

ASSOCIATION OF COMMUNITY
CANCER CENTERS

EVOLVING
BIOMARKERS IN
NON-SMALL CELL
LUNG CANCER
FINAL REPORT



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BACKGROUND

In a 2020 survey conducted by the Association of Community Cancer Centers (ACCC), more than 50% of programs stated that their processes and procedures for established and emerging biomarker testing needed improvement. Rural cancer programs indicated that they face unique barriers to biomarker testing, including insufficient tissue for testing, lack of a multidisciplinary team to review testing processes and procedures, and lengthy turnaround times for test results.

To address these disparities, ACCC developed the Evolving Biomarkers in Non–Small Cell Lung Cancer program with the goal of improving comprehensive biomarker testing for patients with advanced or metastatic non–small cell lung cancer.

APPROACH

ACCC conducted the Evolving Biomarkers in Non–Small Cell Lung Cancer program with 2 cohorts. Each cohort comprised 3 cancer programs. The first cohort participated in the program from January to March 2022 and the second cohort participated from October to December 2022.

Each cancer program was asked to identify a core multidisciplinary team to participate in all program activities. The core team would have ideally included a medical oncologist, administrator, pathologist and nurse navigator and/or advanced practice provider. Program activities included the following:

- Completing an organizational preassessment
- Participating in a virtual workshop with expert faculty
- Completing an individual postworkshop evaluation
- Identifying an opportunity to improve comprehensive biomarker testing
- Creating an action plan to guide improvement efforts
- Participating in a virtual discussion with faculty to share action plan progress and troubleshoot implementation challenges

The 3 primary outcomes evaluated over the course of the program were:

- Increased awareness of ACCC resources to support incorporation of comprehensive biomarker testing into practice
- Increased individual and organizational readiness to implement comprehensive biomarker testing
- Increased multidisciplinary care collaboration to implement comprehensive biomarker testing

Since each cohort followed the same format, evaluation results will primarily be presented in the aggregate and are deidentified per agreement with each of the participating sites.

COHORT PARTICIPANTS

Cohort 1

CaroMont Hematology & Oncology
Gastonia, North Carolina

Englewood Health
Englewood, New Jersey

Fairfield Medical Center
Cancer Care and Infusion Services
Lancaster, Ohio

Cohort 2

Glens Falls Hospital,
The C.R. Wood Cancer Center
Glenn Falls, New York

St Tammany Cancer Center
Covington, Louisiana

Thompson Cancer Survival Center,
Covenant Health System
Knoxville, Tennessee

Thirty-five multidisciplinary professionals participated across the 2 cohorts. Participants included administrators, oncologists, advanced practice providers, nurse navigators, nurses, pathologists, and other multidisciplinary staff.

PROGRAM FACULTY

The faculty for the program was comprised of an oncologist, pulmonologist, nurse navigator, and pathologist. Three faculty members worked with both cohorts and were: Adam Fox, MD, Pulmonologist, Medical University of South Carolina; Pablo Gutman, MD, MBA, chairman, Pathology Department and medical director, Holy Cross Hospital Cancer Institute; and Dana Herndon, MSN, RN, ONN-CG, CPHQ, thoracic oncology nurse navigator, Cone Health Cancer Center. The oncologist who worked with the first cohort was Alexander Spira, MD, PhD, FACP, Virginia Cancer Specialists Research Institute, and the oncologist who worked with the second cohort was Yifan Tu, MD, PhD, Mercy Hospital, South David Sindelar Cancer Center.

ORGANIZATIONAL PREASSESSMENT RESULTS

Prior to the workshop, each program was provided with an organizational preassessment. The core team was encouraged to complete the preassessment together. The preassessment was designed to help prepare each program to conduct their quality improvement initiative following the workshop. The preassessment also measured their organizational readiness and capacity to conduct comprehensive biomarker testing as well as current organizational practices related to comprehensive biomarker testing.

Shared strengths across all 6 sites included as follows:

- Commitment to comprehensive biomarker testing
- Organizational culture oriented toward precision medicine
- Established relationships with external laboratories to execute biomarker testing
- Regular use of practice guidelines (eg, National Comprehensive Cancer Network and College of American Pathologists)
- Test results used as part of shared decision-making with patients

Shared challenges across all sites included as follows:

- Lack of a standing, multidisciplinary team to regularly review advanced non–small cell lung cancer biomarker testing practices and procedures
- Biomarker testing not integrated within clinical information systems (eg, emergency medical records [EMR])

However, there were some differences between programs, regarding established practices and available staff, such as:

- Programs may or may not have established reflex protocols
- Programs may or may not have the appropriate technical expertise to implement comprehensive biomarker testing
- Programs may or may not have the appropriate financial resources to conduct biomarker testing on site
- Programs may or may not have patient navigators available to educate and support patients and caregivers regarding biomarker testing and mitigate distress while waiting for results
- Programs may or may not have staff to navigate reimbursement for biomarker testing

Additional data points captured in the preassessment include number of advanced non–small cell lung cancer cases treated in one-year, brief description of biomarker testing ordering process, and time from ordering test to provider receiving results. These and other metrics are presented in **Appendix A**.

VIRTUAL WORKSHOP

Each cohort participated in a virtual workshop. The workshop was divided into 2 sessions held on separate days and each session was 90 minutes. Each session was primarily discussion based— participants seized the opportunity to ask questions to the faculty as well as their peers. Discussion topics included clinical guidelines, obtaining tissue for testing, patient navigation, creation of tailored biomarker testing workflows, and how to use ACCC’s **Biomarker Testing Implementation Roadmap for Advanced Non–Small Cell Lung Cancer**.

The last session on the agenda spent a fair amount of time focusing on identifying opportunities for improvement. Potential opportunities for improvement included challenges submitted as part of the preassessment (**Appendix A**) as well as additional opportunities that were identified during the discussion with faculty. Participants reviewed opportunities with faculty and discussed if: (1) the opportunity could be addressed in the next 3 months (Yes = high feasibility; No = low feasibility); and (2) addressing the opportunity would have a high impact for patients with advanced non–small cell lung cancer (Yes = high impact; No = low impact).

Each program identified 2 to 3 high impact/high feasibility opportunities to potentially address. Examples of priority areas were:

- Reviewing current processes and workflows to identify areas to improve biomarker testing (eg, time from receipt of tissue to time tissue leaves for testing; who is responsible for ordering testing; billing/prior authorization; how tissue is collected to ensure sufficient tissue is sent)
- Addressing patient distress by leveraging nurse navigators and improving communication around biomarker testing process
- Incorporating liquid biopsy to help inform decisions while waiting for tissue results

Following the workshop, programs were tasked with finalizing their opportunity and developing an action plan that each team would implement over the next 3 months.

POSTWORKSHOP EVALUATION

Twenty-three workshop participants (n = 23) across the 2 cohorts completed the postworkshop evaluation. All respondents rated the workshop from either good to excellent. Respondents were asked statements on a 3-point Likert scale of agreement (ie, disagree, neutral, agree) regarding knowledge gained, confidence, intent to change practice, and identification of a barrier to address and results were positive across the board (**Table 1**).

Table 1. Reported Gains, Confidence, and Intent to Change Practice (n = 23)

<i>Response</i>	<i>Percentage of respondents who agreed</i>
I gained new, practical knowledge about biomarker testing in advanced NSCLC from the workshop.	83%
I am confident in my ability to support the implementation of comprehensive biomarker testing in advanced NSCLC.	83%
I am committed to implementing or expanding comprehensive biomarker testing for advanced NSCLC at my organization.	96%
I intend to change something about my practice to better support implementation of comprehensive biomarker testing for advanced NSCLC.	78%
Our team has identified and prioritized an important barrier or challenge related to comprehensive biomarker testing that we plan to work to improve over the next 3 months.	83%

NSCLC, non–small cell lung cancer.

Respondents were also asked statements on a 3-point Likert scale of agreement to measure their individual readiness to implement comprehensive biomarker testing. Respondents were asked to reflect on their readiness before the workshop as well as after the workshop. **Table 2** shows the percentage of respondents who agreed with the statements.

Table 2. Attitudes and Beliefs Related to Comprehensive Biomarker Testing

<i>Response</i>	<i>Percentage of respondents who agreed (before workshop)</i>	<i>Percentage of respondents who agreed (after workshop)</i>
I believed/believe it is feasible to implement comprehensive biomarker testing for all patients with NSCLC.	57%	91%
I understood/understand my role in implementing comprehensive biomarker testing for advanced NSCLC at my organization.	52%	96%
I believed/believe implementing comprehensive biomarker testing for all patients with advanced NSCLC improves care quality through precision medicine.	70%	100%
I had/have the technical skills and expertise needed to support implementation of comprehensive biomarker testing for advanced NSCLC at my organization.	43%	74%

NSCLC, non–small cell lung cancer.

In addition, 83% of participants were not familiar with the Biomarker Testing Implementation Roadmap prior to the workshop, but the majority of respondents indicated they were either somewhat likely (35%) or very likely (61%) to use the roadmap to support their quality improvement efforts.

Finally, respondents were invited to share any additional comments or feedback regarding the workshop. Exemplary comments were:

“Excellent initiative. Thank you!”

“Excellent workshop.”

“Great discussions and insight gained. A lot of takeaways that our institution can use.”

“Hearing different perspectives and processes was helpful to facilitate improvement.”

“I felt it was an effective workshop. The diverse roles of the expert faculty as well as having multiple hospitals in on the call allow[ed] for an excellent forum to share strengths and struggles and hear suggestions from other programs that have or have overcome similar struggles.”

“It was great hearing what other facilities are experiencing.”

“Our hospital took the initiative to include me (cancer registrar) in this project; since we collect biomarker info in the registry, I see the process from a different angle and can sometimes offer helpful suggestions and I look forward to being included on finding a good solution for our facility.”

“Really appreciated collaborating with the program faculty [and] other participating institutions. Great learnings gained for practice patterns at other facilities. Prioritizing challenges was an excellent exercise—appreciated both identifying our challenges w/prioritizing our challenges but also hearing other organizations’ challenges. Especially appreciated hearing the feedback of the faculty. So thankful that we were chosen to be in this program!”

ACTION PLAN GOALS, IMPLEMENTATION PROGRESS, AND ANTICIPATED NEXT STEPS

Each program was provided with an action plan template that included defining the goal, activities, measures of success, deadlines, and people and/or resources needed to support each activity. To measure progress, ACCC conducted guided interviews with each cohort. **Table 3 and 4** below provide a snapshot of progress made toward the goal as well as anticipated next steps.

Table 3. Cohort 1 Action Plan Goal, Implementation Progress, and Anticipated Next Steps

<i>Program</i>	<i>Action plan goal</i>	<i>Snapshot of progress at 3 months</i>	<i>Anticipated next steps</i>
1	Develop a process to draw blood early on for liquid molecular testing for patients with suspected locally advanced or metastatic lung cancer.	<ul style="list-style-type: none"> Secured buy-in from interventional radiologists, pulmonologists, laboratory director, and outpatient laboratory to develop a new process Identified that a location for kit storage needs to be created 	<ul style="list-style-type: none"> Continue conversations with multidisciplinary team to develop and establish order process
2	Develop and implement future state workflow process for obtaining biomarker testing for patients with NSCLC.	<ul style="list-style-type: none"> Prior to program, no written or defined process so multidisciplinary team met every 2 weeks at a dedicated time to work on creating an electronic order set <ul style="list-style-type: none"> Leadership, IT staff, laboratory staff and others pulled into meetings as needed Created an electronic order set, which engaged multidisciplinary team including laboratory and IT staff Baseline data gathered prior to pilot 	<ul style="list-style-type: none"> Beginning stages of piloting new electronic order set Collect and review pilot data to monitor progress
3	Implement new lung biopsy processing protocol (ie, split tissue between 2 cassettes with goal of 1 cassette for IHC/diagnosis and one for molecular studies).	<ul style="list-style-type: none"> Buy-in from staff prior to program around biomarker testing, but as part of action plan implementation conversations with practice managers, navigators, and other staff helped increase understanding and need for timely testing turnaround Began new lung biopsy processing protocol; 2 specimens sent out to external lab for molecular testing 	<ul style="list-style-type: none"> Waiting for results and will continue to monitor process to ensure it is yielding needed data

IHC, immunohistochemistry; IT, information technology; NSCLC, non-small cell lung cancer.

Table 4, Cohort 2 Action Plan Goal, Implementation Progress, and Anticipated Next Steps

Program	Action plan goal	Snapshot of progress at 3 months	Anticipated next steps
4	Review NSCLC cancer comprehensive biomarker testing processes and procedures and convene multidisciplinary group to start to develop new comprehensive biomarker testing workflow.	<ul style="list-style-type: none"> Presented at cancer committee involvement in ACCC's program, goal of action plan, and importance of broad molecular profiling. Enthusiastic response from multiple team members regarding proposed changes Made switch to genomic profiling testing 	<ul style="list-style-type: none"> Continue to work on billing/reimbursement aspect, but sense of urgency to make the switch and billing/reimbursement can continue to be worked out Track incomplete NGS testing by reference lab due to "quantity not sufficient"
5	Develop new process for tissue collection and slide preparation to improve completion rates for NSCLC comprehensive biomarker testing.	<ul style="list-style-type: none"> Changed use of tissue preservative for specimen collection from cytolyte to formalin for suspected lung cancer patients Process is working well in operating room Time scheduled to present at tumor board to highlight involvement in ACCC's program, goal of action plan, and importance of comprehensive biomarker testing to build buy-in among other stakeholders 	<ul style="list-style-type: none"> Will monitor if change improves yield of cells for molecular testing Plans to implement this change for other tumor types as well
6	Review current NSCLC biomarker testing practices and develop a workflow plan to be implemented throughout all practices with consensus from other disciplines.	<ul style="list-style-type: none"> Scheduled time to present information from the ACCC workshop to members of the Chest tumor conference 	<ul style="list-style-type: none"> Review current biomarker practices for NSCLC. Determine limited number of vendors to utilize based on key physician's input Develop workflow for NSCLC biomarker testing to include where results will be housed within the EMR system, if needed

ACCC, Association of Community Cancer Centers; EMR, emergency medical record; NGS, next-generation sequencing; NSCLC, non-small cell lung cancer.

Although the amount of progress varied across programs, 2 cohort 1 programs noted the COVID-19 pandemic hindered progress. However, all programs indicated they were pleased with the progress that was made, including additional buy-in and commitment from multidisciplinary staff who were not working directly on the action plan, but would be impacted by changes made.

Further, both cohorts reiterated the excellent expertise and insights that the faculty provided, but also learning and hearing from peers at other programs. Participants appreciated hearing shared experiences related to common challenges to performing comprehensive biomarker testing, but also learned additional insights and workarounds from their peers.

For cohort 1, individuals were invited to participate in a brief 3-month follow-up survey. Fifteen people participated in the survey, and of those 80% (n = 12) indicated that as a result of participating in ACCC's Evolving Biomarkers Program, they had changed something about their practice to better support implementation of comprehensive biomarker testing for advanced non-small cell lung cancer. Respondents were then asked to briefly describe changes made and shared the following:

"As cancer registrar, I provided data to evaluate our current process to establish a baseline, as well as participating in development of a report to evaluate timeliness after our process improvement is implemented."

"Working on new order set for biomarker testing."

"Development of an improved workflow."

"We have refined our process of obtaining testing and are working with the multidisciplinary team ensure the testing is ordered more timely so that results do not delay treatment."

"I have been working with pathology department leadership to streamline resulting for biomarker testing. I have meet with team leadership and practice liaison to share process changes and implementation of testing with practice partners. "

"I am not involved in the daily aspect of biomarker testing for lung patients, however, I am much more aware of what is needed and when it is needed. As part of the oncology program, I help with genomic/ blood testing like Guardant360 and have been working with the core group to make sure we have the resources we need for those tests."

"We have started dividing lung biopsy tissue into 2 blocks with the goal of 1 block for molecular testing and 1 block for immunostains/diagnosis."

"Contributed to the development of new workflow and process. "



"I have helped in the implementation of biomarker testing on individual patients. "



"Better follow up with my staff involved in the process to assist with improving efficiency and follow through."



"Developed a standardized process (Process Map); assisted with development of electronic order set; orchestrated biomarker testing work group; and identified barriers and challenges [and] assisted to develop strategies to breakdown these barriers. "



"Educated other staff about biomarker testing; Worked on improving turnaround time so result can be available to ordering provider at earliest possible time; Strive to send plasma testing on most patients."

CONCLUSION

Based on evaluation results, the Evolving Biomarkers in Non–Small Cell Lung Cancer program was effective in:

- Increasing awareness of ACCC resources to support incorporation of comprehensive biomarker testing into practice
- Increasing individual and organizational readiness to implement comprehensive biomarker testing
- Increasing multidisciplinary care collaboration to implement comprehensive biomarker testing

While the program was successful, opportunities remain to continue to support community cancer programs in the utilization of comprehensive biomarker testing in non–small cell lung cancer. Based on conversations during the workshop, follow-up interviews with sites, and observations from ACCC, opportunities* include, but are not limited to:

- Providing more longitudinal support and expertise provided to programs in the development and piloting of workflows

- Supporting research studies to standardize biomarker testing in the community
- Connecting community cancer programs with molecular pathologists to consult on difficult cases
- Convening EMR/emergency health record (EHR) vendors and biomarker testing companies to identify opportunities such as:
 - Streamlining of reports from testing companies
 - Automatically populating results into EMRs/EHRs
 - Improving turnaround time from testing companies
- Advocating for a policy change to eliminate or lessen Medicare's "14-day rule," which guides billing and reimbursement of biomarker testing in a hospital setting. Although sites have all found workarounds and/or determine that their system must absorb the cost to provide quality care, the 14-day rule was consistently mentioned as a concern and/or challenge for lung cancer biomarker testing

*Although opportunities are discussed through the lens of non–small cell lung cancer, many of these opportunities apply broadly across all cancer types and would benefit many patients with cancer where molecular testing is indicated.

ACKNOWLEDGEMENTS

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APPENDIX A: ADDITIONAL METRICS CAPTURED IN ORGANIZATIONAL PREASSESSMENTS

	Program 1	Program 2	Program 3	Program 4	Program 5	Program 6
Number of NSCLC cases treated (August 1, 2020, to August 31, 2021)	Stage I: 43 Stage II: 16 Stage III: 28 Stage IV: 65	Stage I: 42 Stage II: 14 Stage III: 19 Stage IV: 37	Stage I: 5 Stage II: 5 Stage III: 28 Stage IV: 89	Stage I: 16 Stage II: 4 Stage III: 5 Stage IV: 10	Stage I: 24 Stage II: 15 Stage III: 21 Stage IV: 48	Stage I: 138 Stage II: 57 Stage III: 121 Stage IV: 194
Brief description of when, how, and who orders comprehensive biomarker testing with NGS for patients with advanced NSCLC	For most cases, the oncologists order NGS testing. All lung cancer cases are discussed at pulmonary tumor board and cases that need NGS are identified and ordered by oncology.	Orders written electronically via internal Cerner system or by test requisition sheet of the particular company at time of diagnosis by medical oncologists; occasionally ordered by pulmonologists.	The Pathology Department orders biomarker testing for stage IV. Medical oncology orders for stage I – III cancers, and stage IV cancers not ordered by pathology.	Pathology does not, as of now, order NGS on a routine protocol—single gene testing is ordered as per NCCN guidelines when advanced stage disease is identified. If Comprehensive biomarker testing is ordered, it is by the oncologists at their discretion.	Oncologist orders at initial outpatient consult visit.	Mainly ordered by medical oncology based on advanced stage and guideline recommendations.
Time from order of testing to results provided to provider	Time not provided	Tissue 21 days; Liquid 10-14 days	14 days	7 working days	3-21 days	1-3 weeks
Approximate time from diagnosis to first treatment for patients with advanced NSCLC	22.5 days	35-63 days	7-14 days	3 weeks	3-4 weeks	2-6 weeks

	<i>Program 1</i>	<i>Program 2</i>	<i>Program 3</i>	<i>Program 4</i>	<i>Program 5</i>	<i>Program 6</i>
Top 3 to 4 challenges related to comprehensive biomarker testing (open-ended)	<ul style="list-style-type: none"> • Sufficient tissue • Outside lab delays • Patients treated with us but diagnosed elsewhere and not having had enough tissue during biopsy 	<ul style="list-style-type: none"> • Financial resources to conduct timely and comprehensive biomarker testing on site • Process/workflow identification to perform biomarker testing consistently and timely • Staff resources to perform biomarker testing on site 	<ul style="list-style-type: none"> • Adequate tissue from biopsy for biomarker testing • Patient distress/impatience waiting for test results • No in-house molecular pathologist to review results (results are not always very clear) • Molecular testing result not automatically integrated into the EMR (for an additional challenge) 	<ul style="list-style-type: none"> • Standardization of workflow • Insurance coverage • Not enough tissue 	<ul style="list-style-type: none"> • Quantity of tissue available not adequate for testing • Insurance authorization requirements • Patient access to care delays 	<ul style="list-style-type: none"> • Inadequate tissue for biomarker testing/clinical trial eligibility • No internal testing or protocols for reflex testing, no standardization of outside labs being used • Time to get results to time to treat • No good way of having information within EMR easily accessible to providers

EMR, emergency medical record; NGS, next-generation sequencing; NCCN, National Comprehensive Cancer Network; NSCLC, non-small cell lung cancer.



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A publication from the ACCC education program, "**Evolving Biomarkers in Non-Small Cell Lung Cancer.**" Learn more at acc-cancer.org/emerging-biomarkers-NSCLC

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