Getting Tissue for Molecular Testing: An NSCLC Strategic Initiative

Activity Summary Date: Jan, 2015

CME Credit Provider: Temple University School of Medicine
Collaborators: Association of Community Cancer Centers (ACCC), Fox Chase Cancer Center, and MCM Education
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Executive Summary

Getting Tissue for Molecular Testing: An NSCLC Strategic Initiative was a systems-based quality improvement (QI) initiative developed for medical oncologists, pathologists, pulmonologists, radiologists, surgeons, nurses, cancer registrars, and other health care professionals involved in the treatment of patients with non-small cell lung cancer (NSCLC). This initiative was implemented through a multifaceted collaboration among Temple University, Fox Chase Cancer Center, the Association of Community Cancer Centers (ACCC), and MCM Education.

This initiative was focused on guiding five community cancer centers through quality improvement methodologies designed to help them improve molecular testing in patients with advanced NSCLC. ACCC invited member centers to participate in this QI initiative and recruited five centers around the country. Each of the participating centers collected baseline data on their molecular testing rates for EGFR and/or ALK and processes for patients with advanced NSCLC. Working through a series of focus groups, workshops, and educational sessions, each cancer center identified key opportunities for process improvement and implemented them over the course of a year using Plan-Do-Study-Act (PDSA) cycles for process improvement.

Follow-up data on molecular testing rates and processes reveal that each of the centers made significant process changes and educated their clinicians about the importance of properly identifying and targeting molecular pathways of tumor progression in advanced NSCLC. The average baseline molecular testing rate for advanced NSCLC was 68% when the initiative began in mid-2013 and the average follow-up molecular testing rate for advanced NSCLC improved to 89% at the end of 2014.

Clinicians and administrators at each participating center acknowledged the value that this initiative provided at their centers and stated that they would continue to identify key opportunities to make ongoing quality improvements in the area of molecular testing in advanced NSCLC.

This activity summary provides an analysis of key outcomes data, with complete outcomes data (to date) found in the Appendix at the end of this document.

Introduction

Recently, treatment for advanced NSCLC has expanded beyond chemotherapy as the cornerstone of treatment to include a new generation of targeted therapies that interfere with the cellular pathways involved in tumor growth, progression, and cell death. The use of molecularly targeted therapies represents a significant advance in the treatment of patients with advanced NSCLC. However, there remains a major gap between the optimal management of advanced NSCLC and current clinical practice because molecular testing is often not being performed in patients who may benefit from molecularly targeted therapies. Furthermore, many oncologists in the community remain unaware of how best to apply the latest clinical evidence when managing complex patients with advanced NSCLC.

However, there remain significant gaps between the optimal management of patients with advanced NSCLC and current clinical practice in the community setting. Clinicians often remain unaware of new

and emerging clinical evidence and how best to apply these advances to their clinical practice. The goal of this QI initiative was to bring members of the interdisciplinary care team together to identify, discuss, and implement changes designed to improve their molecular testing process for patients with advanced NSCLC.

Planning Committee:

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Director, Thoracic Medical Oncology
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Learning Objectives

Upon completion of this educational activity, the participant should be able to:

1. Discuss the importance of obtaining adequate tissue samples at biopsy of patients with NSCLC in order to do molecular testing.
2. Discuss the impact of an inadequate tissue sample on patient treatment and outcomes.
3. Explain the challenges that may arise in obtaining an adequate tissue sample and strategies to overcome these challenges.
4. Identify targeted treatments that would be indicated for patients with advanced NSCLC with positive biomarker findings.
5. Develop strategies to improve communication across all NSCLC team members.

Participating Cancer Centers

Fox Chase Cancer Center
333 Cottman Avenue
Philadelphia, PA. 19111

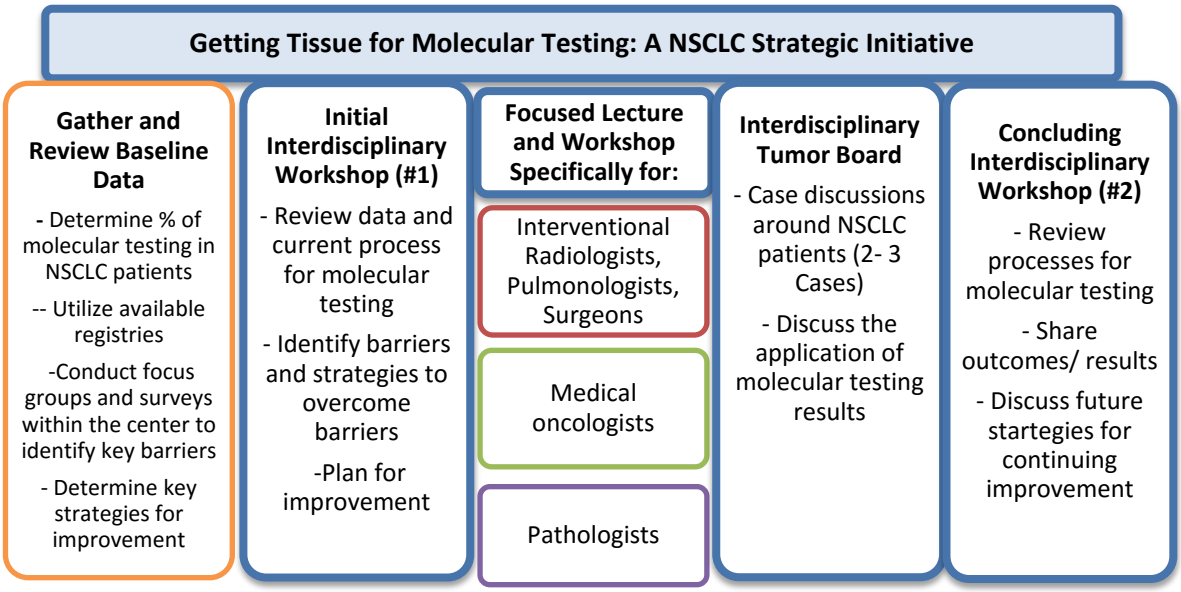
Harbin Clinic
Tony E. Warren, MD Cancer Center
255 West Fifth Street
Rome, GA 30165

Holy Cross Hospital
1500 Forest Glen Road
Silver Spring, MD 20910

Lancaster General Hospital
Ann B. Barshinger Cancer Institute
2102 Harrisburg Pike
Lancaster, PA 17604

Skagit Valley Hospital
307 South 13th Street
Mount Vernon, WA 98273

QI Initiative Design



Molecular Testing Rates: Pre (Baseline) vs. Post (Follow-Up)

	Fox Chase Cancer Center	Lancaster General Hospital	Harbin Clinic	Skagit Valley Hospital	Holy Cross Hospital	Average
Baseline data time period	**Jan 2011-Dec 2012 (24 months)**	**Jan 2011 – Dec 2012 (24 months)**	**Jan 2011 – June 2012 (18 months)**	**Jan – Dec 2012 (12 months)**	**Jan – Dec 2012 (12 months)**	
NSCLC total	259	303	81	52	79	
NSCLC per year	129	151	54	52	79	93
Stage IV lung adenocarcinoma	84	68	37	8	19	43.2
Molecular testing rate (Stage IV lung adenocarcinoma)	84%	65%	76%	62%	53%	68%
Follow-up data time period	**Jan 2013 – Oct 2014 (22 months)**	**Jan 2013 – August 2014 (20 months)**	**June 2013-June 2014 (13 months)**	**Nov 2013 – May 2014 (7 months)**	**Jan 2014 – May 2014 (5 months)**	
Stage IV lung adenocarcinoma	117	37	16	11	32	
Molecular testing rate (Stage IV lung adenocarcinoma)	100%	81%	75%	91%	100%	89%

QI Summary of Centers

Fox Chase Cancer Center

Fox Chase Cancer Center in Philadelphia, PA is accredited by the Commission on Cancer as an NCI Designated Comprehensive Cancer Program. Founded in 1904 in Philadelphia as American Oncologic Hospital – one of the nation's first cancer hospitals—Fox Chase Cancer Center (FCCC) was also among the first institutions to be designated a National Cancer Institute Comprehensive Cancer Center in 1974. FCCC sees more than 8,400 new patients a year. At the FCCC, a significant percentage of their lung cancer patients enter clinical trials. Therefore, the use of molecular testing in advanced NSCLC often includes a panel of multiple molecular markers. Also, approximately 30% of their lung cancer patients are referred to FCCC for a second opinion, so their original diagnostic evaluation and workup is done elsewhere before they arrive at FCCC. The thoracic oncology team met regularly to discuss the optimal approach of testing for molecular mutations in their patients with advanced NSCLC. They also met to discuss how best to improve lung biopsy practices among their radiologists and pulmonologists.

Key improvements:

- Baseline molecular testing rates in advanced NSCLC was 84% in 2011-2012. At the end of the QI initiative, molecular testing rates in advanced NSCLC reached 100% for adequate samples obtained within their organization. The cancer team recognized that they must continue to make improvements in their biopsy process to reduce the need for repeat biopsies.
- The thoracic oncology team optimized their approach for testing specific molecular markers vs. using panel tests for patients with advanced NSCLC. As the cancer center implemented an electronic health record and worked through the transition from paper-to-electronic records, they maintained ongoing communication among the medical oncologists, the physicians performing lung biopsies, and the pathologists about molecular testing for patients with advanced NSCLC.
- Sometimes, the paper pathology requisition form that accompanies lung biopsy samples was lacking information about the need for molecular testing. As a result, the pathologists were not ordering molecular tests on these biopsy samples. The pathology department modified this form to add check boxes for molecular testing to reduce the likelihood that the form did not include any information about molecular test orders.
- The team also held ongoing discussions regarding the role of next-generation sequencing (NGS) for patients with advanced NSCLC. Patients eligible for clinical studies based on NGS were identified and enrolled in trials.
- The interdisciplinary team improved their communication regarding tissue adequacy during biopsy. The pathologists were using tele-pathology resources to provide remote rapid on-site evaluation (ROSE) of biopsy samples. The physicians performing biopsies improved their communication to pathologists about the importance and priority of molecular testing.
- The cancer center expanded their team of pulmonologists who were trained to use advanced endoscopic techniques and tools to perform lung biopsies.

Key challenges:

- Many lung cancer patients are referred to FCCC after they have been diagnosed at another institution. Some of these patients may have had molecular testing performed. In every situation, the cancer team at FCCC attempts to obtain the original biopsy samples to perform the necessary molecular testing. In some instances, patients require a repeat biopsy so that the FCCC team can order the proper molecular tests.
- The merger with Temple Health that began in 2012 created significant changes in staffing and resources in 2014. The main administrative point of contact for this QI initiative left the organization. Changes were made within the CME, quality improvement, and cancer registry departments. As a result of these changes, it became difficult to schedule and coordinate the final workshops and meetings towards the end of the QI initiative.
- When the QI initiative began, FCCC was in the process of preparing for the implementation of an electronic health record (EHR) that summer. This provided both an opportunity for process improvement and a major barrier because clinicians had to learn the new system and change their clinical workflow from paper-based processes to electronic processes. Furthermore, different departments were using different software systems for patient results vs. order entry and these challenges made it difficult for various members of the care team to optimize their clinical workflow processes.

Lancaster General Hospital

Lancaster General Hospital in Lancaster, PA is accredited by the Commission on Cancer as a Comprehensive Community Cancer Program Health. Lancaster General Health (LG Health) is a 631-licensed bed not-for-profit health system with a comprehensive network of care encompassing the greater region of Lancaster, PA. At Lancaster General Hospital, the thoracic oncology team had been performing molecular tests routinely when this QI initiative began. However, they also recognized that they had to do more to educate the other medical specialists about the importance of molecular testing in patients with advanced NSCLC. They were also in the process of discussing the role of individual vs. panel testing for patients with advanced NSCLC. Through this QI initiative, the thoracic oncology team met regularly to discuss improvement strategies around lung biopsies. They also discussed the optimal approach for molecular testing in their patients with advanced NSCLC and agreed to perform reflexive molecular testing in both inpatients and outpatients.

Key improvements:

- Baseline molecular testing rates in advanced NSCLC was 65% in 2011-2012. At the end of the QI initiative, molecular testing rates in advanced NSCLC improved to 81%. The improvement in testing was primarily attributable to a pathology-driven reflexive molecular testing process for all patients with advanced NSCLC.
- The thoracic oncology team established consensus and refined their process around a pathology-driven reflexive molecular testing in patients with advanced NSCLC. After holding several meetings with administrators, medical oncologists, and pathologists, the team agreed to reflexively test both inpatients and outpatients who are diagnosed with advanced NSCLC. After evaluating the pros/cons of sequential testing vs. simultaneously testing of several mutation

markers, the committee agreed that simultaneously testing was the optimal approach for their cancer team.

- The radiologists performed an internal assessment to improve and standardize their needle biopsy techniques. They met to discuss how to improve their fine needle aspiration (FNA) and core biopsy needle techniques.
- The cancer team improved their overall communication about the importance of molecular testing in NSCLC by discussing process issues among physicians performing lung biopsies, the medical oncologists, and the pathologists.
- The thoracic oncology team continued to have ongoing discussions regarding the role of testing for additional mutation markers beyond EGFR and ALK in their patients with advanced NSCLC.
- The oncology team modified their cancer registry to add expandable, structured data fields for EGFR and ALK molecular test results in lung cancer. These fields would indicate specific molecular tests that were ordered and their results. The team decided on an expandable field so that additional mutation markers could be added in the future.

Key challenges:

- Lancaster General opened a new cancer center in 2013 and went through a major transition as they moved their oncology services to this new facility.
- A key nurse involved in data collection moved to a different role in the middle of the QI initiative. This nurse had been serving as a key point of contact and had been collecting and reviewing molecular testing data from the cancer registrars, electronic health records, and pathology reports.
- Staffing changes within the pathology department occurred in the middle of the QI initiative. A new chair for the pathology department arrived at the end of 2014.

Harbin Clinic

Harbin Clinic in Rome, GA is the largest privately owned, multi-specialty physician group in Georgia, comprised of 240 medical professionals representing 37 different medical specialties and sub-specialties. At Harbin Clinic, patients with lung cancer typically get their biopsy at either Floyd Medical Center (FMC) or Redmond Regional Medical Center (RRMC). Redmond Regional Medical Center is accredited by the Commission on Cancer as a Comprehensive Community Cancer Program and Floyd Medical Center is accredited as a Comprehensive Community Cancer Program. Floyd Medical Center is the only safety net facility in northwest Georgia, so they constantly face resource constraints. The oncology team at Harbin Clinic had been discussing ways to optimize molecular testing in NSCLC. Through this QI initiative, the thoracic oncology team met regularly to discuss improvement strategies around lung biopsies. They also discussed the optimal approach for molecular testing in their patients with advanced NSCLC and agreed to perform reflexive molecular testing in both inpatients and outpatients.

Key improvements:

- Baseline molecular testing rates in advanced NSCLC was 76% in 2011-2012. Follow-up molecular testing rates in advanced NSCLC were 75%. This lack of significant change in molecular testing rates is attributable to several factors: a high percentage of patients are diagnosed with lung cancer as inpatients and Floyd Medical Center is a safety net facility with limited resources. Hence, the Medicare 14-day rule remains a major barrier to molecular testing for inpatients. Also, there are patients who are diagnosed with advanced lung cancer who either refuse additional treatment or are referred directly to hospice care. Biopsies for these patients are not sent for molecular testing.
- Despite the stable molecular testing rate, the interdisciplinary team of cancer clinicians established consensus and refined their process around efficient molecular testing in eligible patients with advanced NSCLC.
- The pathology department identified a process to ensure that molecular test results that are entered into the outpatient oncology EHR are easier to track and find. They made this possible by relabeling molecular test results so that they are not easily separated from standard pathology and laboratory reports.
- The pulmonologists and radiologists improved their communication with pathologists as they performed biopsies on patients with suspected lung cancer. They were more deliberate about communicating patient factors and the priority for molecular testing.
- The interdisciplinary team agreed and established a way to improve and standardize communication between pathologists and the physicians performing lung biopsies when the biopsy sample is inadequate. Prior to this QI initiative, that type of feedback was not routinely being communicated to radiologists and pulmonologists performing lung biopsies.

Key challenges:

- Floyd Medical Center is a safety net hospital with limited resources. When Medicare inpatients undergo lung biopsy, their samples are not automatically sent for molecular testing until 14 days have passed after patient discharge. The delays and lags caused by the Medicare 14-day rule remain significant barriers at Harbin Clinic.
- At the start of the QI initiative, the pulmonologists were not trained in advanced endoscopy techniques and they lacked proper equipment to use EBUS when performing lung biopsies.

Skagit Valley Hospital

Skagit Valley Hospital in Mount Vernon, WA is accredited by the Commission on Cancer as a Comprehensive Community Cancer Program. Skagit Valley Hospital is licensed for 137 hospital beds and was one of the smaller participating centers in this QI initiative. Skagit Valley Hospital is also a member of the Seattle Cancer Care Alliance (SCCA) Network which provides community-based physicians throughout the Pacific Northwest with access to the latest cancer diagnostic and treatment information. Unlike the other centers participating in this initiative, Skagit Valley outsourced pathology services to off-site pathologists employed by LabCorp. At the time when this QI initiative began, Skagit Valley was in the process of recruiting a second pulmonologist for their community.

Key improvements:

- Baseline molecular testing rates in advanced NSCLC was 62% in 2012. At the end of the QI initiative, molecular testing rates in advanced NSCLC improved to 91%. The improvement in testing was attributable to improvements in biopsy samples and a greater emphasis to ensure that molecular testing was being requested and ordered.
- The radiologists at Skagit Valley assessed their biopsy process and discussed opportunities to make improvements to obtain more samples and higher quality samples. They also gained understanding about the need to have adequate tissue for molecular testing in advanced NSCLC.
- Through interdisciplinary meetings and individual conversations, the medical oncologists improved their communication with pulmonologists, radiologists, and pathologists about the increasing need for molecular testing in advanced NSCLC.
- The cancer registry team used this QI initiative as an improvement example as they completed their Commission on Cancer (CoC) reaccreditation.

Key challenges:

- The off-site pathologists who were employees of LabCorp provided services to Skagit Valley and other hospitals. These pathologists were difficult to engage in this QI initiative.
- The staffing shortage within the pulmonology department placed a burden on community because of the long wait time to schedule an appointment. Also, the single pulmonologist who was evaluating patients was not trained in advanced endoscopy techniques and did not have the equipment to perform needle biopsies guided by EBUS.

Holy Cross Hospital

Holy Cross Hospital in Silver Springs, MD is accredited by the Commission on Cancer as a Comprehensive Community Cancer Program. Holy Cross serves nearly 200,000 patients each year. Holy Cross also refer many lung cancer patients to the NIH for clinical trials. At Holy Cross, some physicians are employed by Kaiser and others are in group or independent practice. In general, patients seen by a Kaiser pulmonologist who require a lung biopsy are referred to radiology for a CT-guided lung biopsy. Hence, these pulmonologists do not routinely perform lung biopsies on patients with lung cancer.

Key improvements:

- Baseline molecular testing rates in advanced NSCLC was 53% in 2012. At the end of the QI initiative, molecular testing rates in advanced NSCLC reached 100% when biopsy samples were adequate for testing. When samples were inadequate, a second biopsy was performed. The improvement in molecular testing rate was attributable to a pathology-driven reflexive molecular testing process combined with a monthly audit/review process to ensure that the reflexive pathways was being followed by all the pathologists. The quality and quantity of the biopsy sample also improved as more radiologists used core needles over FNA.
- Communication about the importance of adequate biopsy samples and molecular testing in advanced NSCLC was led by the pathology department.

- Most of the radiologists performing CT-guided lung biopsies tended to prefer the use of FNA. As the QI initiative progressed, these radiologists became more comfortable and confident using core needle biopsies when performing lung biopsies.
- The pathology department also developed and communicated a "core needle biopsy protocol" that described how they were processing biopsy samples for molecular testing.
- Medical oncologists reached consensus over the need for specific reflexive molecular testing in NSCLC vs. the use of special panels or next-generation sequencing testing. Before this consensus was established, pathologists had to wait to hear from medical oncologists about their individual preference on selecting a specific testing lab and on ordering specific molecular tests. This inefficiency was eliminated by reaching consensus around a pathology-driven reflexive molecular testing process.
- The cancer registry team added molecular test results into their lung cancer registry so that they could track molecular testing trends and patterns over time.

Key challenges:

- Because some physicians are employed by Kaiser and others are non-Kaiser physicians, the interdisciplinary team of clinicians had to work through internal process issues to reach consensus around certain issues pertaining to molecular testing. The pathology department was a single, non-Kaiser group of physicians and they took the leadership to navigate through these issues.
- When lung cancer patients were identified for potential clinical trials, they would often require additional molecular testing or repeat biopsies for additional tissue. The cancer team had to balance the priority of collecting standard molecular test results reflexively vs. delaying testing in patients who may be eligible candidates for studies who may require more comprehensive molecular testing.

Remaining Educational Gaps

The following educational gaps were identified by participants during workshop discussions, feedback sessions, and written evaluations:

- Controversy surrounds the optimal selection of mutation markers beyond EGFR and ALK in patients with advanced NSCLC. Although there are actionable markers based on current FDA-approved therapies, there are also opportunities for clinical studies for patients who may have position mutation markers that have potential experimental therapies. Some cancer centers in the community are more likely than others to identify and refer lung cancer patients for clinical trials, so the sentiment towards more comprehensive molecular testing is stronger in such centers.

- Controversy surrounds the question: should molecular testing be performed in patients with NSCLC if they have early disease? Some may argue that many of these patients will have recurrent disease, so having the molecular test results immediately available will delay potential treatments in the future. Others argue that testing in early stage is a waste of resources since the information may never be actionable. Some suggest that testing should be delayed since additional mutation markers may be actionable in the future and one would want to test for all of these markers. This controversy remains a challenging topic for cancer centers that are trying to optimize their pathology-driven reflex testing process.

- Knowledge gaps remain regarding the optimal use of next-generation sequencing tests vs. other testing methodologies. Controversy surrounds the issue of sequential testing vs. simultaneous testing of multiple mutation markers.

- Knowledge gaps remain regarding ongoing clinical studies exploring additional mutation markers beyond EGFR and ALK.

- Knowledge gaps remain regarding how patients respond to therapies targeting specific mutations. Recently evidence suggests a pattern of treatment resistance to certain therapies, but many oncologists in the community do not know how best to monitor for such resistance and how to manage patients who may develop resistance to treatment.

- Competency gaps remain among radiologists and pulmonologists regarding the optimal methods to biopsy a lung nodule and yield adequate samples for diagnosis and molecular testing. For radiologists, this is specifically regarding FNA and core needle biopsy techniques. For pulmonologists, this is specifically regarding the use of advanced endoscopy techniques to optimize biopsy results.

- Knowledge gaps remain among many members of the cancer care team regarding the principles behind basic process improvement methodologies. Furthermore, competency gaps remain regarding the application of these methodologies to improve processes, workflow, and patient outcomes.

Future Opportunities for QI

The timing of this QI initiative coincided with the FDA approval of several new targeted therapies for advanced NSCLC, so there was greater awareness in the oncology community about the growing importance of molecular testing in this setting.

- The landscape of molecular testing in advanced NSCLC is becoming increasingly complex. Therefore, there are opportunities to guide cancer centers to ensure that they are optimizing the testing process to reduce waste, minimize wait time for results, and ensure that patients are managed based on the application of the latest evidence-based principles.
- There are still opportunities to guide radiologists, pulmonologists, and surgeons to improve how they perform lung biopsies to optimize tissue adequacy for molecular testing. This may include a combination of education, workshops designed to improve procedural techniques, and ongoing audit/feedback cycles so that physicians are informed when their biopsies are inadequate for testing.
- There are opportunities to improve teamwork and communication across the interdisciplinary cancer care team. This is becoming increasingly relevant in areas where physician groups and hospitals are undergoing mergers and acquisitions. There are also growing opportunities to equip clinicians and administrators with the necessary training and skills so that they can demonstrate strong leadership in the clinical setting.
- As lung cancer screening programs become ubiquitous in this country, cancer centers in the community need guidance to ensure that they are using resources optimally and providing the best level of care coordination and follow-up for patients who have abnormal screening tests. There will be greater opportunities to educate these centers with best practices, to share success stories from other centers, and guide centers through the application of proven process improvement methodologies.

Conclusion

Getting Tissue for Molecular Testing: An NSCLC Strategic Initiative was a successful QI initiative based on the collaborative efforts of Temple University, Fox Chase Cancer Center, the Association of Community Cancer Centers (ACCC), and MCM Education. The QI initiative provided critical guidance and educational resources for clinicians to improve their process of performing molecular testing in patients with advanced NSCLC. As the landscape of cancer care continues to evolve rapidly with the emergence of additional therapies targeting specific lung cancer mutations, the process of testing must be optimized to ensure that these patients are being treated appropriately. The process of molecular testing in patients with NSCLC is multifaceted and numerous variables can make an impact on the quality of this process. Oncologists want to have the necessary information so that they can make proper treatment decisions. They depend on the radiologists, surgeons, and pathologists who are obtaining lung biopsies to get adequate samples so that the pathologists can make the right diagnostic interpretation and send

the samples for appropriate molecular testing. This QI initiative brought members of the interdisciplinary team together to discuss improvement opportunities ranging from tissue acquisition to the workflow of ordering and receiving molecular test results. As clinicians implemented small incremental changes and measured their progress, their molecular testing process improved over the course of this QI initiative.

Appendix

Summary of Center Profile and Participation

	Fox Chase Cancer Center	Lancaster General Hospital	Harbin Clinic	Skagit Valley Hospital	Holy Cross Hospital	Average
Location	Philadelphia, PA	Lancaster, PA	Rome, GA	Mount Vernon, WA	Silver Spring, MD	
# of medical oncologists	4	17	3	5	12	8.2
# of pulmonologists	4	11	4	2	3	4.8
# of radiologists	6	10	8	4	7	6.2
# of pathologists	8	8	5	2	5	5.6
CME focus group (date, # of attendees)	5/6/13 12	4/18/13 14	6/10/13 15	6/24/13 10	10/29/13 32	
CME Workshop #1 (date, # of attendees)	10/8/13 8	1/16/14 15	12/9/13 14	11/20/13 23	1/17/14 31	
CME for medical oncology (date, # of attendees)	1/17/14 7	4/17/14 10	4/21/14 7	2/13/14 3	2/24/14 9	
CME on biopsy (date, # of attendees)	2/7/14 6	4/17/14 10	5/6/14 4	4/3/14 2	2/24/14 21	
CME for pathology (date, # of attendees)	3/24/14 15	7/22/14 9	5/8/14 5	2/20/14 2	3/21/14 12	
CME tumor board (date, # of attendees)	4/28/14 5	9/29/14 10	10/27/14 17	1/14/15 18	5/16/14 19	
CME workshop #2 (date, # of attendees)	12/23/14 6	10/16/14 10	11/17/14 10	9/24/14 16	6/20/14 15	