National Lung Cancer Roundtable

Optimizing Lung Cancer Biomarkers in Practice Summit

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National Lung Cancer Roundtable (NLCRT) Biomarker Summit

Optimizing Lung Cancer Biomarkers in Practice

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NLCRT Biomarker Summit Overview

The American Cancer Society (ACS) National Lung Cancer Roundtable (NLCRT) Summit on *Optimizing Lung Cancer Biomarkers in Practice* represents a mission-oriented approach to harness the collective power and expertise of the entire lung cancer community. NLCRT member organizations were brought together during a 2-day virtual meeting to align on strategies to raise awareness of broad, systemic challenges to deploying comprehensive biomarker testing for patients with lung cancer. The overarching goal of the meeting was to develop strategies to increase the proportion of lung cancer patients receiving comprehensive biomarker testing and ensure all eligible non-small cell lung cancer (NSCLC) patients are tested in order to receive the most effective treatment.

Key objectives of the NLCRT biomarker summit:

- Bring organizations together to bridge gaps in comprehensive biomarker testing (biomarker testing that includes all guideline recommended driver mutations)
- Share clinical and patient experiences related to comprehensive biomarker testing
- Review best practices regarding tissue acquisition, choice of assay, design, turnaround time, and reimbursement
- Align on strategies to optimize patients' and physicians' awareness of comprehensive biomarker testing to increase the percentage of patients receiving biomarker testing
- Develop strategies that NLCRT and member organizations can embrace to optimize use of lung cancer biomarkers in practice

The 2-day summit began with an overview of the current state of biomarker testing and introduction of the "Big Goal" for comprehensive biomarker testing as *"Access to High Quality Biomarker Testing for All Eligible NSCLC Patients: No Patient Left Behind".* Patient testimonials followed this introduction to highlight the impact of comprehensive biomarker testing on patient treatments, outcomes, and quality of life. Next, participants were brought up to date on the current state of biomarker testing and the importance of collaborative efforts and communication among proceduralists (ie, pulmonologists, thoracic surgeons, and interventional radiologists), pathologists, oncologists, and nurse navigators. Representatives from key stakeholder groups across the continuum of biomarker testing (primary care physicians [PCPs], proceduralists, pathologists, oncologists, and payers) shared their "confessionals," (ie, their experiences and

perceptions of prevailing patterns in their own practice that create barriers related to comprehensive biomarker testing for patients).

The confessional was followed by a second panel of experts that provided a deep dive into the 5 key challenge areas for biomarker testing that were a focus of the biomarker summit.

<u>The 5 key challenge areas:</u>

- Knowledge gaps regarding the need for comprehensive biomarker testing and consistent communication
- Procurement of adequate tumor tissue for testing
- Choice of assay, design, and turnaround time
- Accurate interpretation of results
- Reimbursement, cost, and coverage for comprehensive biomarker testing

The main themes echoed by all five panel members were related to adequate knowledge, performance gaps, and challenges in information dissemination in the rapidly advancing field of lung cancer biomarker testing and its impacts on treatments.

Finally, a panel of participants from industry, payer, and advocacy organizations discussed the challenges they regard as most important to ensure that comprehensive biomarker testing for all eligible patients becomes routine, efficient, and achieves high quality, and the ways in which their organizations can contribute to a national collective initiative to advance comprehensive biomarker testing and ensure patients receive state-of-the-art testing and care.

Small group meetings were built into the t 2-day summit schedule. Throughout the meeting on day 1, participants broke into small groups to discuss the day's topics. The second day of the summit consisted of strategic breakout groups for each of the 5 key challenge areas (listed above) for biomarker testing. Based on their new and shared understanding of the barriers to biomarker testing, summit participants proposed and prioritized strategies with multi-stakeholder emphasis to overcome the barriers to comprehensive biomarker testing for NSCLC.

NLCRT Biomarker Summit Key Executive Report

Day 1: Tuesday, September 22, 2020 – Afternoon Session

Welcome

Ella A. Kazerooni, MD, MS, FACR

Dr. Kazerooni opened the meeting by welcoming participants and highlighting the history and objectives of the ACS National Lung Cancer Roundtable (NLCRT) Summit as follows:

- To harness the collective power and expertise of the entire cancer community
- To lower the impact of lung cancer through risk reduction, early detection, and the assurance of optimal diagnosis and therapy in a patient-centered, evidence-based, inclusive, diverse, proactive, and visionary manner
- To take on challenges that no single organization can successfully take on alone

Overview and Objectives of the Biomarker Summit

M. Patricia Rivera, MD, ATSF, FCCP

Dr. Rivera discussed the importance of comprehensive biomarker testing for optimal patient treatment and highlighted the current challenges in biomarker testing as key areas of focus for the NLCRT. She also covered the objectives of the meeting to bring organizations and stakeholders together to share clinical experiences, review barriers and best practices, and align on strategies to overcome the barriers to biomarker testing.

The "Big Goal": The Ideal State of Biomarker Testing

Access to High-Quality Biomarker Testing for All Eligible NSCLC Patients: No Patient Left Behind

Bruce E. Johnson, MD, FASCO

Dr. Johnson set the stage for the first breakout session by discussing the importance of access to high-quality, comprehensive biomarker testing for all eligible patients with NSCLC. The advent of targeted therapy has resulted in significant improvements in survival and health-related quality of life in patients with targetable biomarkers. However, despite the growing number of drugs available that target specific mutations in patients with NSCLC, data show that comprehensive biomarker testing is not uniformly performed. To highlight this, Dr. Johnson described the results from a NLCRT/ACS/ASCO/GO_2 Foundation/LUNGevity/ROS1ders survey on the current state of biomarker testing among oncologists. According to the survey, which included 138 respondents, only 42% of physicians order biomarker testing for 100% of their patients with nonsquamous NSCLC. Test rates for squamous cell NSCLC were about half that for nonsquamous NSCLC. Survey results also revealed that testing upon recurrence/progression was requested less than 50% of the time by 39% of respondents and 100% of the time by only 23% of respondents for patients with

nonsquamous NSCLC, with retest rates about half that for squamous cell NSCLC. Turnaround time varied, with only 6% of respondents reporting that their patients received test results on average within 1 week, 59% within 2 weeks, 29% within 3 weeks, and 7% within 4 weeks or longer. Reimbursement for biomarker testing was 99% for Medicare but ranged from 52% to 86% for private payers and other options. The survey was weighted toward academic centers; biomarker testing rates are likely lower in community settings.

BREAKOUT SESSIONS: The "Big Goal"

After Dr. Johnson's presentation, summit participants broke into small groups to discuss the current state of biomarker testing and the biomarker summit's "Big Goal" of "*No Patient Left Behind*." Key points from the breakout session are highlighted below.

- The need to increase comprehensive biomarker testing has been a topic of discussion for several years. The goal of "no eligible NSCLC patient left behind" was embraced by summit attendees because it is time for progress for all NSCLC patients eligible for biomarker testing.
- It is concerning that some patients with NSCLC who receive biomarker testing initiate treatment (ie, chemotherapy, immunotherapy) before testing results are available, highlighting the importance of emphasizing that biomarkers are actionable targets and their presence guides optimal treatment decisions that impact patient outcomes.
- Equity among different patient groups makes the "Big Goal" achievable.
- Reimbursement needs to improve. It is disappointing that biomarker testing is only reimbursed 50% of the time despite clinical trials that demonstrate the benefits of targeted therapies.
- Collaborative effort is required. The NLCRT will stimulate multidisciplinary collaborations that drive actions to achieve wide availability and comprehensive biomarker testing regardless of where a patient receives care.

Patient Advocate Experiences

Following the small group sessions, summit attendees returned to the main session to hear two patients share their NSCLC journey, including the impact of biomarker testing on their treatment, outcomes, and quality of life.

Gina Hollenbeck, RN, BSN – President of ALK Positive

Ms. Hollenbeck described her experience after being diagnosed with Stage 4 lung cancer. She was fortunate to have an oncologist who understood the importance of biomarker testing and was found to be ALK positive. Biomarker testing not only enabled her to treat her cancer with a "little pill," but also helped provide a reason why, as a person who never smoked, she developed lung cancer. She emphasized the importance of making sure every patient with lung cancer has the opportunity to receive biomarker testing, including increasing awareness in community settings and improving reimbursement, both for testing and for targeted therapies. Even if a targeted treatment is not currently available, new ones are constantly being developed, and, ultimately,

treatment of all cancers could benefit from identifying and targeting the oncogenes and mutations that drive them.

Janet Freeman-Daily, ENG, MS – Co-founder of ROS1ders

Ms. Freeman-Daily was diagnosed with lung cancer in 2011. Despite aggressive treatment, her cancer progressed to borderline Stage 4. Through research and online patient communities, she learned about biomarker testing, but tested negative for all the gene alterations tested. Ms. Freeman-Daily's cancer continued to progress, returning every time she stopped chemotherapy. When results from the ROS1 clinical trial were published, her oncologist had not heard of it and did not know how to test for it, so she remained on her current treatment plan, but again progressed immediately upon stopping chemotherapy. She consulted with another doctor who informed her a test for ROS1 had been developed. She was tested and found to have the ROS1 mutation. Ms. Freeman-Daily has now been on twice-daily oral crizotnib for eight years with no evidence of disease on scans. Although not cured, she is living with lung cancer as a chronic disease with a good quality of life as a result of finding the appropriate therapy through biomarker testing. She has since co-founded ROS1ders, a global group for patients and caregivers with the ROS1 mutation, which aims to achieve better outcomes by supporting ROS1 patients and their caregivers, increasing awareness and education, improving access to effective diagnosis and treatment, and accelerating research.

The Current State of Biomarker Testing

Professional Confessional Panel

Richard C. Wender, MD; Farhood Farjah, MD, MPH, FACS; Edward S. Kim, MD, FASCO; Maureen F. Zakowski, MD, JD; and Bryan A. Loy, MD, MBA

Ideally every eligible patient with NSCLC would arrive at their first oncology appointment with results from a comprehensive biomarker panel. A collaborative effort across the patient care continuum is needed to achieve this goal. In addition, barriers to comprehensive biomarker testing need to be identified and addressed at all stages of a patient's journey, from PCP to Payer. Towards this goal, representatives from stakeholder groups across the continuum for biomarker testing shared their contributions to barriers to comprehensive biomarker testing for their patients.

For primary care providers, Dr. Wender identified the three key barriers to comprehensive biomarker testing for as diagnosis, awareness, and nihilism/hopelessness. PCPs still often have the perception that only people who smoke get lung cancer, which can delay diagnosis for those who do not smoke. PCPs may also have a nihilistic view of lung cancer and be unaware of newer treatment options, which can offer hope and positively impact patient care. Finally, lack of continued engagement in patient care following diagnosis is an issue for patients with lung cancer at the PCP level.

For proceduralists, Dr. Farjah discussed the lack of knowledge about comprehensive biomarker testing and collection of inadequate amounts of tissue samples for testing as two key areas contributing to low rates of biomarker testing. Keeping abreast of the constantly evolving lung cancer treatment landscape is challenging as most

proceduralists are not specialized to lung cancer. In addition, variability in tissue collection technique can limit the amount of tissue sample available for analysis, with one-quarter to one-half of patients having inadequate amounts of tissue sample available for comprehensive biomarker testing.

For oncologists, Dr. Kim acknowledged that they are at the frontline for treatment of lung cancer patients and need to take responsibility for ensuring that all patients receive comprehensive biomarker testing. A key barrier for oncologists includes difficulty staying up to date with the evolving treatment landscape, especially for general oncologists. In addition, biomarker test results are not presented in a consistent manner and can be difficult to interpret, which can complicate treatment decisions and may dissuade some providers from ordering testing. Finally, pressure to start treatment quickly and delays in biomarker testing turnaround time can lead to initiation of treatment prior to test result availability.

For pathologists, Dr. Zakowski identified the key barriers to biomarker testing for as knowledge gaps and diagnostic insecurity. Many pathologists are generalists and cannot keep up with the rapidly changing lung cancer field. In addition, diagnostic insecurities and fear of litigation can lead pathologists to exhaust available tissue samples unnecessarily when confirming the initial diagnosis. Limited communication with colleagues is another challenge for pathologists who are often isolated from their clinical colleagues.

For payers, Dr. Loy discussed methods payers use to provide affordable and appropriate utilization of biomarkers. The prior authorization process is often required to determine coverage for biomarker testing to satisfy the need for payers to have evidence of benefit of the test and/or the targeted agent. With the pipeline of evolving targeted agents and the associated biomarkers, there is a frequent need to evaluate the evidence and guidelines in order to maintain contemporary coverage policies. In an effort to provide high quality and affordable care, payers may be selective regarding which biomarker labs are in network. When different payers have different coverage policies and different in-network labs, this can create administrative burden on the ordering providers. Finally, variances in coding may require administrative resources to review medical documents and reconcile with submitted claims.

BREAKOUT SESSIONS: Confessional Panel Discussion

Participants broke into small groups to discuss their thoughts about the confessional panel, including what they learned and potential solutions. Key highlights from the breakout sessions are highlighted below.

General Comments

- To achieve the “Big Goal” of comprehensive biomarker testing for all eligible lung cancer patients, a coordinated sequence of events is required, and currently there are gaps at every stage.

- The need for increased awareness and education is a consistent thread highlighting the need for effective ways to inform, train, and update healthcare providers across subspecialties.
- Delivery of care is commonly fragmented by lack of integration across medical specialists. A system in which there is timely communication and clear understanding of roles and responsibilities is needed.
- The inertia of "business as usual" needs to be overcome and replaced with procedural and protocol changes across all specialties/stakeholders to keep up with the rapidly evolving field of biomarkers testing of lung cancer.
- Efforts to streamline testing will be aided by professional groups agreeing on a common standard of care for comprehensive biomarker testing, including acceptable turn-around time and a minimum set of markers to be tested.

Primary Care Physicians

- There is a need to move beyond the nihilism of lung cancer as a death sentence to ensure primary care physicians (PCPs) effectively council patients following their diagnosis with an appropriate plan of care.
- PCPs need to stay engaged in the care of lung cancer patients throughout the continuum of care, similar to how they manage chronic diseases (ie, encourage patients to ask oncologist about comprehensive biomarker testing).

Proceduralists

- Lack of awareness about lung cancer comprehensive biomarker testing contributes to inadequate amounts of tumor tissue sample being collected and available for testing.
- Proceduralists should be aware of whether comprehensive biomarker testing is needed or might be needed in the future to better inform their tissue acquisition process during diagnostic and staging procedures.
- Equally important is ensuring proceduralists are educated and trained on appropriate tissue collection techniques.
    - Measures (ie, performance feedback) are needed to identify proceduralists who may require additional training or mentoring.

Oncologists

- Increased awareness of the importance of comprehensive biomarker testing is needed for general oncologists, who may not be aware of the rapid advances being made in the treatment of lung cancer.
- The medical oncology community is challenged to keep abreast of the rapidly evolving treatment landscape. It is therefore important to ensure all oncologists have access to easily digestible, up-to-date information on new and emerging biomarkers, treatment options, and availability of clinical trials, as well as updated information on the minimum, core set of markers to include in testing.
- Complex biomarker test reports can be difficult to interpret highlighting the need to develop standardized easy to interpret templates that display biomarker test results and associated recommended actions in a consistent manner.

- Timely access to multidisciplinary tumor boards (ideally within the same week) is also important.

Pathologists

- Increased awareness of the importance of comprehensive biomarker testing is needed for pathologists, many of whom are generalists, and are challenged to keep up with the rapidly changing lung cancer field.
- Diagnostic dilemmas and concern for potential litigation can lead pathologists to exhaust available tissue samples unnecessarily when confirming the initial diagnosis, reducing the amount of tumor sample available for biomarker testing.
- Pathologists are often not in close contact with their clinical colleagues, which can complicate communication with practitioners involved in patient care.

Payers

- Prior authorization, which is often required to determine eligibility for biomarker testing, can be time consuming for clinicians and their practice support staff. This, together with concerns that reimbursement for biomarker testing will not be approved, can discourage doctors from ordering testing.
- Payers need to be provided with information on how the results of the biomarker panels can benefit patient care and guide effective treatments to ensure timely reimbursement.
- Payers need to be educated on the benefit of large (greater than 50) biomarker panels, including in the context of applicability to clinical trials or as sources of critical information for drug development.

Day 1: Tuesday, September 22, 2020 – Afternoon Session

Deep Dive: Barriers to Optimizing Use of NSCLC Biomarkers

Nikki Martin; Gerard A. Silvestri, MD, MS, FCCP; Lynette M. Sholl, MD, FCAP; Raymond U. Osarogiagbon, MBBS, FACP; Jennifer Malin, MD, PhD

A panel of experts took a deep dive into the 5 key challenge areas for comprehensive biomarker testing to identify specific barriers and potential solutions for each.

Ms. Martin covered the topic "*Knowledge Gaps Regarding the Need for Testing & Communication"* from the patient perspective. She highlighted gaps in patient awareness and knowledge of biomarker testing, including patient confusion due to the numerous varied terms currently being used to describe biomarker testing, and disparities in education on biomarker testing in low-income areas and at smaller hospitals.

Dr. Silvestri provided an overview of challenges related to *"Procurement of Adequate Tissue for Sampling"* by describing the results of an NLCRT/CHEST survey of 453

pulmonologists examining knowledge of endobronchial ultrasound (EBUS) procedure guidelines, knowledge of FDA-approved targets, and awareness of treatment guidelines and institutional testing policies. Survey results indicated that almost half of general pulmonologists see only 1–4 lung cancer patients per month and demonstrated a correlation between patient volume, number of EBUS procedures performed per month, and practice type (ie, academic vs community) on procurement of sufficient tissue for comprehensive biomarker testing.

Dr. Sholl provided an overview of the topic "*Choice of Assay & Design and Turnaround Time,"* including highlighting the pros and cons of single gene tests; small, <50 gene panels (amplicon sequencing); and large (50–1000+) gene panels (next generation sequencing [NGS]). Single-gene tests, while low cost, fast, and easy to interpret, can ultimately take longer and cost more to identify the correct mutation if multiple sequential rounds of testing are needed. Indeed, a decision analytic model established that comprehensive NGS or hotspot NGS actually delivered results more than 2 weeks faster than sequential gene testing, and comprehensive NGS saved over $1 million compared to other testing strategies for a 1-million-member health plan. Institutional reflexive testing also improves turnaround time for biomarker testing; however, barriers to reflexive testing include overhead costs, the need to batch samples which impacts turnaround time, and compliance concerns regarding Stark law, which prevents pathologists from self-referral.

Dr. Osarogiagbon highlighted key barriers in terms of *"Accurate Interpretation of Results."* He began by noting that the worst inaccuracy is not testing at all due to nihilism, low expectations, and/or lack of knowledge with regard to comprehensive biomarker testing and targeted therapies. The lack of uniform biomarker reports and the complexity of biomarker test results can further hinder identification of the appropriate therapy based on test results.

Finally, Dr. Malin discussed key challenges in terms of *"Reimbursement, Cost & Coverage."* She began by describing how coverage criteria is determined using a hierarchy of evidence with statistically robust, well-designed, randomized controlled trials at the top of the hierarchy. In addition, for a biomarker test to be reimbursed, evidence of clinical validity must be shown (ie, the test must lead to an action or therapy that improves patient outcomes). As such, barriers to comprehensive biomarker testing include lack of consensus and clear definition of what guideline-recommended comprehensive biomarker testing encompasses and the wider variety of multi-gene and biomarker panels available for NSCLC with mismatch between panels and testing with clinical utility.

BREAKOUT SESSIONS: Barriers Discussion

Knowledge Gaps, Procurement of Adequate Tissue, and Choice of Assay & Design

Participants broke into small groups to discuss their reactions to the presentations. Key points from the breakout group discussions are highlighted below.

Patient Knowledge Gaps Regarding Comprehensive Biomarker Testing

- It is important to ensure all lung cancer patients are educated about the need of comprehensive biomarker testing and that key information is made broadly available in an easy-to-understand formats.
- More education is needed to help patients understand that the optimal treatment may differ from patient to patient based on their specific biomarker profile (ie, immunotherapy may be the best option for one patient while a targeted therapy might be the best approach for another).
- Patient stories are a critical component to inspire other patients and avoid nihilistic views held by some in the medical community.
- Adopting and adhering to common consistent terminology (currently >22 different terms being used to describe biomarker testing) can help increase patient awareness, avoid confusion, and facilitate informed shared decision making.
    - "Comprehensive biomarker testing" has been identified as recommended terminology in early efforts to develop consistent terminology (http://www.commoncancertestingterminology.org/).

Procurement of Adequate Tissue for Sampling

- Higher volume of diagnostic procedures (such as endobronchial ultrasound, mediastinoscopy, percutaneous biopsy, thoracentesis) performed and awareness of guidelines to procure adequate tumor tissue, both of which are more prevalent in academic settings, are associated with greater knowledge regarding the need for biomarker testing and procurement of adequate tumor tissue for testing.
- Proceduralists called up to make a diagnosis of lung cancer who see very few lung cancer patients have less awareness about biomarker testing and the appropriate standards for securing adequate tumor tissue. This highlights the need for educational efforts on the importance of biomarker testing and/or referral of patients with lung cancer to high-volume practices with the appropriate diagnostic expertise.
- Proceduralists in practice settings with a policy regarding biomarker testing are also more likely to test for more biomarkers than those in practices without such a policy. However, the difference is not as striking as differences in testing rates in the academic versus community setting.

Choice of Assay & Design and Turnaround Time

- Biomarker testing rates are better for some biomarkers (ie, *EGFR* and *ALK*), but testing rates for other markers are not as prevalent and need to improve.
    - A flowchart defining which mutations to test for and when will be helpful.
- Single gene tests: small, <50 gene panels, and large (50–1000+) gene panels (next generation sequencing [NGS]) all have pros and cons (ie, single gene and smaller panels cost less but do not include less common mutations while larger panels can be more costly and harder to interpret but include broad coverage of available biomarkers). The ongoing challenge is to define the optimal testing approach (ie, the correct balance between cost, speed, and comprehensive results).
- Guidelines and data support utilization of large NGS panels for biomarker testing, but these are not being used routinely.
- Reflexive testing leads to increased testing and quicker turnaround; wide-scale implementation of reflexive testing would be beneficial.

Accurate Interpretation of Results

- "The worst inaccuracy is no test" was an important point that resonated with participants.
- Interpreting the complex genomic test results is challenging, and clinicians have difficulty interpreting what results mean.
    - In some cases, fear of interpreting results incorrectly can result in providers avoiding testing.
- Accurate algorithms that direct treatment based on biomarker test results can help physicians be confident in their ability to correctly interpret biomarker test results.
- There is a need to build technology and medical informatic systems to help standardize access to biomarker testing, interpretation of results, and decision-making based on results.

Reimbursement, Cost & Coverage

- Payers are not always provided the information they needed about the benefits of biomarker testing, delaying pre-authorizations.
- Ensuring guidelines for biomarker testing are clear is critically important; NCCN guidelines currently recommend testing for 7 biomarkers conducted as part of "broad" molecular profiling – but do not provide a clear definition of what "broad" means.
- A wide variety of tumor multi-gene panels are available, but only 2 current procedural terminology (CPT) codes (1 for panels up to 50 biomarkers, and 1 for panels of more than 50 biomarkers) complicating payer decisions on what is reimbursable.
- Determining the ideal biomarker panel that are updated in timely manners for patients with lung cancer, something that everyone can support, could help towards achieving a biomarker test that is widely ordered, easily approved, and consistently reimbursed.
- Some payer guidelines only approve biomarker testing once per tumor. More education is needed around rebiopsy at progression (could have different mutation or histological transformation) and its value in patient care.

Advocacy, Payer, and Industry Panel

An advocacy panel, which included representatives from industries, advocacy groups, and payer organizations, continued with the meeting's theme to discuss the challenges they regard as most important in ensuring that comprehensive biomarker testing becomes routine, efficient, and high quality. Opportunities for collaboration to overcome these barriers were also discussed. Key points made by the panelists included the following:

- Education across all stakeholders is key to ensuring access to comprehensive biomarker testing for eligible lung cancer patients.
- Communication across stakeholders is important but needs to be streamlined as peer-to-peer consultation takes time and can contribute to delays in turnaround time.
- Incorporation of comprehensive biomarker testing results into electronic medical records will help create a history and paper trail for each patient that is easily

accessible across the care continuum and can be searched retrospectively when new drugs are approved.

- Ensuring payer policies align with current treatment guidelines is important to increase coverage and avoid delays with prior authorizations.
- Public policy outlining the minimum testing needed for every lung cancer patient (ie, testing based on guidelines, acceptable turnaround time, and maximum out-of-pocket expense, etc.) could standardize testing.
- Strategies to reduce cost to the patient, which can contribute to lack of testing, and identification of ways to connect patients with financial resources are needed.

Strategic Framework Exploration to Overcome Barriers

Key themes that emerged from the strategic framework breakout groups were the need to improve awareness, minimize knowledge gaps, and develop effective ways to disseminate information regarding comprehensive biomarker testing across all stakeholders. National organizations can play a role, not only at national meetings, but also through disseminating information at the local, state, or regional chapter meetings, as well as ongoing webinars. Specific strategies developed by meeting participants during the breakouts on day 2 included the following:

Knowledge Gaps Regarding the Need for Testing & Communication

1. **Identify Knowledge Gaps**. Undertake mixed-methods research to identify gaps in knowledge about comprehensive biomarker testing; review what other organizations have already done to avoid duplication.
2. **Develop Consistent Terminology.** Create uniform and consistent terminology, content, and messaging to describe comprehensive biomarker testing building on what advocacy groups (ie, LUNGevity) have already done.
3. **Implement Effective Dissemination**. Identify ways to effectively disseminate the messaging to all patients and across the medical community, including developing ways to reach underserved communities (ie, partnering with professional organizations at the national, local, state, and regional level).
4. **Increase Awareness of Financial Resources.** Utilize navigator services (in collaboration with the Academy of Oncology Nurse and Patient Navigators and the Oncology Nursing Society) to inform patients about and help them navigate financial resources available to help cover the cost of comprehensive biomarker testing.

Procurement of Adequate Tissue for Sampling

1. **Create Standardized Protocols**. Create a playbook with guidance on obtaining adequate tumor tissue for biomarker analysis and establish educational programs for pulmonary and thoracic surgeons to bridge knowledge gaps surrounding tissue acquisition and harmonize the process.
2. **Define Optimal Biopsy Approach**. Work toward a dual strategy of liquid- and tissue-based biopsies at the time of diagnosis and at disease progression as the emerging gold standard for biomarker testing.
3. **Provide Performance Feedback**. Develop an outcome measure to evaluate the percent of patients for whom adequate tissue is collected for biomarker testing, what percent of patients are tested, and how many times adequate specimen for analysis is collected.

Choice of Assay & Design and Turnaround Time

1. **Define Optimal Biomarker Panel**. Incentivize reimbursement of comprehensive panel assays by defining an optimal panel and suggested technology that could be endorsed by NCCN and other guidelines.

2. **Communicate Emerging Clinical Data**. Communicate clinical data in a clear and rapid manner to all stakeholders to ensure rapid adoption of new biomarkers into recommended panels and guidelines.
3. **Implement Reflex Testing**. Mandate reflex testing at the earliest time in the patient's course (ideally DNA and RNA based NGS plus PD-L1 testing) with the goal that all patients receive comprehensive biomarker testing in a timely manner.
4. **Formulate Metrics to Assess Performance.** Create a national platform for health systems that provides feedback at the local level on their performance with respect to comprehensive biomarker testing; formulate metrics on the utilization of biomarkers (assigned to medical team or individual) to measure areas where improvement is needed.

Accurate Interpretation of Results

1. **Generate Standardized Biomarker Report Templates.** Work with providers, institutions, and diagnostic companies to generate standardized templates for biomarker reports that are easy to read and highlight the key information including displaying actionable mutations in a prominent place and directly linking them to the recommended treatment.
2. **Provide Clinical Trial Information**. Include information on clinical trial options in a user-friendly way for genomic changes when no standardized FDA approved treatment is currently available.
3. **Increase Access to Tumor Boards.** Work with professional societies and comprehensive cancer centers to facilitate program development to enhance access to local experts and molecular tumor boards. Consider virtual meetings to provide broader outreach outside academic centers.

Reimbursement, Cost & Coverage

1. **Implement Standardized Guidance for Reimbursement**. Implement a standardized framework for evidence review and create state-based laws or mandates for public and private payers for biomarker testing coverage to ensure more uniform coverage across payers.
2. **Educate Clinicians on Reimbursement Process.** Provide resources to clinicians to guide them through the process needed for reimbursement and coverage decisions and navigate the prior authorization process.
3. **Update CPT Codes to Align with Biomarker Panels.** Rework current procedural terminology (CPT) codes for biomarker testing so that they align with the available multi-gene panels and are based on the biomarkers included, not just the number of biomarkers. In addition, the potential for private payers and government plans to implement a policy and infrastructure similar to the Molecular Diagnostic Services (MoIDX) program, which was developed in 2011 to identify and establish coverage and reimbursement for molecular diagnostic tests, could be explored.
4. **Investigate Impact of Medicare 14-day Rule**. Quantify the impact of the Medicare 14-day rule (a requirement to bill a hospital for clinical laboratory

services ordered less than 14 days after patient discharge) on testing delays and propose new policy solutions to improve turnaround time for that circumstance.

Conclusion and Next Steps

Advances in the lung cancer treatment landscape are providing opportunities to substantially improve the lives of patients with lung cancer; however, to reap these benefits all eligible patients with NSCLC need access to comprehensive biomarker testing. A multidisciplinary approach is required to tackle current barriers and challenge areas and ensure all stakeholders are aligned on strategies to optimize comprehensive biomarker testing. Through a combination of expert talks and strategic breakouts NLCRT summit participants explored key barriers currently encountered across the care continuum and developed prioritized strategies to overcome these barriers. Implementation of these strategies will be the first step toward achieving the "Big Goal" of *"Access to High Quality Biomarker Testing for All Eligible NSCLC Patients: No Patient Left Behind".*

Thank you

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