Molecular Testing in the Community Oncology Setting

MOLECULAR TESTING

Resources & Tools for the Multidisciplinary Team

The evolution of biomarker-driven medicine is having an impact on oncology patient care—both diagnostically and therapeutically. Recent research suggests that actionable mutations are found in 62 percent of patients with lung adenocarcinoma.[1] To ensure that cancer programs are optimizing molecular testing processes, the Association of Community Cancer Centers (ACCC), in collaboration with Pfizer Oncology, launched a multi-phased initiative in 2012 titled, "Molecular Testing in the Community Oncology Setting."[2] Phase I consisted of member surveys and a published report that summarized key findings from the survey and outlined effective strategies to overcome common barriers.

BY JOSEPH KIM, MD, MPH

Learning Lab Participants

In 2013, ACCC proceeded with Phase II, Learning Labs for Process Improvement, a program for member institutions that focused on improving molecular testing at the system level through experiential learning labs. Eight member centers were selected to participate in this project:

1. Anne Arundel Medical Center, DeCesaris Cancer Institute, Annapolis, Md.
2. IU Health Goshen Center for Cancer Care, Goshen, Ind.
3. Riverside Health System, Riverside Cancer Care Center, Newport News, Va.
4. Shawnee Mission Medical Center, Shawnee Mission, Ks.
5. Southside Regional Medical Center, Petersburg, Va.
6. St. Vincent's HealthCare, Jacksonville, Fla.
7. The Methodist Hospitals, Oncology Services, Merrillville, Ind.
8. The Thomas Johns Cancer Hospital, Richmond, Va.

Each program identified an administrator and a physician champion who helped to gather baseline data, schedule the learning lab workshop, and hold follow-up meetings with staff to monitor progress as they proceeded in the process-improvement journey.

Collecting Baseline Data

Participating programs gathered baseline performance data on molecular testing in lung cancer at the start of the project to assess their current clinical practices and workflows. The process of collecting this information involved working with their cancer registry teams to review patient charts and interview clinicians to gather feedback on key workflow issues.

The 8 programs offered 12 months of recent de-identified, aggregated, data from their cancer registries and patient charts which indicated:

- The total number of lung cancer patients
- The population of lung cancer patients who had adenocarcinoma compared with other histology subtypes
- The number of lung adenocarcinoma patients by disease stage
- The breakdown of lung adenocarcinoma patients by disease stage who had *EGFR* or *ALK* molecular testing.

Additionally, programs were asked to review their current clinical workflow processes and answer questions on issues such as:

- What types of steps occur in the patient flow when someone has a suspected lung mass and requires a biopsy?
- How often are lung biopsies performed by radiologists compared with pulmonologists? Compared with surgeons?
- How do physicians performing lung biopsies communicate with pathologists about the need for molecular testing?
- What are key reasons why some lung cancer patients are not receiving molecular testing?

By reviewing its data and existing workflows, each program had a starting point to engage its team members in an open dialogue about the current state of molecular testing in lung cancer at that center and about some potential opportunities for improvements.

> ... each program is taking a personalized approach to their process improvement plan based on their staffing resources, organizational structure, relationships with physician groups, and other factors.

Tailored Workshops

Based on each program's baseline data, tailored learning lab workshop materials were prepared and ACCC scheduled learning lab workshops. Participants at these two-hour workshops included cancer center administrators, senior executive leaders, physicians (medical oncologists, pulmonologists, pathologists, radiologists, radiation oncologists, and surgeons), nurses, patient navigators, quality improvement professionals, cancer registrars, and other members of the multidisciplinary cancer care team.

During the workshop, attendees:

- Reviewed the 2013 College of American Pathologists/International Society for the Study of Lung Cancer/Association of Molecular Pathologists guidelines on molecular testing in lung cancer[3]
- Discussed key opportunities for process improvement
- Explored how to proceed with implementing some of those changes.

Learning lab attendees were also introduced to the Plan-Do-Study-Act (PDSA) cycle for improvement. At the conclusion of each workshop, attendees were asked to schedule a follow-up meeting to discuss and prioritize areas for improvements and corresponding action items.

PDSA Framework

Each program held a follow-up meeting to outline two to three improvement plans and applied the PDSA cycle for improvement to develop specific action items, agree on progress metrics, and document the changes over a three-month period. Table 1, right, summarizes key areas for improvement and potential action items that were identified by the learning lab participants. (For more information, go to www.accc-cancer.org/molecculartesting.)

Three-Month Follow-Up

Three months after the learning lab workshops, the eight programs were asked to evaluate their progress and provide an update on the improvement plans based on the PDSA framework. The following areas for improvement emerged as top priorities in several programs:

- Biopsy samples insufficient for molecular testing
- Molecular tests not ordered for eligible patients
- Lack of pathology-driven reflexive molecular testing.

However, each program is taking a personalized approach to its process improvement plan based on staffing resources, organizational structure, relationships with physician groups, and other factors. Centers had performed root cause analyses to determine why certain issues were problematic and had held several meetings or formed committees to discuss improvement strategies. This article describes how the different programs made improvements in these three areas. To learn how programs approached other areas for improvement, go to www.accc-cancer.org/molecculartesting.

Biopsy samples insufficient for molecular testing. The majority of lung needle biopsy procedures are performed either by radiologists who use computed tomography (CT)-guidance or by pulmonologists who perform a bronchoscopy.[4] Needle biopsy methods generally include: 1) fine-needle aspiration (FNA), which may be performed by radiologists or pulmonologists and 2) core-needle biopsy (CNB), which is only performed by radiologists. In some cases, tissue can be obtained from thoracic surgeons, who acquire tissue samples from lung cancer patients using minimal to fully invasive techniques (i.e., aspiration, needle, incisional and excisional biopsies, open surgeries, and resection).

In general, CNB yields larger segments of tissue (histology) that are better for molecular testing.[5] FNA yields fluid and cells (cytology) and when the sample is adequate, the pathologist can create a cell block for molecular testing analysis.[6]

Several learning lab participants found that their radiologists strongly preferred using FNA over CNB, so there was an opportunity to educate these radiologists about the importance of using CNB when it is safe and appropriate. One center performed an internal review and assessment of its CT-guided biopsies to compare complication rates between FNA and CNB and found improvements in biopsy sample adequacy with CNB and no significant differences in complication rates between FNA and CNB.

Some programs found that their physicians were only obtaining minimum amounts of biopsy tissue for diagnosis and were not aware of the importance and relevance of molecular testing in lung cancer. These programs offered further education to these physicians, improved communication between the pathologists, and provided feedback to ensure that additional biopsy samples were being obtained.

> When programs realized that sometimes a physician may forget to order molecular tests on lung cancer patients, they focused their efforts on building or improving their reflex molecular testing pathway.

Molecular tests not ordered for eligible patients. During the learning lab workshops, some attendees were puzzled when the discussion led to the following question: "Some of our eligible lung cancer patients did not receive molecular testing on their biopsies. Why was molecular testing not performed?" This question provided an opportunity for each team to perform a root cause analysis to better understand why those patients did not receive molecular testing and the teams identified these reasons:

- The amount of biopsy tissue was inadequate for testing
- The physician forgot to order the molecular test
- The patient decided not to receive any further treatment
- The physician did not feel that the test would change treatment options.

When biopsy samples are extremely limited in quantity, it becomes increasingly important to communicate the priority of molecular testing to the pathologist who will be processing the biopsy material. Several pathologists shared how they would handle the biopsy

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Table 1. Key Areas for Improvement and Potential Action Items

IDENTIFIED AREAS FOR IMPROVEMENT	POTENTIAL ACTION ITEMS
Biopsy samples insufficient for molecular testing	✔ Reach out to programs with effective endobronchial ultrasound (EBUS) procedures and request to let team observe ✔ Improve fine-needle aspiration (FNA) biopsy results by scheduling meeting with radiologist, pulmonologist, and pathologist to review literature on FNA and discuss the optimal approach ✔ Review how radiologists are performing CT-guided lung biopsies and identify opportunities to standardize, make improvements in techniques, and increase appropriate use of core needle over FNA ✔ Compare adequacy rates of core needle biopsy samples vs. FNA
Molecular tests not ordered for eligible patients	✔ Review individual charts to determine why patients were not tested ✔ Discuss findings with team and consider ways to make improvements for future patients ✔ Review how disease staging impacts reflexive molecular testing process ✔ Create a reflexive molecular testing process
Lack of pathology-driven reflexive molecular testing	✔ Develop and implement a reflexive molecular testing pathway ✔ Update process and policy to include: • Simultaneous testing for *EGFR* & *ALK* • Documentation of why *EGFR* & *ALK* were not completed • Create process and tools for monitoring
Clinicians not capturing and documenting key quality measures for reporting	✔ Add molecular testing results to cancer registry as structured data fields ✔ Improve documentation around specific National Quality Forum (NQF), American Society of Clinical Oncology (ASCO), Quality Oncology Practice Initiative (QOPI) or other validated quality measures ✔ Revise progress notes templates or add tabs, fields, and/or sections so that nurses and physicians are consistently documenting information in EHR ✔ Include document of completion for molecular testing, along with test results ✔ Define process or create a template to assure inclusion of documentation of the reason for not completing testing
Lack of standardized reporting formats for molecular test results	✔ Standardize the application of the College of American Pathologists (CAP) lung biomarker reporting template in the EHR system
Difficulty using the cancer registry to measure molecular testing quality	✔ Add *EGFR* and *ALK* test results into cancer registry as a structured data field which will allow periodic review of molecular testing rates in an easier, more efficient manner ✔ Develop more uniform approach for entering NSCLC information into registry
Lack of an established pathway when evaluating a suspicious lung mass	✔ Monitor lung cancer patient data obtained from imaging reports, pathology reports and surgical reports, to include size of lesion, location of lesion, and mode of biopsy to see if there are patterns that drive mode of biopsy decisions ✔ Include information about a lung "hotline" to report abnormal chest x-ray and CT scan reports for radiology charts ✔ Include lung "hotline" information on patient instruction forms for chest X-ray or CT scan
Delays when ordering molecular tests for inpatients due to the CMS "14 Day" rule	✔ Working with senior administration to develop an approved center policy for molecular testing for inpatient diagnosis; educating staff and physicians about policy

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sample differently and preserve tissue for molecular testing if they knew that molecular testing was a priority. These discussions led some programs to create new policies designed to improve communication between the physician performing the biopsy and the pathologist. Other programs even modified their pathology requisition form to include more clinical information about the patient and the priority for molecular testing.

When programs realized that sometimes a physician may forget to order molecular tests on lung cancer patients, they focused their efforts on building or improving their reflex molecular testing pathway.

Lack of pathology-driven reflexive molecular testing. Programs agreed that a pathology-driven reflexive molecular testing pathway reduces delays and ensures that a greater percentage of appropriate biopsy samples will undergo molecular testing. (Note: reflex testing is a testing policy that does not require a separate clinician order for each case, is appropriate if agreed on by the lung cancer care team, and may help ensure expedited and consistent routing of specimens for molecular testing.) Most programs agreed that a lung needle biopsy sample that has an adenocarcinoma component should undergo *EGFR* and *ALK* testing at a minimum. Some programs felt that additional mutation markers could be actionable based on the 2014 NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer.[7] Programs also felt that the pathologist should not wait for disease staging information before sending the sample for molecular testing.

Programs that developed and implemented a pathology-driven reflexive pathway formed an interdisciplinary task force to evaluate options and make recommendations to their leadership team. Programs that already had a reflexive molecular testing pathway agreed that they needed to further refine the process to ensure that biopsies were not being missed.

In Closing

This education project helped participating programs apply process improvement methodologies that improved molecular testing in lung cancer patients. Programs relied heavily on a physician to effectively champion these change processes and to work with administrators and other staff members to identify key issues and barriers, as well as ways to overcome them. Every participating program remarked how this project was beneficial because it was able to identify actionable opportunities to make specific process changes that led to improved workflow and patient care. For more information about this project report go to: www.accc-cancer.org/moleculartesting.

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Advisory Committee

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