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BIOMARKER TESTING IN PATIENTS WITH NON-SMALL CELL LUNG CANCER

A Mixed-Methods Approach to Understand Clinician Use of Biomarker Testing for Patients with NSCLC

In Brief

While recent advances in precision medicine have substantially changed the management of lung cancer, care must be taken to ensure that these advances do not worsen health disparities. This study included a case component that divided overall respondents into two cohorts to observe how patient characteristics, such as age, socio-economic status, race/ethnicity, and health literacy, affected the likelihood of ordering biomarker testing. Descriptive data analysis and sub-analyses between cohorts captured differences in decision making and attitudes. Two virtual focus groups provided context to these data. The survey found that the main reason clinicians order biomarker testing is to determine treatment decisions, but half also reported using the results to inform patient discussions and determine eligibility for clinical trials. From the clinician's perspective, the least critical factors when ordering biomarker testing were health literacy, caregiver presence, race/ethnicity, and age. Yet, likelihood to order biomarker testing decreases when patients have an unstable housing situation or low health literacy. Based on this study, there is a need for continued clinician education on equity in the ordering of biomarker testing.

Advances in the understanding of cancer genomics and the impact of patient-specific characteristics on optimizing treatment plans has substantially changed oncology practice. In the management of non-small cell lung cancer (NSCLC), the BATTLE and BATTLE-2 trials, among others, showed success when matching patients with targeted therapy based on their biomarker status.¹⁻³ Use of precision medicine was initially seen as an opportunity to address and eliminate disparities by determining treatment largely on the genetic makeup of a tumor or mutation and an individual's needs for cancer care. Yet, care must be taken to ensure it does not exacerbate existing health disparities.⁴

In 2020, the American Association for Cancer Research released a report⁵ focusing on disparities inherent in the management of patients with cancer. One of these sections deals specifically with the "imprecision of precision medicine" due, in part, to the limited understanding of etiology and the genetics of cancer within underserved populations. A precision medicine testing approach requires increased samples from patients in currently underserved populations along with testing access and accuracy in testing interpretation.^{6,7} While there are multiple initiatives

intended to mitigate these gaps in key population genomic information,⁸ other variables may contribute to disparities in biomarker testing, including access to quality healthcare, ability to pay/insurance status, mistrust in the healthcare system, and how patients and clinicians comprehend the importance of biomarker testing with treatment planning. To use precision medicine to reduce disparities of care, all eligible patients with cancer must be offered comprehensive biomarker testing. Yet, recent studies have shown lower biomarker testing rates in patients with cancer from historically marginalized groups^{9,10} and specifically for patients with lung cancer.¹¹⁻¹³

To highlight areas of need for continued clinician education and information, this study explores attitudes of oncology clinicians toward the use of biomarker testing in patients with NSCLC with a focus on understanding factors that contribute to disparities of care in patients of lower socio-economic status. The study attempts to identify inherent barriers to the equitable offering of biomarker testing in patients with NSCLC to recommend specific interventions that can be implemented to optimize care.

Survey Development

A case-based survey was designed to assess oncology clinicians' perceptions on attitudes toward the use of biomarker testing in patients with lung cancer. For the case portion, clinician respondents were randomly split into two slightly modified versions of the case to identify whether patient-specific factors, such as socio-economic status, age, race/ethnicity, and health literacy, affected clinicians' decision to order biomarker testing. The survey used four vignettes that described patients at different lung cancer disease stages with integrated real-world physical and social determinants of health complexities that might influence the ordering of biomarker testing.

Likert-type scales and multiple-choice responses were analyzed to show how clinicians approach biomarker testing use. Questions were asked to understand clinicians' general use of biomarker testing, rationale for testing, barriers, and their demographics.

Study Sample and Data Collection

Clinician survey invitations were distributed by e-mail from June to August 2020 to a random sample of oncology clinicians through ACCC member lists, commercially available lists, and a Sermo social media advertisement. The inclusion criteria specified ACCC-member clinicians that currently see patients with NSCLC who are on Medicaid, are dual Medicare-Medicaid eligible, or are uninsured.

Survey Analysis

Descriptive statistics were conducted on key items of the clinician and patient survey, using Chi-square analysis for categorical variables and T-tests for continuous variables to examine differences between key demographics, including academic versus community and urban versus suburban and rural. Statistical analysis was conducted using SPSS 27 (IBM: Armonk, N.Y.). Values were considered significant when p is less than 0.05.

Post-Survey Focus Groups

Survey results were used to develop a focus group guide, which was used to further probe into key themes identified in the survey. Focus group participants were selected based on their Medicaid population being at least 5 to 10 percent of their total patient population, including two sites with more than 20 percent of their patient population being insured by Medicaid. Two clinician focus groups were conducted via Zoom and recorded, with one focusing on community oncology practices (3 participants) and one on academic cancer centers (3 participants). Focus groups were transcribed verbatim and a thematic analysis was conducted until saturation was reached to identify emergent themes. The study protocol was approved by Advarra internal review board (Columbia, Md.) on April 13, 2020, and the

instruments (Appendix A: Survey and Appendix B: Focus Group) are available online at acc-cancer.org/eliminating-disparities.

Sample Demographics

Data were collected from 105 oncology clinicians—6 were removed from the final sample due to not meeting the established inclusion criteria. A final sample of 99 clinicians was used for analysis (Table 1, page 6). Most of the sample included medical oncologists, radiation oncologists, surgical oncologists, oncology nurses, and pharmacists, who were all involved with a program that treats patients with NSCLC. The sample was evenly split between those practicing in urban (49 percent) versus suburban/rural settings (51 percent), and 68 percent self-identified as working in a community practice setting versus 32 percent who self-identified as academic practitioners. Overall, 20 percent of respondents indicated that their cancer program sees more than 100 patients with NSCLC per month. Academic oncologists reported a higher patient load; 39 percent of academic clinicians see more than 100 patients with NSCLC per month compared to 11 percent of community clinicians. Roughly a third of the clinicians in this study have taken cultural competency and/or cultural humility training. This training most often focused on race/ethnicity and gender/sex competency; only 14 percent had any prior training on competency related to socio-economic status.

Use of and Rationale for Biomarker Testing

Respondents were presented with a patient case consistent with lung cancer (Table 2, page 7). At the point of obtaining a biopsy, nearly all respondents were very (34 percent) or extremely likely (44 percent) to order biomarker testing; only 4 percent responded that they were unlikely to do so. When asked generally why they recommend biomarker testing, 86 percent indicated that the results impact their treatment recommendations. Just over half of clinicians indicated that they recommend biomarker testing because results inform discussions with patients about prognosis (57 percent), guidelines recommend testing (56 percent), or results impact clinical trial eligibility (54 percent). Academic clinicians were significantly more likely than community clinicians to have responded that biomarker testing results inform patient discussions about prognosis (73 percent versus 48 percent, $p = 0.021$). Only 10 percent responded that they recommend biomarker testing because patients expect it.

Respondents were asked to rate different patient-specific factors related to their approach to discussing biomarker testing with a patient. A 1 to 5 point scale was used, where 1 = not at all significant and 5 = extremely significant. Of the factors provided, respondents rated a patient's level of interest in being involved in decision making as most significant (3.81/5) and patient's health literacy as least significant (3.42/5).

Respondents were then asked about the significance of different clinical and demographic factors in their approach to biomarker testing on the same 1 to 5 point scale. From the clinicians' perspectives, the most critical clinical factors were histology, clinical trial eligibility, and patient preference for biomarker testing; the least significant patient factors were health literacy, caregiver presence, race/ethnicity, and age.

Decision Making for Ordering Biomarker Tests

Respondents were then presented with several patient case scenarios; half of the sample was randomly presented with each version to observe the impact of selected variables on their decision to order biomarker testing (Table 3, page 8). Each case presented a potential disparity: socio-economic status (case 2), age (case 3), race/ethnicity (case 4), and health literacy (case 5). Little difference was seen in clinicians' response to a patient's age or race/ethnicity; respondents indicated high likelihood to order biomarker testing with these cases. But a small difference was seen in how clinicians responded to socio-economic status. Fifty-seven percent indicated they were extremely likely to order biomarker testing in a patient with a stable, executive-level job compared to 32 percent who were extremely likely to order testing for an unemployed, homeless patient. The difference between test ordering was more drastic in case 4: only 32 percent of respondents were highly likely to order biomarker testing for a patient with perceived low health literacy compared to 63 percent for a patient who asks complex questions about their care and are perceived to have high health literacy. Going further, 8 percent of respondents were not at all or only slightly likely to order biomarker testing if the patient was noted to have low health literacy. Additionally, clinicians in an academic setting were significantly less likely than community-based clinicians to order biomarker testing for a patient with perceived low health literacy ($p = 0.016$).

Focus Group Perspectives

The consensus among focus group participants was to offer biomarker testing to all patients with advanced NSCLC early in the clinical decision-making process so that test results were available prior to being seen by a medical oncologist. However, other participants indicated that this strategy is not universally supported and may not be achievable at all cancer programs or practices due to a host of factors.

While training regarding formal health literacy assessment was not evaluated in the survey, no focus group participant knew whether their institution had standard policies for assessing the health literacy of patients with lung cancer. Focus group participants indicated that their patients were unlikely to understand the full implications of testing or ask

questions about the implications of their results. Focus group participants identified nurse navigators or lay navigation services as needed resources to guide patients through cancer intake and treatment processes.

Concluding Thoughts

Overall, oncology clinicians indicated they are likely to discuss biomarker testing with a patient with NSCLC at some point along their disease trajectory. There were few differences in clinicians' likelihood to order biomarker testing based on patients' age or race. Decreases in biomarker testing were seen, however, in representative patient cases: those who are unemployed without a stable home and those with a perceived low health literacy. This may indicate that disparities in the use of biomarker testing may arise from both clinicians' perceptions of a patient's employment and/or housing status and their subjective assessment of a patient's ability to follow-up on or understand their results. Yet when asked directly, clinicians did not perceive health literacy to be a very significant factor in their ordering of biomarker testing for patients.

Clinicians did report being more likely to consider patients' preferences for testing, as well as their level of interest in being involved in shared decision-making, when considering whether to order biomarker testing. This would suggest that guideline-concordant biomarker testing is more likely to occur if a patient specifically requests testing. Placing this degree of responsibility on patients—to comprehend the role of biomarker testing at the time of diagnosis and/or disease progression—seems out of sync with most patients' understanding. This is especially true when considering that focus group clinicians do not view most patients with lung cancer as a highly health-literate population.

Based on this study, a patient with an uncertain housing situation or insurance status may be less likely to be offered biomarker testing compared to a more affluent patient. It is uncertain whether this decrease is due to a perceived or real inability to pay for the testing or the stability of their situation. Some clinicians in the panel may be more sensitive to the burdens related to biomarker testing and, therefore, more reluctant to offer testing based on the presumption that a patient cannot follow-up. While there is only a small reduction in the likelihood of ordering biomarker testing in this dyad, it may indicate an educational opportunity for social services training for oncology clinicians, including the need for referral to social workers, patient assessment, and the management of specific challenges faced by this patient population.¹⁴ Additionally, continued resources and tools developed with engagement from communities to increase patient engagement may be needed.

Perception of poor health literacy also appears to be a key driver for ordering biomarker testing, yet it is unclear how well clinicians understand the health literacy of their patients. No focus group participant was aware of any health literacy assessment policies or tools for patients with lung cancer at their institution. Only 32 percent of respondents indicated that their cancer program implemented cultural competency or humility training, and it is likely that formal postgraduate training on health literacy assessment is rarer.

A review of health literacy research¹⁵ found no standard approach to health literacy assessment in the United States, and most assessments focus only on basic functional skills, including ability to read and complete medical forms, not on participating in healthcare discussions or applying health information to one's situation.¹⁶ While tools exist to help understand a patient's health literacy, like the Rapid Estimate of Adult Literacy in Medicine (REALM) and the Test of Functional Health Literacy in Adults (TOFHLA), these tools are used primarily for research,¹⁷ require training for administration,¹⁸ and have not definitively been shown to improve patient outcomes.¹⁹ Health literacy assessment results should not be a determinant of whether biomarker testing occurs but insight into the level of patient education that is needed when testing is conducted. Providers need training on patient-directed tools to help patients of all literacy levels understand biomarker testing and their results. Additionally, training in organizational health literacy has been cited by the Centers for Disease Control and Prevention as a critical component of bridging the gap in patient health literacy.²⁰

This study has some limitations. While results from clinical assessment research demonstrate that case vignettes, compared with other methods of measuring processes of care (e.g., chart review and standardized patients), are a valid, non-invasive, and cost-effective method of determining clinician practice and intent,²¹⁻²⁴ only a subset of potential scenarios were used. Further, these results represent a small convenience sample of 99 ACCC member clinicians.

In summary, this study shows inherent biases in the ordering of biomarker testing for patients with NSCLC and a need for improved practical training for the cancer care team on the assessment of health literacy. Community-based initiatives may be a promising outlet, as poor health literacy has been shown to be linked to marginalized neighborhoods²⁵ and health literacy has been determined to be a modifiable risk factor for achieving equity in healthcare.²⁶ Further, community initiatives related to precision medicine that integrate diverse patients in the design of awareness and educational campaigns are viewed as more trustworthy within ethnically

diverse communities.²⁷ Next, study authors will develop an intervention, based on a validated care sequence tool, to ensure discussions about biomarker testing are easily integrated into care pathways for every patient with NSCLC.

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The full version of this article, including Tables 1-3, can be found online at acc-cancer.org/eliminating-disparities.

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TABLE 1. Clinician Respondent Demographics (n = 99)

	Percentage (%)
Clinical Role	
Medical oncologist or hematologist/oncologist	40%
Radiation oncologist/radiologist	20%
Pulmonologist	15%
Pathologist	8%
Medical director	8%
Surgical oncologist	5%
Other (oncology nurse, oncology pharmacist, etc.)	4%
Years in cancer practice after training	
1-4	14%
5-10	29%
11-20	41%
Over 20	15%
Practice setting	
Academic	32%
Community	68%
Practice location	
Urban	49%
Suburban	43%
Rural	8%
Patients with NSCLC treated each month by cancer program	
None	0%
Less than 20	14%
21-50	45%
51-100	20%
More than 100	20%
Has taken any cultural competency or cultural humility training?	
Has had training in any of the following areas within cultural competency:	
Race/ethnicity	32%
Gender/sex	27%
Age	20%
Disability	20%
Sexual orientation	19%
Religion	15%
Socio-economic status	14%

TABLE 2. Clinician Approach to Biomarker Testing: Patient Case Study 1

Case 1: A 64-year-old Caucasian female with a 30-year history of “social” smoking and recent onset of lethargy and cough. A chest X-ray shows a new right-sided focal lesion and possibly enlarged hilar lymph nodes. She denies bone pain, neurologic symptoms, or any other complaints. A chest CT reveals a peripheral right upper lobe mass with hilar lymphadenopathy consistent with lung cancer. You order a bronchoscopic lung biopsy for tissue diagnosis.

	Percentage (%)
Likelihood to have a discussion with patient about biomarker testing at some point?	
Not at all likely	4%
Slightly likely	2%
Moderately likely	15%
Very likely	34%
Extremely likely	44%
For what reason(s) do you order or recommend biomarker testing in your patients with lung cancer? (select all that apply)	
1-4	14%
5-10	29%
11-20	41%
Over 20	15%
How significant are the following factors in your approach to discussing biomarker testing with this patient? (1-5 scale: 1 = not at all significant, 5 = extremely significant)	
Patient’s level of interest in being involved in decision making	3.81%
Patient’s insurance status and coverage	3.37%
Patient’s family support	3.25%
Patient’s health literacy	3.42%
In general, how significant are the following patient factors that may impede your use of biomarker testing in patients with lung cancer? (1-5 scale: 1 = not at all significant, 5 = extremely significant)	
Histology	3.87%
Clinical trial eligibility	3.47%
Patient preference	3.47%
Patient’s general health/fitness	3.37%
Insurance coverage	3.23%
Patient age	3.23%
Smoking history	3.13%
Patient’s health literacy	2.86%
Presence of a caregiver	2.75%
Race/ethnicity	2.66%
Gender	2.57%

CT = Computed tomography

TABLE 3. Clinician Approach to Order Biomarker Testing: Patient Case Studies 2-5

CASE 2: Patient was recently diagnosed with Stage IV NSCLC with metastasis to the liver. 1) He works as a vice president for a management consulting firm or 2) He is unemployed and has been staying at local shelters since being evicted from his apartment one week ago. Medical history prior to cancer included only seasonal allergies and medication-managed hypertension. The patient has an adequate performance status and, as such, is a candidate for systemic therapy. As of today, no biomarker testing has been performed.

	High SES (n=49)	Low SES (n=50)
How likely are you to order biomarker testing for this patient?		
Not at all likely	0%	0%
Slightly likely	0%	0%
Moderately likely	12%	18%
Very likely	31%	50%
Extremely likely	57%	32%

CASE 3: The patient is 1) a 42-year-old or 2) 76-year-old female with locally advanced, non-resectable NSCLC. History and physical suggest no major comorbidities, and her ECOG performance status is 1. The patient is open to systemic therapy options, if available.

	Young patient (n=50)	Older patient (n=49)
How likely are you to order biomarker testing for this patient?		
Not at all likely	0%	2%
Slightly likely	2%	0%
Moderately likely	12%	10%
Very likely	32%	39%
Extremely likely	54%	49%

CASE 4: A 68-year-old 1) African American or 2) Asian male with Stage IV NSCLC is referred to your clinic for a discussion of available treatment options. Outside records confirm his diagnosis and adequate imaging is available, but you find that no molecular testing has been performed.

	African American patient (n=49)	Asian Patient (n=50)
How likely are you to order biomarker testing for this patient?		
Not at all likely	0%	0%
Slightly likely	2%	4%
Moderately likely	6%	10%
Very likely	41%	30%
Extremely likely	51%	56%

CASE 5: The patient has Stage IV NSCLC and is being seen at your facility for the first time. When performing her initial assessment, the clinic nurse noted that the patient appeared to have trouble completing the new patient survey and further questioning 1) led to a determination of low health literacy or 2) fielded several complex questions the patient wanted answered, and it was noted the patient appeared to have high health literacy.

	Low health literacy (n=50)	High health literacy (n=49)
How likely are you to order biomarker testing for this patient?		
Not at all likely	2%	0%
Slightly likely	6%	0%
Moderately likely	22%	8%
Very likely	38%	29%
Extremely likely	32%	63%