

PROCESS IMPROVEMENT IN MOLECULAR TESTING:

ASSESS. CHANGE. TEST.

CASE STUDY: Sarah Cannon Cancer Institute at Johnston-Willis Hospital

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 Richmond, Virginia, the **Sarah Cannon Cancer Institute at Johnston-Willis Hospital** (*formerly known as Thomas Johns Cancer Hospital) is a Commission on Cancer-accredited Comprehensive Community Cancer Program. Johnston-Willis Hospital is a member of the HCA Healthcare network and in 2017, HCA Virginia partnered with Sarah Cannon to expand its comprehensive cancer treatment services in central Virginia.

PURPOSE AND BACKGROUND

Patients with advanced NSCLC who harbor driver mutations and gene rearrangements may derive clinical benefit from receiving biomarker-driven therapies. However, molecular 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 biomarker testing rates as a quality measure.

In 2014, the Sarah Cannon Cancer Institute at Johnston-Willis Hospital participated in the Association of Community Cancer Centers (ACCC) Learning Labs for Process Improvement project. The team 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 their team had sustained these process improvements.

PROCESS IMPROVEMENT GOALS AND OBJECTIVES

After reviewing their molecular biomarker testing rates in patients with advanced NSCLC, the team at Sarah Cannon Cancer Institute at Johnston-Willis Hospital 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 workshop, the team reviewed patient data from October 2012 through September 2013 and found that 38% of their patients with stage IV lung adenocarcinoma had received molecular testing.

Improvement Plan: After the Learning Lab workshop, the team at the Sarah Cannon Cancer Institute at Johnston-Willis Hospital discussed ways to improve their lung biopsy processes, their tissue handling process, and their molecular testing rates for patients with lung cancer.

- **Preserving Tissue:** Pathologists, recognizing the growing importance of biomarker testing, began implementing a process to automatically create two separate tissue blocks. This allowed their pathologists to perform their diagnostic evaluation on the first block and to use the second block for biomarker testing.¹
- **On-site Evaluation During Biopsy:** The pathologists make themselves available during biopsy procedures so that they can assess samples for adequacy while standing at the bedside. This type of rapid on-site evaluation (ROSE) helps to ensure that adequate samples are obtained during the procedure.²
- **Established Testing Protocols:** Their Molecular Subcommittee reviews and updates their biomarker testing protocols for NSCLC. Currently, all patients diagnosed with lung adenocarcinoma have their biopsies sent for a standardized molecular testing panel that includes EGFR, ALK, and ROS1 for biomarker testing.³ If the patient has known metastatic disease, then the biopsy sample undergoes an expanded testing panel that includes other potentially targetable mutations.

(continued on back)



RESULTS

In 2017, the team reviewed patient data from January 2016 through December 2016. Among patients with stage IV lung adenocarcinoma, 87% received EGFR testing, 82% received ALK testing, and 74% received ROS1 testing.

TIME PERIOD	BASELINE: Oct. 2012 – Sept. 2013	POST-INTERVENTION: Jan. 2016 – Dec. 2016	CHANGES
Total # of patients with NSCLC	203	173	
# of patients with stage IV lung adenocarcinoma	71	38	
<ul style="list-style-type: none"> • Testing rate for EGFR • Testing rate for ALK • Testing rate for ROS1 	38% (27 out of 71) 38% (27 out of 71) Not Available	87% (33 out of 38) 82% (31 out of 38) 74% (28 out of 38)	Increased by 49% Increased by 44% Not Available

CONCLUSION

At the Sarah Cannon Cancer Institute at Johnston-Willis Hospital, the Molecular Subcommittee works closely with all members of the multidisciplinary team to establish and update testing policies designed to provide the highest quality of care. The proactive involvement of their pathologists ensures that all clinical departments are engaged with applying the latest evidence when making treatment decisions.

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 CHEST guideline also supports this approach. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3961820/>
- 3 NCCN Clinical Practice Guidelines in Oncology for NSCLC support this approach. Available at: 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: acc-cancer.org/resources/MolecularTesting-LearningLabs.asp

©2017. Association of Community Cancer Centers. All rights reserved. No part of this publication may be reproduced or transmitted in any form or by any means without written permission.



Association of Community Cancer Centers