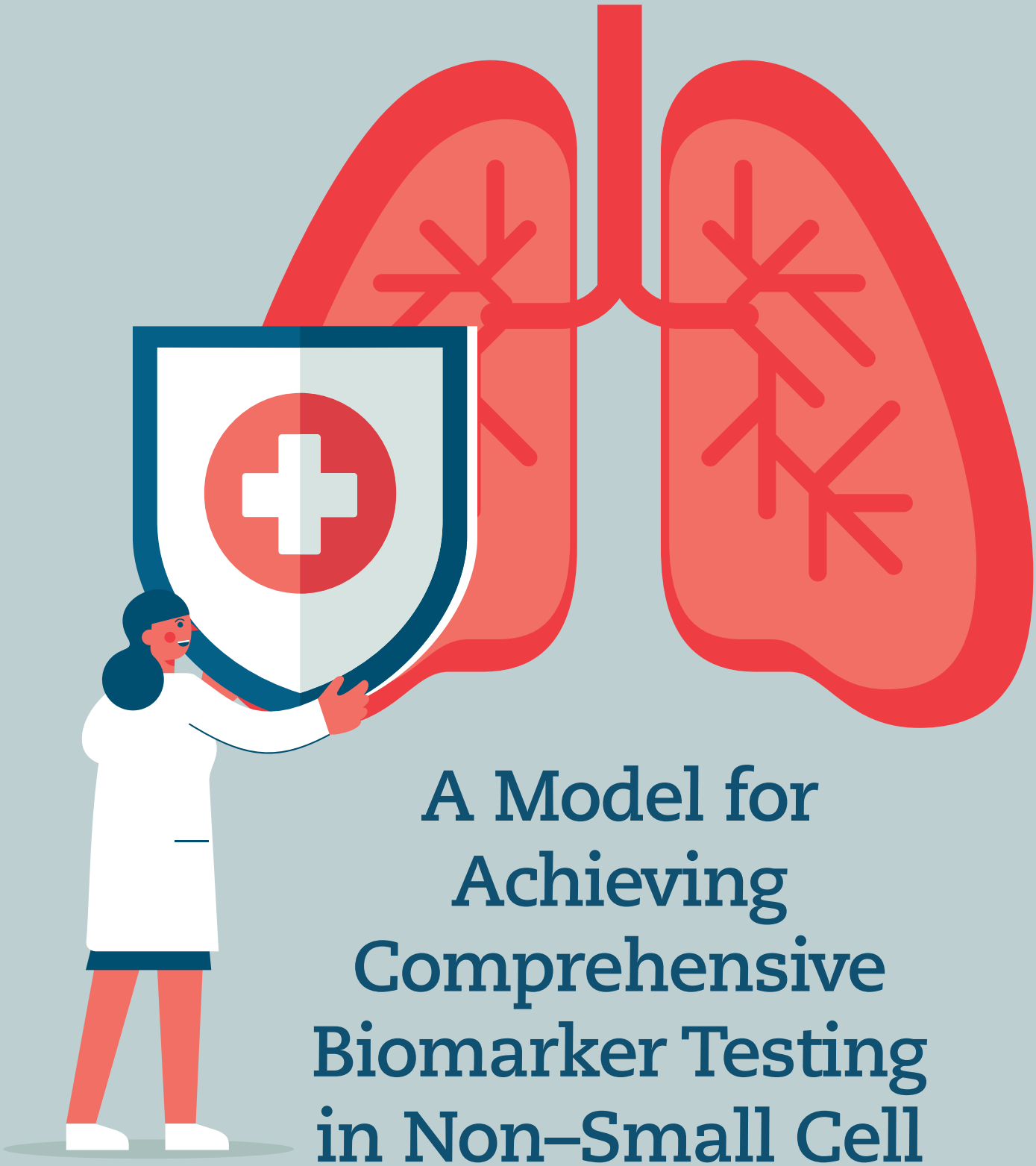

A Model for Achieving Comprehensive Biomarker Testing in Non–Small Cell Lung Cancer

BY MOLLY MENDENHALL, MBOE, BSN, RN, LSSBB; DAVID WATERHOUSE, MD, MPH; RANDY DROSICK, MD; PATRICK WARD, MD, PHD; AND DAN DAVIES

Lung cancer accounts for almost 25% of all cancer deaths in the United States, with non–small cell lung cancer representing 85% of all lung cancer diagnoses.[1] However, the 5-year survival rate for patients with lung cancer has increased from 21% in 2014 to 25% in 2018.[2] While some of the improved survival rate can be attributed to a decrease in smoking rates and an uptick in preventive lung cancer screenings, the largest contributing factor is novel biomarker targeted therapies in the subset of patients with metastatic non–small cell lung cancer.

The Importance of Biomarker Testing

The National Cancer Institute outlines that biomarker testing is a way to look for genes, proteins, and other substances (called *biomarker* or *tumor testing*) that can further provide information about that patient's cancer and suggest optimal cancer treatment.[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 non–small cell lung cancer .[4] It is important to delineate the different biomarker definitions and how they may affect patient treatments. Some patients may only receive biomarker testing for 1 gene, often referred to as *hot spot testing*. Additionally, some patients may receive what is called *next-generation sequencing*, where a panel of biomarkers are tested, excluding PD-L1. However, some patients receive what is called *comprehensive biomarker testing*, which is the tumor testing panel that includes PDL-1. For this study, Oncology Hematology Care (OHC) implemented a system to implement and improve comprehensive biomarker testing on a patient subset.

To date, there is universal agreement that not all cancers are the same and not all cancers should be treated the same. To extrapolate this further, as we continue to see the increase in the number of biomarkers, we will also continue to see the number of biomarker targeted therapies increase. Historically, biomarkers were initially only *ALK*, *ROS*, and *EGFR*, but thankfully that landscape has shifted and exponentially grown (Figure 1). It is important to note that this list may look different per location and practice due to local demographics and populations; however, the standard actionable biomarker testing list will not change. Today, 40% to 50% of patients with non–small cell lung cancer will have an actionable biomarker, and each day that number increases. Nearly 70% of the positive biomarkers will have an impact on a patient's first line of treatment selection. While lung cancer has paved the way, biomarker testing is becoming applicable to multiple other disease states as well. A comparable diagnosis state would be advanced breast cancer, where no physician would treat a patient today without ER, PR, or HER2 marker results. This shift has begun in the treatment of advanced non–small cell lung cancer as well.

Nearly 70% of the positive biomarkers will have an impact on a patient's first line treatment selection.

Not only do targeted therapies have an impact on first-line treatment, but they are often superior to standard care and are often less toxic for patients. Prior to targeted therapies, patients diagnosed with metastatic lung cancer were thought to be untreatable. At best, patients were offered standard treatment with platinum-based therapy or perhaps best supportive care. This treatment regimen was often accompanied by a 3- to 6-month life expectancy. Thanks to comprehensive biomarker testing and targeted therapies, the prognosis for these patients is improving. As of today, there are 32 FDA-approved targeted therapy treatments for lung cancer alone. In 2020, Howlader et al wrote, "Over the past decade, the treatment paradigm for advanced [non–small cell lung cancer] has evolved dramatically. The identification of 'druggable' oncogenes (ie, EGFR and ALK) has provided new, effective treatment targets, improving survival significantly among patients harboring the corresponding driver mutation."[5–7]

So why, with all these facts in mind—the importance of biomarker testing and how it can lead to improved survival and patient outcomes—are we not making biomarker testing a top priority and testing every appropriate patient? Even though the NCCN[4] recommends next-generation sequencing for biomarker testing for all patients with advanced non–small cell lung cancer, the uptake

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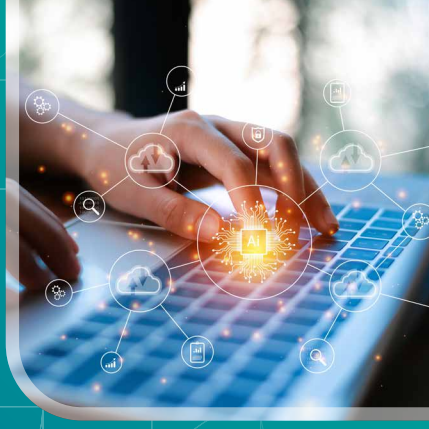

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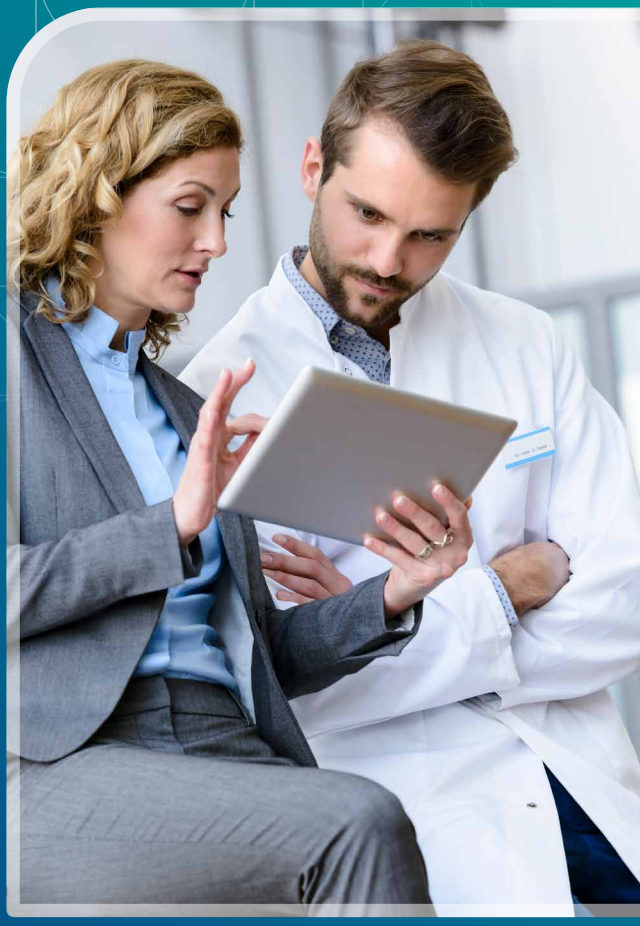

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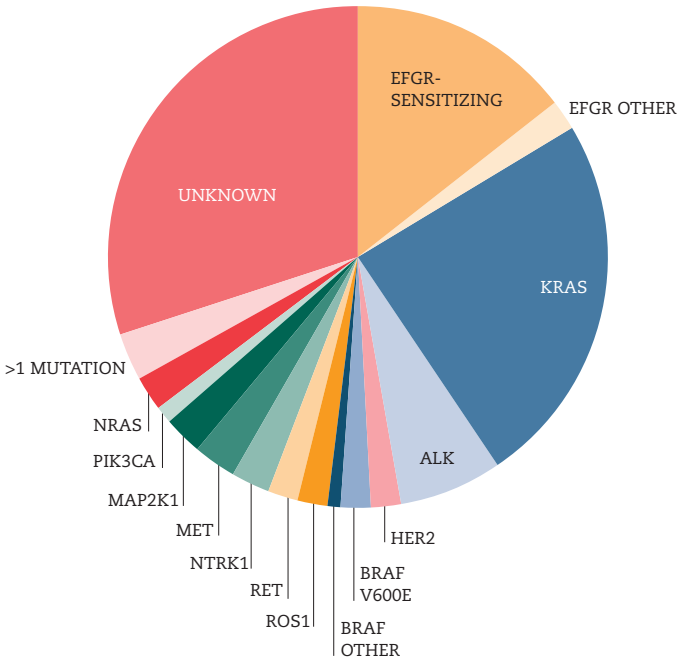
Figure 1. Driver Mutations in Lung Adenocarcinoma



Driver mutations in lung adenocarcinoma	
EGFR-sensitizing	15%
EGFR other	2%
KRAS	25%
ALK	7%
HER2	2%
BRAF V600E	2%
BRAF other	1%
ROSI	2%
RET	2%
NTRK1	0–5%
MET	3%
MAP2K1	0–5%
PIK3CA	1%
NRAS	0–5%
> 1 mutation	3%
Unknown	31%

+ PD-L1

Continued from page 21

among community and academic oncology programs is suboptimal. For patients who are diagnosed with metastatic non–small cell lung cancer, it is imperative to order and collect comprehensive biomarker testing to determine what the optimal treatment will be, as this practice has "proven to help people with lung cancer live longer with a better quality of life."[8]

Biomarker Real-World Studies

In examining OHC's data and the impact on patient care, we knew that all patients with advanced non–small cell lung cancer should have received testing. However, we found a significant gap, and we are not alone. This problem is not unique to OHC or even community-based practices, but hospital and academic centers as well. Sadly, this problem is universal. National data have proven that we are not testing at the rates we should be. Many physicians asked will respond, "yes, of course we are testing every patient," but the data show otherwise. Despite consensus and data-driven recommendations by NCCN and other organizations, there is variable uptake in clinical practice today.[9]

When MyLung Consortium Protocol 1 results were released by The US Oncology Network,[10] they provided a retrospective close-up look at current biomarker testing rates and turnaround times. This study ran from 2018 through 2020 and included the biomarkers *ALK*, *BRAF*, *EGFR*, and *ROS1* for 3474 patients.[11] This study was manually audited due to the difficulty of not having structured data fields. Data showed that 90% of the patients had at least 1 biomarker test; however, next-generation sequencing testing rates were poor, resulting in less than 50% having comprehensive testing. This cumulative time period did show an overall testing rate increase from 33% at the start of the study to 44% at the end of the 2-year period.

The results of MyLung Protocol 1 led to MyLung Protocol 2. This prospective, noninterventional cohort study ran from December 2020 through September 2022 and included 1000 newly diagnosed patients with early-stage or metastatic non–small cell lung cancer being treated in 12 community oncology practices that were part of The US Oncology Network.[12] OHC was one of the 12 practices involved in this study. MyLung Protocol 2 looked at *ALK*, *BRAF*, *EGFR*, *ROS1*, *KRAS*, *MET*, *NTRK*, *RET*, and *PD-L1*. The data collected in protocol 2 were biomarkers, timing of biomarker testing, use of single vs multigene next generation sequencing testing, clinical and socioeconomic factors, and reasons when testing was not collected. Study results found that 83% of patients had at least 1 actionable biomarker tested. Looking further into these data, 37% of the stage I to -IIIC patients and 57% of the stage IV patients had comprehensive biomarker testing completed. Digging even further into these data, OHC's testing rate during this time period was 68% internally. While OHC results were higher than the average, the OHC team was far from satisfied.

In 2024, plans are moving forward for MyLung Protocol 3. This study is being built off the foundations of MyLung Protocols 1 and 2 and will be a multi-interventional study to improve comprehensive biomarker testing and subsequent assignment of targeted therapies. Investigating interventions is where we come full circle and how work at OHC was one of the first steps in addressing these deficits.

OHC's Biomarker Study 4-Step Methodology

To address these testing gaps, OHC submitted a request for proposal with Pfizer and obtained a 1-year grant to support a quality improvement initiative. OHC's project centered around 4 primary initiatives:

1. Educational YouTube videos
2. A new standardized non–small cell lung cancer initial consult note
3. A new standardized non–small cell lung cancer order set
4. Automated data reports

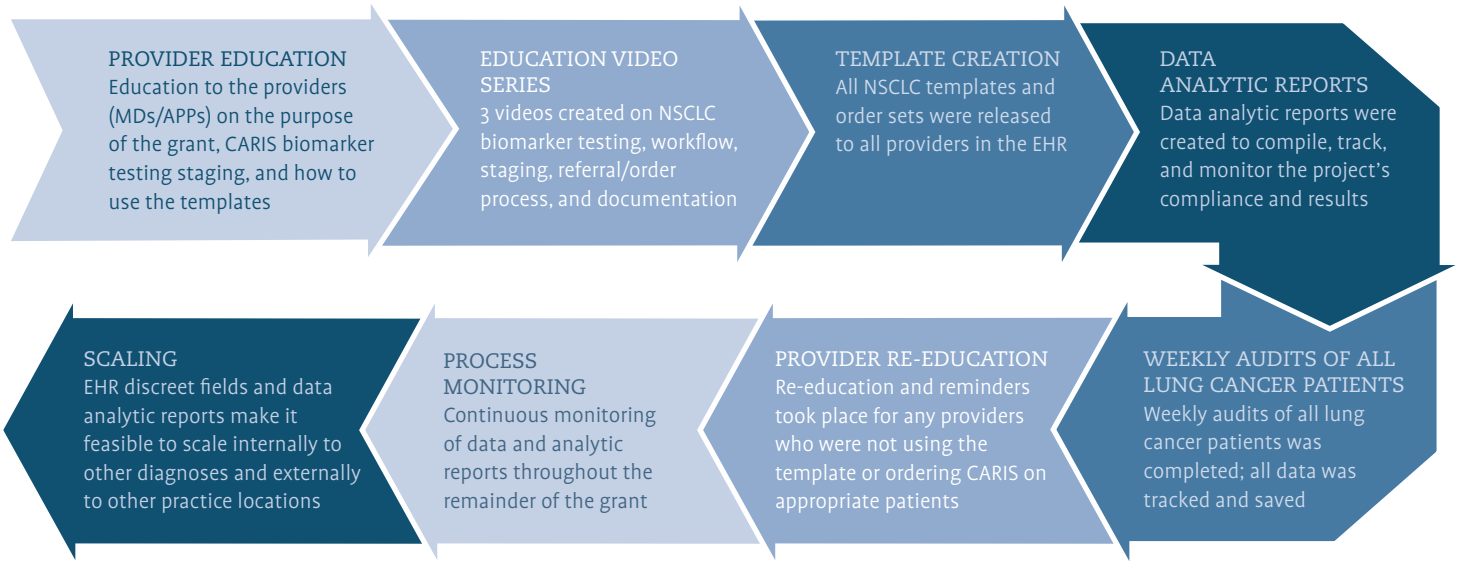
OHC used plan-do-study-act (PDSA) methodology with the overall goal being to improve comprehensive biomarker testing on patients with metastatic non–small cell lung cancer over a 1-year period.

In cycle 1 of OHC's study, we created 3 two-minute educational YouTube videos that OHC physicians could watch at their convenience. The first video—perhaps the most influential—answered "the why question." This video communicated the importance of comprehensive biomarker testing and its impact on patient outcomes. Additionally, the video outlined the standardized way physicians would document non–small cell lung cancer diagnosis coding and staging. This diagnosis coding and staging would become one of the most important key takeaways from our study. Limiting the physicians non–small cell lung cancer coding helps to create more accuracy in staging and data collection. The second video taught physicians how to document on the new standardized non–small cell lung cancer initial consult note template. The third video educated physicians on how to select and order from the new standardized non–small cell lung cancer order set in tandem with the new note template. These YouTube videos proved to be highly effective with our physicians due to their ease of use, aiding in adoption.

Cycle 2 of the quality initiative study was a newly designed Non-Small Cell Lung Cancer Initial Consult Note template in our electronic health record (EHR), McKesson's iKnowMed Generation 2 (G2).[13] This new note contained all the primary initial consult note components but also included NCCN guidelines for non–small cell lung cancer and testing guidelines. The new non–small cell lung cancer NCCN guideline section had all the key itemized requirements that a patient may need post initial diagnosis. This section in the provider note was designed for ease of use, outlining exactly what the patient may need in an organized fashion so that physicians could simply checkmark by item. The goal of this note template was to devise a tool that was streamlined into already existing workflows. In other words, the use of this template (in partnership with the order set discussed next) eased—not increased—physician burdens when seeing a new patient with metastatic non–small cell lung cancer.

Cycle 3 of the initiative (in partnership with the new standardized note template discussed above) was the metastatic non–small cell lung cancer order set. This order set included all the essential NCCN guidelines that an advanced non-small cell patient may require, mirroring the note template. Orders included in this set included labs,

Figure 2. Oncology Hematology Care Methods: Study Design, Data Collection, and Implications



APP, advanced practice provider; EHR, electronic health record; NSCLC, non–small cell lung cancer.

scans, biomarker testing, research consult, supportive care consult, port placement, and surgery consult. This order set helped physicians order all needed items with one simple selection. The goal of this order set was to ensure that no orders were missed on a patient and to provide ease of use for the physicians. A real-world example would be a patient being seen by the physician for their initial consult who already completed a "CT of the chest/abdomen." With one click in the EHR, the physician can remove that order. In this order set, OHC made the decision to include 1 primary next-generation sequencing vendor in the order set. Many practices support multiple vendors; however, OHC found success limiting internally to 1 primary tumor testing vendor and 1 primary liquid testing vendor. While this decision may be difficult, use of a primary vendor improved standardization and buy-in. OHC physicians became accustomed to the reporting format they were receiving back into the patient's EHR. This standardization improved physician workflow and streamlined processes.

Cycle 4 of this study, and arguably the most crucial, was the custom automated data reports and scorecards. The old saying "you can't fix what you can't measure" rang true for this study. A weekly audit report allowed us to monitor every new patient encounter, provide timely education to physicians, and adjust any workflow processes as needed. The automated reports were delivered in Excel format and included all key inclusion criteria for the study. Each week this automated Excel file was updated with all pertinent data from the EHR. Any unstructured data fields that could not be automated from within the EHR would then be manually curated on the Excel file, estimated at about 1-hour of manual work a week. For this manual process, OHC utilized a nurse to fill in any clinical data fields that were missing. It is important to note that if a practice is looking for cost savings, an administrative staff member could be trained to complete this function. These reports helped to generate weekly scorecards to track all key study outcomes. Weekly, these scorecards would compile all data fields and produce compliance percentages on staging, template utilization, order set utilization, biomarker tests ordered, biomarker testing results received, research consults, and biomarker result documentation in structured fields.

All 4 initiatives were launched in tandem with a full practice-wide "roadshow" to all physician locations (Figure 2). This additional hands-on education and training reiterated the YouTube video trainings and allowed for in-person question and answer sessions with physicians. Physician champion buy-in was essential to this non–small cell lung cancer initiative being so impactful, however, we would argue that executive leadership and administrative buy-in is equally important. For quality improvement projects to be successful at a practice level, it takes a multitude of departments and leaders to drive success. Our physician champions initiated peer-to-peer education, which helped increase practice-wide buy-in.

Study Result and Impact

Prior to launch of OHC's quality improvement initiative, we saw a 68% comprehensive biomarker baseline testing rate through manual chart abstraction. In the 1-year grant period from September 1, 2021, through August 21, 2022, OHC saw 362 new patients with lung cancer populate on the automated custom data reports. Of that number, 316 patients ultimately met criteria for inclusion in our study for evaluation. After further examination, 111 of 316 patients (35%) had stage IV disease and met the full requirements for inclusion. Of these, 103 of 111 patients (92.7%) had comprehensive biomarker testing ordered; 8 of the 111 patients (7.3%) did not have biomarker testing ordered due to hospice enrollment, declining treatment, or opting out of testing. OHC's 4-part quality interventions helped to show significant improvement in testing from a baseline of 68% to 92.7% in a 1-year period in the advanced non–small cell lung cancer disease state (Figure 3).[14] Figure 4 illustrates study data.

Post study, a full examination was conducted on OHC's actionable biomarker testing rates (Figure 5). Evaluating the actionable

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Figure 3. Comprehensive Biomarker Baseline Testing Rates of Patients With Advanced Non–Small Cell Lung Cancer

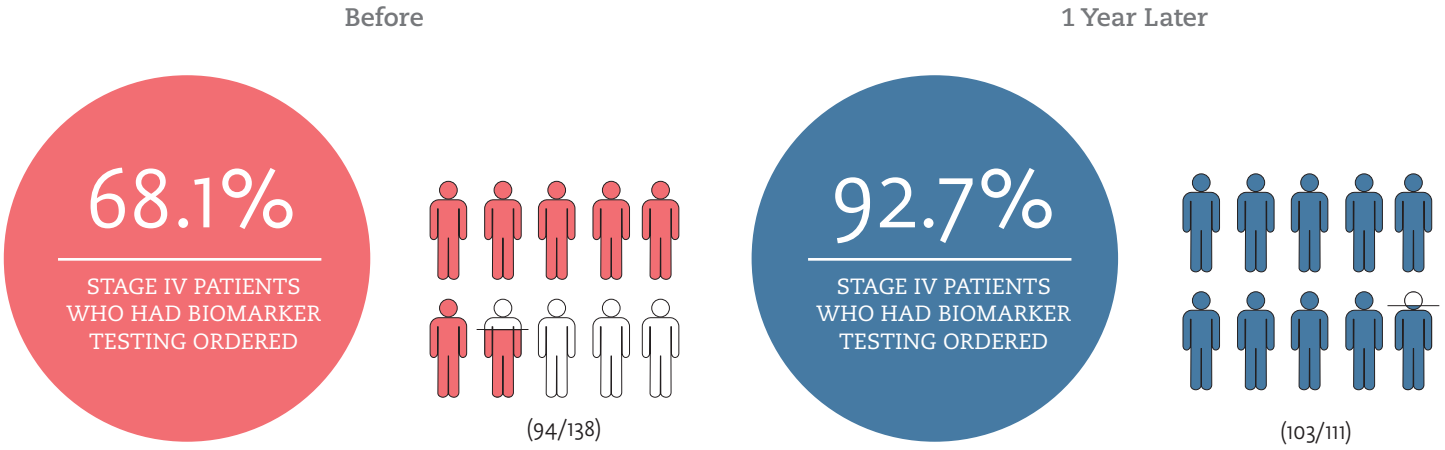
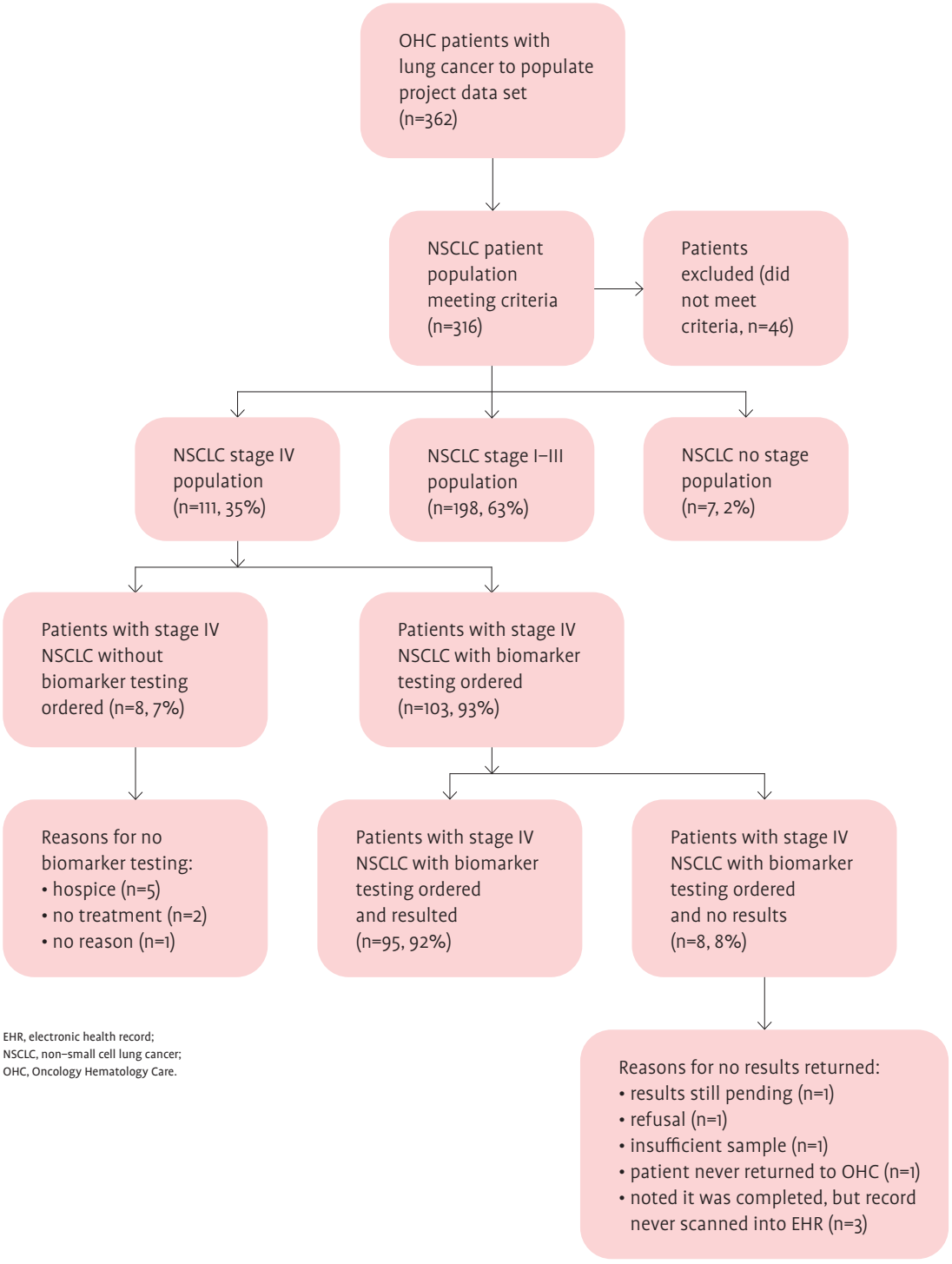


Figure 4. Study Data for Oncology Hematology Care Quality Improvement Initiative



EHR, electronic health record;
NSCLC, non–small cell lung cancer;
OHC, Oncology Hematology Care.

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biomarker results on the included patient population, OHC found the following positive mutations:

- PD-L1 > 1% (n=88)
- Tumor mutational burden high (n=44)
- *KRAS* G12C (n=12)
- *EGFR* exon 19, exon 20, exon 21 (n=6)
- *ALK* fusion protein (n=6)

We found no patients harboring actionable biomarkers: *ROS1*, *BRAF*, *NTREK*, *RET*, *MET*, or *ERBB2* (*HER2*). This finding is not entirely surprising as our sample size is relatively small, and some of these biomarkers are considered less common.

We have also looked further into whether the actionable biomarkers found were then used to inform first-line and second-line decision-making. For example, if the patient had a first-line actionable biomarker, such as *EGFR* or *ALK*, were they treated with an NCCN-compliant treatment regimen? Five patients who had an actionable *EGFR* mutation received NCCN-compliant first-line targeted therapy, while the sixth patient was started initially on immunotherapy plus chemotherapy (chemo/IO). The 1 patient who received chemo/IO was started on treatment prior to the return of their biomarker results; after the first cycle of therapy, this patient was then switched to an NCCN-compliant treatment. This finding highlights the need to not only order comprehensive biomarker testing but also to wait for the results to return before initiating the first line of therapy, not just an OHC finding, but a national issue. All 6 of the patients who were identified as having an *ALK* fusion protein received an NCCN-compliant targeted therapy.

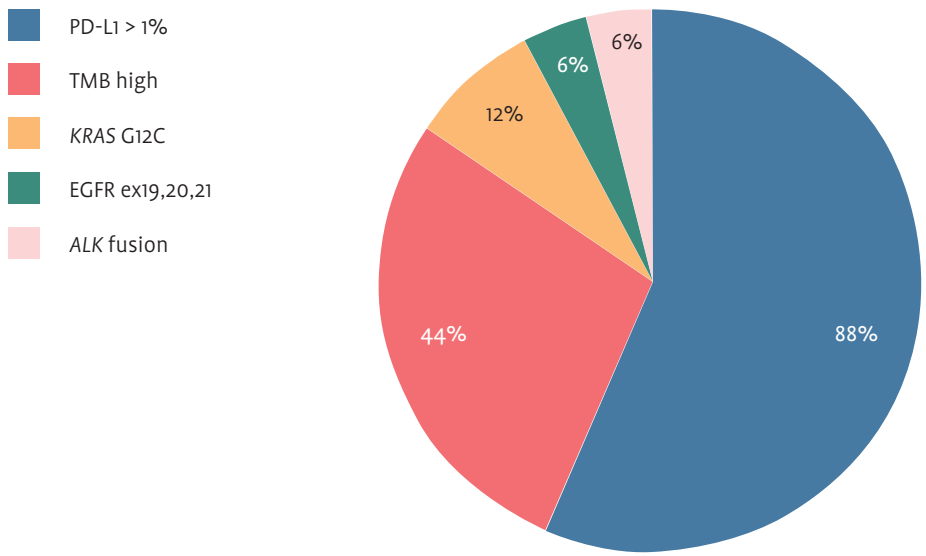
Other biomarkers only inform second-line or later therapies, such as those patients who had a *KRAS* G12C mutation (n=12) or ERBB2 (n=0). Several of the patients with *KRAS* G12C mutation either progressed through their first-line therapy or could not tolerate treatment elected best supportive care, while a few remained on their initial first line therapy. Sadly, we understand that real-world data suggests that only 60% of OHC patients will be well enough or willing to go on to second- and later-line therapies.[15] This statistic underscores the importance of obtaining comprehensive biomarker testing and ultimately ensuring that it is used to optimize first-line treatment. Anecdotally, the OHC team noticed that the provider's template notes acknowledged those mutations and suggested the possibility of such treatment in the future (upon progression). To date, only 2 patients with a *KRAS* G12C mutation have gone on to receive a second-line treatment, and both have received an appropriate targeted agent.

4 Key Takeaways

OHC's quality improvement initiative produced significant results, which led the team to further break down what factors led to this success in hopes that other practices could mirror our success. Post study, a full examination was conducted on OHC's actionable biomarker testing rates (Figure 5). Evaluating the actionable biomarker results on the included patient population, OHC found the following positive mutations.

Ease of use. This was crucial to the success of this project and the immediate uptick in adherence from our physicians. Finding a way to streamline this process into an already overwhelmed physician workflow was essential. Physicians are juggling countless

Figure 5. Actionable Biomarker Testing Rates



priorities throughout their workday. Finding a way for physicians to work smarter and not harder was perhaps the most important component of this new quality workflow. The initiative's ease of use improved efficiency, decreased EHR click-count fatigue, and increased overall biomarker ordering compliance. Additionally, it is important to emphasize just how simple this process truly was. Some of the best solutions do not have to be the most complex.

EHR limitations. This is very familiar to the health care industry. EHRs are not (yet) robots. To date, most EHRs are not even built with fully integrated AI (artificial intelligence) components. With the lack of AI and integration in our current state, our quality improvement initiative was built to find a way to seamlessly address these current limitations. Until our EHRs are more advanced, all health care institutions need to strive to put systems in place that health care providers can control. While EHR limitations may not be within the control of a cancer program within a hospital or large health care system, we would urge you to put in place infra-structure that helps you take ownership and move patient care forward.

Automation. Without the assistance of AI and to minimize manual processes, we created as much automation into the process as possible. Automated custom data reports help to simplify the EHR data gaps health care providers face. Although the proposed auditing process is feasible, it is not optimal and is labor intensive. Automation of this process and building automated data fields for biomarkers will be essential for widespread scaling and adoption. Additionally, future AI interfacing of biomarker results back into the EHR will elevate targeted therapy per actionable biomarker compliance. Many EHRs are currently working on this enhancement. However, it is important to call out that health care providers cannot simply build in a new enhancement tool; a new AI tool is needed to facilitate continuous quality improvement for better patient care.

Stage, stage, stage. This is a familiar phrase: garbage in, garbage out. OHC experienced an unexpected barrier: The team could not do a study on a patient population if that patient population was not in OHC data. The OHC team discovered within the EHR a high magnitude of ways to enter in a diagnosis of non–small cell lung cancer, making it nearly impossible to find all patients for inclusion in the study. To complicate matters further, many EHRs do not prompt providers to complete all staging or enter in all prognostic indicators, including biomarker results. Even if staging is entered at diagnosis, some providers do not keep patient staging updated as the disease progresses. These compounding staging problems reinforced just how big of an impact staging can have on quality studies. OHC's recommendation to all oncology programs and practices is to build out education and standardization of staging as a primary focus, especially if health care providers want to initiate quality improvement projects such as this one. Complete and accurate staging, including biomarkers, will play a pivotal role in patient targeted therapy treatment selection.

It may be important to note that no matter how easy a process is to create, health care providers will still face unanticipated problems and roadblocks. A real-world example may be team members who become primary outliers of the project initiative. Ultimately, these outliers can lead to lack of buy-in, lack of standardization, and missing biomarker orders. Having physician and executive leadership champions will be immensely helpful in this regard. OHC physician champions were able to do real-time peer-to-peer reeducation on site as issues arose. While weekly reminder emails and even making physicians re-do their note templates can be effective, physician champions are irreplaceable. As you roll out your quality improvement initiative, anticipate the unanticipated.

2 Easy Implementation Tips

Start small. Quality improvement initiatives can feel large and daunting, but they do not have to be. Consider starting conversations with your providers on the importance of biomarker testing through a textable 2-minute video. These simple education opportunities can help raise awareness and start a domino-like effect for the quality improvement initiative.

Standardization. The more your organization can standardize and streamline workflow, the more efficient the practice will be. Most cancer programs or practices have some semblance of control over the contents of their practice notes and orders. Consider adding NCCN guidelines to your physician notes and order sets. Standardizing biomarker testing into the physician's workflow will help decrease ambiguity on ordering, increase quality testing rates, simplify the process variability, and ensure consistency and productivity of physicians.

Where to Go From Here

National data suggest that nearly half the time biomarker testing is ordered and results provided, health care providers are not using the results optimally. If the collective goal is treatment optimization for patients with cancer, health care providers cannot stop at simply ordering comprehensive biomarker testing. Health care institutions and providers need to ensure we have systems in place to then order the appropriate targeted therapy per actionable biomarker. A key takeaway is to challenge each other to not only investigate cancer testing rates, but then investigate if the appropriate targeted therapy was ordered for the patient. Today, OHC is partnering with The US Oncology Network and McKesson to create and build interfaces in the EHR for next-generation sequencing vendor automation back into the patient's chart. This automated interfacing would populate discrete data fields in the patient's diagnoses to aid in staging completeness and treatment regimen selection.

This quality improvement initiative was found to be a reproducible and scalable solution for not only other malignancies but other cancer programs and practices as well. OHC was able to produce similar significant results in its metastatic breast cancer population by deploying the same PDSA methodology to genetic NCCN guideline evaluation and subsequent testing. To date, this study's methodology is currently being scaled as a best practice initiative across the country through The US Oncology Network and McKesson practices.

In tandem with being reproducible and scalable, this quality improvement initiative was found to be cost-effective. The benefit of this quality improvement project is that your cancer program or practice does not have to purchase new equipment or new technology

platforms or even hire additional employees. The only potential cost is the funding for any manual auditing processes that cannot be automated by an EHR. While OHC opted to utilize a clinical employee for the manual auditing pieces needed, an administrative employee could be trained and utilized.

OHC's ultimate goal is for oncology programs and practices across the nation to begin using this best practice methodology to produce similar results for all patients with advanced non–small cell lung cancer. To achieve true patient-centered care and improved patient outcomes, health care providers and institutions must first achieve and maintain high comprehensive biomarker testing rates and then use those results to treat patients optimally with targeted therapy. OI

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