This case study demonstrates implementation of a process improvement (PI) project focusing on molecular biomarker testing in patients with advanced non-small cell lung cancer (NSCLC).

Located in Petersburg, Virginia, the Cancer Treatment Center at Southside Regional Medical Center (SRMC) is a Commission on Cancer-accredited Comprehensive Community Cancer Program. In 2015, SRMC began its lung screening program and the cancer treatment center has seen an increase in lung cancer patients. Medical oncology providers at SRMC are with Virginia Cancer Institute, a practice chosen in 2016 to participate in the Center for Medicare and Medicaid Innovation’s Oncology Care Model.

PURPOSE AND BACKGROUND
Patients with advanced NSCLC who harbor driver mutations and gene rearrangements may derive clinical benefit from biomarker-driven therapies. However, molecular biomarker testing may not be performed due to a host of reasons including: lung biopsy samples may be insufficient for testing; tests are not ordered for eligible patients; testing is delayed; and clinicians are not capturing and documenting molecular testing rates as a quality measure.

In 2014, the Cancer Treatment Center at SRMC participated in the Association of Community Cancer Centers (ACCC) Learning Labs for Process Improvement project. The team at SRMC gathered baseline data from their tumor registry and electronic patient records, participated in an on-site learning lab workshop, and conducted follow-up meetings with staff to monitor process improvement efforts. In 2017, ACCC had the opportunity to hear how SRMC had sustained these process improvements.

QUALITY IMPROVEMENT GOALS AND OBJECTIVES
After reviewing their molecular biomarker testing rates in patients with advanced NSCLC, the team at the SRMC identified several key improvement opportunities:

- **Clinical Goal:** Develop a consistent and timely process for NSCLC biomarker testing and interpretation so that appropriate patients receive targeted therapies.

- **Programmatic Goal:** Improve the quality and quantity of biopsy tissue samples sent for testing, standardize the molecular biomarker testing process, and track biomarker testing as a quality measure.

METHODS

**Baseline Assessment:** Prior to participating in the 2014 Learning Lab, the team at SRMC reviewed patient data from November 2012 through October 2013 and found that 41% of their patients with stage IV lung adenocarcinoma had received molecular testing.

**Improvement Plans:** Following the Learning Lab workshop in 2014, the team at SRMC identified several key opportunities for improvement and assigned members of their team to track key action items. They formed task forces, updated policies, and had their pathologists provide recommendations to other members of the treatment team.

- **Greater Pathology Involvement:** The pathologists at SRMC became deeply involved to identify and operationalize improvement plans around molecular biomarker testing processes. A pathology-driven testing environment empowered the pathologists to ensure that the right tests were being ordered for patients with advanced NSCLC.

- **Improving Lung Biopsy Samples:** The radiologists agreed to increase the amount of tissue that is obtained during CT-guided lung needle biopsies by using core needles instead of fine needle aspiration (FNA). This allowed their radiologists to obtain more tissue for molecular testing.

- **Tracking Molecular Testing Rates:** The pathology team started tracking molecular biomarker testing rates to ensure that appropriate samples were being sent for testing in a timely fashion. A pathologist created a tracking spreadsheet and checked the testing status each week for all lung biopsy samples. The spreadsheet also tracked biopsies from non-lung sites, such as liver biopsies or lymph node biopsies. If the non-lung biopsies turned out to be lung cancer metastases, then the pathologists ordered molecular tests for those samples.
RESULTS
In 2017, the team reviewed patient data from January 2016 through December 2016 and found that their total lung cancer patient population had increased by 41%. Among patients with stage IV lung adenocarcinoma, 72% received EGFR testing, 64% received ALK testing, and 53% received ROS1 testing.

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<tr>
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<tbody>
<tr>
<td>Total # of patients with NSCLC</td>
<td>90</td>
<td>127</td>
<td>Increased by 41%</td>
</tr>
<tr>
<td># of patients with stage IV lung adenocarcinoma</td>
<td>17</td>
<td>36</td>
<td>Increased by 112%</td>
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<tr>
<td>• Testing rate for EGFR</td>
<td>41% (7 out of 17)</td>
<td>72% (26 out of 36)</td>
<td>Increased by 31%</td>
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<tr>
<td>• Testing rate for ALK</td>
<td>41% (7 out of 17)</td>
<td>64% (23 out of 36)</td>
<td>Increased by 23%</td>
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<tr>
<td>• Testing rate for ROS1</td>
<td>Not Available</td>
<td>53% (19 out of 36)</td>
<td>Not Available</td>
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CONCLUSION
While molecular biomarker testing rates have improved at SRMC, the team also recognizes the need to continue their efforts and expand testing as newer targeted therapies become available. They are currently evaluating the possibility of routinely using broader next-generation sequencing (NGS) so that multiple tests may be conducted simultaneously. As their volume of lung cancer patients continues to increase, the team at SRMC remains committed to providing the best possible care by incorporating a data-driven approach to quality improvement.

END NOTES


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For details on the ACCC Molecular Testing: Learning Labs for Process Improvement and to access a process improvement planning tool, visit: accc-cancer.org/resources/MolecularTesting-LearningLabs.asp