

PROCESS IMPROVEMENT IN MOLECULAR TESTING:

ASSESS. CHANGE. TEST.

CASE STUDY: Southside Regional Medical Center, Cancer Treatment Center

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.¹
- **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.²
- **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.¹

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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.

TIME PERIOD	BASELINE: Nov. 2012 – Oct. 2013	POST-INTERVENTION: Jan. 2016 – Dec. 2016	CHANGES
Total # of patients with NSCLC	90	127	Increased by 41%
# of patients with stage IV lung adenocarcinoma	17	36	Increased by 112%
<ul style="list-style-type: none"> • Testing rate for EGFR • Testing rate for ALK • Testing rate for ROS1 	41% (7 out of 17) 41% (7 out of 17) Not Available	72% (26 out of 36) 64% (23 out of 36) 53% (19 out of 36)	Increased by 31% Increased by 23% Not Available

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

- 1 CAP/IASLC/AMP Molecular Testing Guideline supports this approach. Lindeman NI, et al. Molecular testing guideline for selection of lung cancer patients for EGFR and ALK tyrosine kinase inhibitors: Guideline from the College of American Pathologists, International Association for the Study of Lung Cancer, and Association for Molecular Pathology. *J Thorac Oncol.* 2013;8(7):823-59.
- 2 NCCN Clinical Practice Guidelines in Oncology for NSCLC support this approach. https://www.nccn.org/professionals/physician_gls/PDF/nscl.pdf

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

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