ASSOCIATION OF COMMUNITY CANCER CENTERS

IMPROVING CARE COORDINATION FOR ADVANCED NSCLC

RESULTS FROM A NATIONAL QUALITY SURVEY FOR PATHOLOGISTS AND PULMONOLOGISTS

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Lung cancer is the leading cause of cancer-related deaths in the United States,[1] accounting for approximately 25 percent of all cancer deaths.[2] According to estimates from the American Cancer Society, more than 220,000 new cases of lung cancer will be reported in 2020.[1] While the prognosis of lung cancer remains poor, important advances in lung cancer screening, diagnosis, staging, and treatment over the past decade have translated into an improvement in overall survival.[3]

Non-small cell lung cancer (NSCLC), which accounts for more than 85 percent of all lung cancer diagnoses,[4] remains a complex and unpredictable disease at presentation, owing to its heterogeneity (differences between tumors of the same type in different patients, and between cancer cells within a tumor; both can lead to different responses to therapy).[5] Consequently, key components of optimal care delivery for patients with NSCLC include complete and accurate staging of patients to assess the extent of disease[6] and obtaining an adequate sample for accurate tumor subtyping.[7] These steps are of critical importance as inaccurate clinical staging can result in incorrect treatment,[6] while inadequate tumor sampling may delay detailed molecular characterization.[7] In addition, a multidisciplinary approach remains the cornerstone of NSCLC management, especially for locally advanced NSCLC.[8] Indeed, it has been reported that multidisciplinary teams provide improved adherence to evidence-based guidelines and better-informed treatment decisions, which in turn translate to improved clinical outcomes.[9,10] Notably, pathologists[11] and pulmonologists[12] are an intrinsic part of lung cancer multidisciplinary teams. Recent advances in pathology and the advent of personalized therapy have resulted in pathologists playing a pivotal role in many aspects, including diagnosis, tumor typing and subtyping, and molecular testing.[11] Likewise, pulmonologists play a crucial role in the prompt diagnosis, staging, and treatment of patients with lung cancer.[12] Moreover, they often manage comorbidities and are increasingly involved with palliative and end-of-life care.[12]

Despite the availability of an array of treatment options for patients with NSCLC, fragmentation in the U.S. healthcare system can prevent patients from gaining consistent access to optimal care.[13] Moreover, the approval of multiple agents with a similar mechanism of action presents clinicians with a complex decision making process, especially due to limited availability of comparative efficacy data.[14] In addition, the increased availability of predictive biomarkers and other diagnostic testing can also result in more complexity in treatment planning and decision making, particularly for patients with stage III and IV NSCLC.[13, 14] Consequently, there remains an overarching need to identify and provide guidance on key issues related to the optimal care of patients with NSCLC across different community cancer programs/settings in the U.S.

To address this need, a multiphase project, involving a multidisciplinary team, was implemented by the Association of Community Cancer Centers (ACCC) and its partner organizations, with the main goal being to support the optimization of care for patients diagnosed with stage III and IV NSCLC.[13] Here, we report results from subanalyses of the ACCC survey that were undertaken to analyze discipline-specific survey findings from the perspectives of pathologists and pulmonologists, who serve as key advisors within oncology multidisciplinary teams, in order to inform NSCLC guidelines on quality of care.

Study Design

Full details of the study design, including the survey instrument, were reported previously.[15] In brief, this was a national, double-blind, comprehensive online survey undertaken between January 24, 2019, and April 25, 2019, as the first phase of the multiphase project. Since the study did not involve patient data, details that could be linked to protected health information, or the identification of a specific hospital or facility, a request for review and approval was not submitted to an Institutional Review Board.

Sample and Setting

Participants were oncology multidisciplinary team members, including thoracic surgeons, radiation oncologists, medical oncologists, pulmonologists, pathologists, and representatives from patient advocacy groups. Demographic information including profession/specialty of the survey respondent, type of affiliated cancer program, and location and region (i.e., rural/suburban/urban) of the primary cancer program was collected. Responders

who did not specify the cancer program type were included in an "unknown" category. The survey was customized for each oncology multidisciplinary team specialist, with questions encompassing screening, diagnosis, staging, treatment, and care coordination for patients with NSCLC.

This article focuses on the roles of pathologists and pulmonologists as key advisors within multidisciplinary teams from U.S. cancer programs and examines relevant care delivery practices in relation to treatment-related outcomes through subanalyses of the ACCC survey questions and findings. Research questions were formulated to examine relationships between relevant care delivery practices at community-based oncology programs and outcomes related to treatment, diagnosis, familiarity with current diagnostic modalities and guidelines, genomic profiling, criteria for unresectability, and challenges encountered in clinical practice (Table 1, right).

Statistical Analysis

Descriptive statistics were calculated for select survey questions relevant to pathologists and pulmonologists and statistical tests, including Pearson's chi-square crosstabulation, independent t-test, and linear-by-linear association, were performed for the subanalyses. Sample size varied for each research question based on the variables used in the subanalyses. Categorical data were presented as an absolute number (proportion). Parametric analyses were supplemented with nonparametric equivalents for continuous variables with non-normal distributions, and statistical significance was determined based on the P values of these nonparametric tests.

Results

The analyses included a total of 639 participants from 160 unique oncology programs across 44 states in the U.S. Of these, 17.8 percent (n=114) were pathologists and 8.9 percent (n=57) were pulmonologists. Most responders indicated that a pathologist was almost always (26.6 percent, n=63/237) or frequently (27.0 percent, n=64/237) present at the bedside to assess the adequacy of samples. Similarly, most responders indicated that a cytotechnician was almost always (35.0 percent, n=82/234) or frequently (20.9 percent, n=49/234) present at the bedside to assess the adequacy of samples. Overall, 40.5 percent (n=177/437) of responders indicated that they almost always followed a pathology-driven reflex biomarker testing protocol; however, a small proportion of responders (11.0 percent, n=48/437) indicated that they had no plans for developing such a protocol.

Outcomes: Research Questions 1 and 2

No association was observed between outcomes (time-to-treatment initiation) and the use of a pathology-driven reflex biomarker testing protocol (P=0.407). However, a significant positive association was observed between the bedside presence of a pathologist for assessing the adequacy of samples and the frequency of inadequate computed tomography (CT)-guided needle biopsy (r=0.226, P=0.018) or bronchoscopic biopsy (r=0.161, P=0.014). No significant association was observed for the combined measure of bedside presence of a pathologist or a cytotechnician to assess for sample adequacy and the frequency of inadequate CT-guided needle biopsy (r=0.181, P=0.059) or bronchoscopic biopsy (r=0.073, P=0.267).

Diagnosis and Screening: Research Question 3

Most responders (47.8 percent, n=54/113) indicated that 3 to 5 pathologists provided diagnostic services for patients with lung cancer at their program. Similarly, most responders (49.1 percent, n=28/57) also indicated that 3 to 5 pulmonologists performed transbronchial biopsies and/or provided care for patients with lung cancer. No significant difference was observed in the average number of pathologists providing diagnostic services (P=0.368) or pulmonologists performing transbronchial biopsies and/or providing care for patients with lung cancer (P=0.169) across program types. However, a numerically greater proportion of responders from the Academic Comprehensive Cancer Program (ACAD) reported that 1 to 2 pulmonologists (44.4 percent, n=4/9) rather than 3 to 5 (7.1 percent, n=2/28) or ≥11 (30.8 percent, n=4/13) pulmonologists performed biopsies and/or cared for patients with lung cancer.

Diagnosis and Screening: Research Question 4

During bronchoscopic biopsy for patients with suspected stage III and IV NSCLC, a significant correlation was observed between the number of biopsies obtained by pulmonologists and the number of biopsies submitted to pathologists (P<0.0001). While a greater proportion of pathologists than pulmonologists reported receiving two to three biopsies, a greater proportion of pulmonologists reported submitting four to six biopsies for review.

Diagnosis and Screening: Research Question 5

Overall, no significant difference was observed in the number of patients with NSCLC treated per year by pulmonologists versus responders from other specialties (P=0.33). Since treatment was not further defined in the survey question, the interpretation by pulmonologists may encompass prescription of an inhaler, participation in multidisciplinary team care, or other aspects. In line with responders from other specialties, most pulmonologists treated 20 to 50 patients (32.7 percent, n=18/55) with NSCLC per year, followed by pulmonologists who treated 101 to 200 patients (23.6 percent, n=13/55), > 200 patients (21.8 percent, n=12/55), 51 to 100 patients (20 percent, n=11/55), and <20 patients (1.8 percent, n=1/55) with NSCLC per year.

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Table 1. Research Questions to Examine Relevant Care Delivery Practices

Outcomes

1. Does the presence of a pathology-driven reflex biomarker testing protocol influence outcome?
2. Does the bedside presence of a pathologist or a cytotechnician during a biopsy procedure influence the amount of tissue obtained during the procedure?

Diagnosis

3. To what extent does the availability of a pathologist or pulmonologist differ by program type?
4. Is there a disconnect between the number of samples that pathologists obtain and the number of samples that pulmonologists think they obtain?
5. What is the role of pulmonologists in the diagnosis of NSCLC?

Familiarity with current diagnostic modalities

6. Is there a difference in knowledge on biomarker testing among pathologists and pulmonologists as compared with other specialties and by program type?

Genomic profiling

7. To what extent does the use of broad genomic profiling using NGS for biopsy samples differ among pathologists and pulmonologists?

Familiarity with current guidelines

8. To what extent does pathologist and pulmonologist familiarity with current guidelines for NSCLC management differ by region or program type?

Unresectability criteria

9. Is there a difference in criteria determining unresectability in stage III NSCLC by region or program type?

Other

10. Is there a difference in the availability of NSCLC protocols on criteria for unresectability by region/program type?

Challenges

11. To what extent are the challenges faced by pathologists and pulmonologists different from those faced by other specialties?

Abbreviations: NGS, next-generation sequencing; NSCLC, non-small cell lung cancer.

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Familiarity with Current Diagnostic Modalities: Research Question 6

Pathologists

Although most pathologists (66.7 percent, n=74/111) were familiar with the use of next-generation sequencing (NGS) for NSCLC, a substantial proportion (33.3 percent, n=37/111) were not familiar with NGS. The familiarity of pathologists with the use of NGS was not significantly different versus that of responders from other specialties (X^2=0.243, P=0.622) and did not show any significant association by cancer program (X^2=9.352, P=0.405). A comparable proportion of pathologists were familiar versus not familiar with the use of liquid biopsy testing (52.3 percent [n=58/111] versus 47.7 percent [n=53/111]) and tumor mutational burden (TMB) (48.6 percent [n=54/111] versus 51.4 percent [n=57/111]). However, compared with responders from other specialties, a significantly greater proportion of pathologists were not familiar with the science around liquid biopsy testing (47.7 percent [n=53/111] versus 35.4 percent [n=107/302]; X^2=5.189, P=0.023) and TMB (51.4 percent [n=57/111] versus 39.1 percent [n=118/302]; X^2=5.011, P=0.025) for NSCLC. By program type, fewer non-pathologists from unknown programs were familiar versus not familiar with the use of liquid biopsy testing (8.7 percent [n=17/195] versus 24.3 percent [n=26/107]). Similarly, fewer non-pathologists from National Cancer Institute-Designated Network Cancer Programs (NCIN) were familiar versus not familiar with the use of TMB for NSCLC (1.1 percent [n=2/184] versus 5.1 percent [n=6/118]). In contrast, more pathologists from the Integrated Network Cancer Program (INCP) were familiar versus not familiar with the use of TMB (13 percent [n=7/54] versus 1.8 percent [n=1/57]).

Pulmonologists

Although most pulmonologists (64.8 percent, n=35/54) were familiar with the use of NGS for NSCLC, a substantial proportion (35.2 percent, n=19/54) were not familiar with the use of NGS. Compared with responders from other specialties, no significant difference was observed in the proportion of pulmonologists familiar with the use of NGS (X^2=0.396, P=0.529), liquid biopsy testing (X^2=0.105, P=0.746), and TMB (X^2=1.48, P=0.224) for NSCLC. By program type, more non-pulmonologists from the Veterans Affairs Cancer Program (VACP) were not familiar versus familiar with the use of NGS (1.8 percent [n=2/111] versus 0.0 percent [n=0/248]); however, more pulmonologists from unknown programs were not familiar versus familiar with NGS (36.8 percent [n=7/19] versus 8.6 percent [n=3/35]).

A numerically greater proportion of pulmonologists were familiar versus not familiar with the use of liquid biopsy testing (59.3 percent [n=32/54] versus 40.7 percent [n=22/54]). However, an equal number of pulmonologists were familiar versus not familiar with TMB (50 percent [n=27/54] versus 50 percent [n=27/54]). By program type, more non-pulmonologists from unknown programs were not familiar versus familiar with the use of liquid biopsy testing for NSCLC (21.7 percent [n=30/138] versus 9 percent [n=20/221]); however, more pulmonologists from the NCIN program (13.6 percent, [n=3/22] versus 0.0 percent [n=0/32]) and unknown programs (36.4 percent [n=8/22] versus 6.3 percent [n=2/32]) were not familiar with liquid biopsy. By program type, more non-pulmonologists from unknown programs were not familiar versus familiar with the use of TMB (19.6 percent [n=29/148] versus 10 percent [n=21/211]); however, more pulmonologists from the Hospital Associate Cancer Program (HACP) program were familiar versus not familiar with TMB (22.2 percent [n=6/27] versus 3.7 percent [n=1/27]), while more pulmonologists from unknown programs were not familiar versus familiar with TMB (29.6 percent [n=8/27] versus 7.4 percent [n=2/27]).

Genomic Profiling: Research Question 7

Most pathologists (54.7 percent, n=58/106) occasionally performed broad genomic profiling using NGS for patients with NSCLC; this was followed by pathologists who routinely (28.3 percent, n=30/106) or rarely (17 percent, n=18/106) performed genomic profiling. Similarly, most pulmonologists occasionally (48.8 percent, n=21/43) or routinely (46.5 percent, n=20/43) performed NGS, while a small proportion of pulmonologists (4.7 percent, n=2/43) rarely performed these tests.

The use of NGS by pathologists and pulmonologists did not significantly vary by region (pathologists: X^2=2.212, P=0.697; pulmonologists: X^2=1.497, P=0.827) or program (pathologists: X^2=27.693, P=0.067; pulmonologists: X^2=17.259, P=0.505). However, several differences were observed within specific programs. For example, more pathologists from the VACP rarely ordered NGS for NSCLC (11.1 percent, n=2/18), while no pathologists ordered NGS occasionally (0.0 percent, n=0/58) or routinely (0.0 percent, n=0/30). Similarly, more pulmonologists from the NCIN rarely ordered NGS for NSCLC (50 percent, n=1/2), while no pulmonologists ordered NGS occasionally (0.0 percent, n=0/21).

Familiarity with Current Guidelines: Research Question 8

In terms of familiarity with the 8th edition of the American Joint Committee on Cancer tumor/node/metastasis (TNM) staging system, most pathologists (71.9 percent, n=82/114) and pulmonologists (85.2 percent, n=46/54) were familiar with the latest NSCLC staging system. Familiarity with the staging system did not significantly differ by region among either pathologists (X^2=0.383, P=0.826) or pulmonologists (X^2=0.461, P=0.794).

Among non-pulmonologists from unknown programs, a greater proportion were familiar versus not familiar with these guidelines (9.4 percent [n=31/331] versus 22.1 percent [n=17/77]). Additionally, more pulmonologists from the VACP (12.5 percent [n=1/8] versus 0.0 percent [n=0/46]) and unknown programs (50 percent [n=4/8] versus 13 percent [n=6/46]) were not familiar versus familiar with the guidelines. In contrast, fewer non-pathologists from the VACP (0.3 percent [n=1/295] versus 3.8 percent [n=2/53]) and unknown programs (8.8 percent [n=26/295] versus 26.4 percent [n=14/53]) were familiar versus not familiar with the guidelines.

In terms of familiarity with the 2018 update to the College of American Pathologists (CAP), the International Association for the Study of Lung Cancer (IASLC), and the Association for Molecular Pathology (AMP) molecular testing guideline for lung cancer, most pathologists (73 percent, n=81/111) and pulmonologists (68.5 percent, n=37/54) were familiar with the latest molecular testing guideline. Familiarity with the molecular testing guideline did not significantly differ by region among either pathologists (X^2=0.466, P=0.792) or pulmonologists (X^2=0.469, P=0.791). By program type, more pulmonologists from the Comprehensive Community Cancer Program (CCCP) (35.3 percent [n=6/17] versus 8.1 percent [n=3/37]) and unknown programs (47.1 percent [n=8/17] versus 5.4 percent [n=2/37]) were not familiar versus familiar with the 2018 update. In contrast, fewer non-pathologists from unknown programs were familiar versus not familiar with the 2018 update (9.8 percent [n=20/204] versus 21.6 percent [n=27/125]).

Criteria for Unresectability in Stage III NSCLC: Research Question 9

With the exception of suspected mediastinal nodal metastases, no significant correlation was observed between region and any of the criteria for unresectability (contralateral mediastinal nodal metastases, bulky multi-station ipsilateral nodal metastases, mediastinal nodal metastases confirmed by biopsy, CT, or positron emission tomography [PET]/CT evidence of mediastinal nodal metastases, and low-volume multi-station or single nodal station ipsilateral nodal metastases). However, some variation between regions was observed; for example, more urban responders indicated that suspected mediastinal nodal metastases were unresectable rather than resectable (76.9 percent [n=40/52] versus 55.7 percent [n=327/587]). Conversely, more suburban responders indicated that suspected mediastinal nodal metastases were resectable rather than unresectable (33.9 percent [n=199/587] versus 19.2 percent [n=10/52]). In a comparison between pulmonologists and other responders by region, differences were observed between pulmonologists from urban regions who indicated that suspected mediastinal nodal metastases were unresectable (83.3 percent [n=10/12]) rather than resectable (51.1 percent [n=23/45]) and between other responders from urban regions (75 percent [n=30/40] versus 56.1 percent [n=304/542], respectively).

With the exception of low-volume multi-station ipsilateral nodal metastases, criteria for unresectability varied by program type. For contralateral mediastinal nodal metastases, more responders from the ACAD program (22 percent [n=35/159] versus 12.5 percent [n=60/480]) and unknown programs (17.6 percent [n=28/159] versus 10.8 percent [n=52/480]) indicated that these were unresectable rather than resectable. In contrast, more responders from the HACP program indicated that these were resectable rather than unresectable (11 percent [n=53/480] versus 5.7 percent [n=9/159]). For bulky multi-station ipsilateral nodal metastases, more responders from the ACAD program indicated that these were unresectable rather than resectable (23.2 percent [n=32/138] versus 12.6 percent [n=63/501]). For mediastinal nodal metastases confirmed by biopsy, more responders from the ACAD program (21.5 percent [n=29/135] versus 13.1 percent [n=66/504]), and unknown programs (18.5 percent [n=25/135] versus 10.9 percent [n=55/504]) indicated that these were unresectable rather than resectable. In contrast, more responders from the NCIP program indicated that these were resectable rather than unresectable (16.5 percent [n=83/504] versus 7.4 percent [n=10/135]). For CT or PET/CT evidence of mediastinal nodal metastases, more responders from the INCP program (10.4 percent [n=10/96] versus 3.7 percent [n=20/543]) and the ACAD program (24 percent [n=23/96] versus 13.3 percent [n=72/543]) indicated that these were unresectable rather than resectable. However, more responders from the NCIP program indicated that these were resectable rather than unresectable (16.2 percent [n=88/543] versus 5.2 percent [n=5/96]). For suspected mediastinal nodal metastases, more responders from the INCP program indicated that these were unresectable rather than resectable (13.5 percent [n=7/52] versus 3.9 percent [n=23/587]). In contrast, more responders from the NCIP program indicated that these were resectable rather than unresectable (15.5 percent [n=91/587] versus 3.8 percent [n=2/52]). For low-volume single nodal station ipsilateral nodal metastases, more responders from the NCIP program indicated that these were resectable rather than unresectable (15.3 percent [n=93/609] versus 0.0 percent [n=0/30]).

A comparison was also conducted for pulmonologists and other responders by program type. For contralateral mediastinal nodal metastases, differences were observed among pulmonologists from HACP (5.3 percent [n=2/38] versus 26.3 percent [n=5/19]) and other responders from CCCP (9.9 percent [n=12/121] versus 17.4 percent [n=804/461]) and ACAD (23.1 percent [n=28/121] versus 12.4 percent [n=57/461]) who indicated that these were unresectable rather than resectable, respectively (other responders: X^2=19.333, P=0.023). For bulky multi-station ipsilateral mediastinal nodal metastases, differences were observed among other responders from ACAD (22.9 percent [n=25/109]

versus 12.7 percent [n=60/473]), HACP (2.8 percent [n=3/109] versus 11 percent [n=52/473]), and other programs (19.3 percent [n=21/109] versus 10.1 percent [n=48/473]) who indicated that these were unresectable rather than resectable, respectively (other responders: X^2=28.458, P=0.001). For mediastinal nodal metastases confirmed by biopsy, differences were observed among other responders from CCCP (9.2 percent [n=10/109] versus 17.3 percent [n=82/473]), ACAD (22.9 percent [n=25/109] versus 12.7 percent [n=60/473]), NCIP (6.4 percent [n=7/109] versus 16.7 percent [n=79/473]), and other programs (17.11 percent [n=19/109] versus 10.6 percent [n=50/473]) who indicated that these were unresectable rather than resectable, respectively (other responders: X^2=25.836, P=0.002). For CT or PET/CT evidence of mediastinal nodal metastases, differences were observed among other responders from INCP (11.5 percent [n=9/78] versus 3.8 percent [n=19/504]), ACAD (25.6 percent [n=20/78] versus 12.9 percent [n=65/504]), and NCIP (5.1 percent [n=4/78] versus 16.3 percent [n=82/504]) who indicated that these were unresectable rather than resectable, respectively (other responders: X^2=25.340, P=0.003). For suspected mediastinal nodal metastases, differences were observed among other responders from INCP (15 percent [n=6/40] versus 4.1 percent [n=22/542]) who indicated that these were unresectable rather than resectable, respectively (other responders: X^2=18.039, P=0.035). For low-volume multi-station ipsilateral nodal metastases, differences were observed among pulmonologists from HACP (38.5 percent [n=5/13] versus 4.5 percent [n=2/44]) and other responders from other programs (23.7 percent [n=9/38] versus 11 percent [n=60/544]) who indicated that these were unresectable rather than resectable, respectively (other responders: X^2=10.926, P=0.281). For low-volume single nodal station ipsilateral nodal metastases, differences were observed among pulmonologists from VACP (14.3 percent [n=1/7] versus 0.0 percent [n=0/50]) and other responders from ACAD (30.4 percent [n=7/23] versus 14 percent [n=78/559]) and NCIP (0.0 percent [n=0/23] versus 15.4 percent [n=86/559]) who indicated that these were unresectable rather than resectable, respectively.

Other: Research Question 10

A comparable proportion of responders indicated that their cancer program did versus did not have specific protocols that defined resectability for stage III NSCLC (44.4 percent [n=103/232] versus 44.8 percent [n=104/232], respectively). A small proportion of responders were unsure as to whether such protocols were available (10.8 percent [n=25/232]).

The availability of NSCLC protocols on criteria for unresectability did not vary significantly by program type (X^2=23.721, P=0.164) but varied significantly by region (X^2=10.716, P=0.03). More responders from rural regions reported that their cancer program did versus did not have specific protocols that define resectability for stage III NSCLC (12.5 percent [n=13/104] versus 2.9 percent [n=3/103]).

Challenges: Research Question 11

Overall, the challenges faced by pulmonologists and pathologists were different from those encountered by responders from other specialties.

Pathologists

In terms of caring for patients with advanced/metastatic NSCLC, the most significant challenge faced by pathologists versus responders from other specialties was primary care providers (PCPs) not referring patients with suspected NSCLC for screening (P=0.032). More pathologists (15.7 percent, n=16/102) versus responders from other specialties (6.4 percent, n=29/452) indicated that patient refusal to undergo biopsy or other tests significantly impacted NSCLC diagnosis and/or staging. More pathologists versus responders from other specialties considered cost-related barriers to significantly impact on NSCLC diagnosis and/or staging (28.8 percent [n=30/104] versus 16.1 percent [n=73/453]).

Pulmonologists

Compared with responders from other specialties, the most significant barrier faced by pulmonologists in caring for patients with advanced/metastatic NSCLC was scheduling challenges and/or access to a CT scanner (P<0.0001). Overall, PCPs not referring patients for screening was considered less of a challenge for pulmonologists versus responders from other specialties (P<0.001). Compared with responders from other specialties, more pulmonologists considered scheduling (18.9 percent [n=10/53] versus 7.6 percent [n=26/342]) and non-referral of patients (44.4 percent [n=24/54] versus 28.4 percent [n=94/331]) as barriers that significantly impacted lung cancer screening. Most pulmonologists indicated that cost-related barriers had a minimal impact on screening versus responders from other specialties (56.9 percent [n=29/51] versus 38.5 percent [n=126/327]); however, most responders from other specialties indicated that cost had some impact on screening versus pulmonologists (40.7 percent [n=133/327] versus 23.5 percent [n=12/51]).

Discussion

The ACCC survey provides valuable insights into how pathologists and pulmonologists function as part of a multidisciplinary team involved in the diagnosis and management of patients with stage III/IV NSCLC in U.S. cancer programs. Most responders indicated that three to five pathologists and pulmonologists were involved in providing diagnostic services or performing transbronchial biopsies, respectively, at their cancer programs. Accurate diagnosis has important implications for patient care[16] and increasingly requires both pathologists[11] and pulmonologists[12] to interact closely with other members of the multidisciplinary team. Overall, a significant positive association was observed

between the bedside presence of a pathologist and the frequency in which samples were considered inadequate for molecular testing using techniques such as CT-guided needle biopsy or bronchoscopic biopsy. This unexpected finding may be a consequence of response bias and temporality of these survey questions, with respondents perhaps reporting their initial assessment of sample inadequacy and modifying their practices accordingly.

Ensuring the availability of adequate samples is key to accurate diagnosis and molecular testing.[7] Accordingly, there is a need for greater guidance around the most appropriate techniques to obtain tissue samples of adequate size and quality at the first biopsy, a fact highlighted by differences in opinion reported from two surveys of 250 U.S.-based pathologists and 100 pulmonologists from the American College of Chest Physicians as to the most appropriate method for obtaining tissue samples.[17] Moreover, the biggest challenge encountered by both pulmonologists and pathologists in terms of biomarker testing was not always being able to acquire a tissue sample of sufficient size (60 percent and 73 percent, respectively) or quality (31 percent and 39 percent, respectively).[17] Likewise, in a global survey of 562 oncologists from 10 countries (including the U.S.), insufficient tissue sample was identified as one of the main reasons for not performing epidermal growth factor receptor mutation testing.[18]

Other commonly reported reasons for inadequate biopsy samples include a change in molecular testing strategy that may render the process of collecting and processing specimens inadequate,[19] poor specimen quality,[20] and the technique used for sample evaluation—for example, preparation of cell blocks may lead to cross-linking and chemical modification of DNA.[21] Notably, the acquisition of an inadequate tissue sample may lead to the need for repeat procedures, which could potentially negate the minimally invasive aspect of the diagnostic procedure.[7] Hence, a need exists to implement guidelines on optimal techniques for acquiring samples of adequate size and quality to facilitate accurate diagnosis and prevent patients from having to undergo additional invasive procedures for sample procurement.[17, 22] Consequently, the development and standardization of algorithms or protocols for the diagnosis and staging of NSCLC will optimize diagnostic accuracy, ensure the procurement of adequate tissue samples, maximize testing efficiency, and help inform treatment decisions.[23, 24]

Notably, results from a systematic review and meta-analysis of 25 studies that assessed the effect of rapid on-site evaluation on sample adequacy and diagnostic yield highlighted that the rapid evaluation of specimens at the time of the procedure improved the adequacy rates of fine-needle aspiration cytology across a wide range of tissue types by 12 percent, although considerable variability across studies was observed.[25] More recently, an expert panel was convened to perform a systematic review and released evidence-based recommendations on appropriate collection and handling of thoracic small biopsy and cytology samples.[22] These recommendations included the use of rapid on-site evaluation for adequacy assessment, if available and clinically feasible, in case of transthoracic needle procedures (strong recommendation with moderate evidence) and for transbronchial needle aspirates, if available (recommendation with moderate evidence).[22]

Sample adequacy can also be ensured by optimizing tissue handling after acquiring biopsy samples and collaborating closely with other members of the multidisciplinary team, such as pulmonologists and intervention radiologists.[26] Indeed, on-site evaluation of biopsy samples by cytotechnologists, with consultation or interpretation provided by cytopathologists, has shown to improve the assessment of sample adequacy,[27] enhance diagnostic yield,[28] and reduce false-negative rates.[28] In addition, timely feedback from pathologists to clinicians about sample adequacy can increase the likelihood of obtaining a diagnostic result.[29]

Accurate diagnosis and staging of lung cancer are essential in terms of making informed treatment decisions,[6, 16] and both pathologists[11] and pulmonologists[12] play an important role in this regard. Pulmonologists are not only involved in the diagnosis, staging, and treatment of patients with lung cancer but also have key roles in the interpretation of clinical and radiographic findings, the performance of interventional procedures, such as endobronchial ultrasound, and the development and implementation of algorithms for the diagnosis and treatment of lung cancer.[12] Pathologists play an important role in maximizing the diagnostic yield from biopsy samples, which is a limited and precious resource.[30] Unsurprisingly therefore, the majority of pathologists (71.9 percent) and pulmonologists (85.2 percent) participating in the survey reported being familiar with the latest NSCLC staging system, further highlighting their valuable role as part of a multidisciplinary team. However, although most pathologists and pulmonologists were familiar with the use of diagnostic modalities and current treatment guidelines, a sizeable proportion were familiar with neither (between 14.8 percent and 50 percent of responders from both disciplines). Moreover, although responders from both disciplines were familiar with NGS (66.7 percent of pathologists and 64.8 percent of pulmonologists), a significantly greater proportion of pathologists were not familiar with the science around liquid biopsy (47.7 percent) and TMB (51.4 percent) compared with responders from other specialties. Among pulmonologists, 59.3 percent and 50 percent were familiar with the science around liquid biopsy testing and TMB, respectively. In comparison, 86.2 percent, 77.1 percent, and 78.9 percent of medical oncologists participating in the survey were familiar to very familiar with the use of NGS and the science around liquid biopsy and TMB, respectively.[31] These findings therefore underscore the need for increasing awareness and improving education among pathologists and pulmonologists about diagnostic modalities and current treatment guidelines for the management of NSCLC.

This is of paramount importance as familiarity with guidelines can inform decision making in relation to appropriate diagnostic testing and the overall treatment plan.

Notably, only 28.3 percent of pathologists and 46.5 percent of pulmonologists routinely ordered NGS testing for patients with NSCLC despite the majority (66.7 percent of pathologists and 64.8 percent of pulmonologists) being familiar with the procedure. Moreover, only 40.5 percent of responders indicated that they almost always followed a pathology-driven reflex biomarker testing protocol. These results are in line with findings from two surveys that reported that although one-third of pathologists (33 percent) and nearly half of pulmonologists (43 percent) implemented reflex testing in their programs or in local healthcare communities, there remains the potential to significantly increase its use.[17] Taken together, these findings clearly highlight the need for greater awareness and adoption of genomic profiling and reflex testing. However, current barriers to more widespread adoption, which should be overcome, include inadequate tissue samples for processing and molecular analysis,[32, 34] long response times,[32] poor integration into routine pathology practice, and uncertainty around reimbursement of expenses.[32]

Guidelines from CAP, IASLC, and AMP recommend that pathologist-initiated reflex testing should accommodate the intricacies of clinical management and include an open dialogue between pathologists and oncology teams.[24] Crucially, pathologist-initiated reflex testing enables an effective assessment of sample adequacy and facilitates recommendations for repeat biopsy, if required.[35] In addition, a reflex testing strategy allows pathologists to prioritize sample processing for molecular diagnostics and eliminates the need for re-review of samples, thereby reducing the time from sample submission to final result reporting, ensuring more efficient molecular testing, and increasing success rates.[35] In addition, the use of reflex testing with NGS can increase the implementation of biomarker testing.[36] However, in our survey, no significant association was observed between the time-to-treatment initiation and the use of pathology-driven reflex biomarker testing. This may be explained by the series of intervening steps from reflex testing to rapid therapy initiation, including receipt of results, interpretation by a treating clinician, prescribing targeted therapy, prior authorization processes, and applications for financial assistance programs, if relevant. Another reason may be fewer differences between reflex testing and the current standard of care, owing to evolving acceptance of these methods over time.

Overall results from the ACCC National Quality Survey conducted among multidisciplinary specialists, including oncologists, thoracic surgeons, pathologists, pulmonologists, and representatives from patient advocacy groups, reported that the most challenging barriers to delivering high-quality NSCLC screening, diagnosis, and care coordination were lack of community awareness, limited access to diagnostic procedures, and lack of patient adherence to appointment schedules, respectively.[15] Adding further knowledge in this area, this survey highlights the specific challenges and barriers faced by pathologists and pulmonologists that may impact the delivery of high-quality care for patients with NSCLC, such as poor referral from PCPs for screening, challenges with scheduling appointments, patient refusal to undergo tests, and missed appointments. Notably, barriers to lung cancer screening commonly cited by PCPs include concerns regarding the cost to patients or insurance coverage, uncertainty around patient benefits, and potential harms.[37, 38]

Consequently, raising awareness on the importance of diagnostic and molecular testing may not only assist the cancer care team but also increase referral rates from PCPs.[33] In addition, assisting PCPs in understanding reimbursement policies,[39] identifying clinical features suggestive of NSCLC through the development of referral guidelines,[40] and implementing accelerated diagnostic pathways[41] may reduce delays in diagnosis and aid PCPs in identifying patients that require further investigation. Moreover, increasing patient awareness about the availability of cancer screening services and encouraging patients to discuss these services with care providers is also recommended.[39] The education of patients around the importance of timely diagnosis may also improve their engagement with the care team. Furthermore, shared decision-making can help bridge the gap between patient expectations and treatment goals,[42,43] improve understanding about those factors that may influence patients' decision making in relation to treatment,[44] increase treatment adherence, reduce healthcare costs, and enhance overall patient satisfaction.[45]

As observed in our survey, the care of patients with NSCLC can vary between programs or regions. Indeed, such differences were observed in terms of familiarity with diagnostic modalities and guidelines among pathologists and pulmonologists. Addressing such variations will require solutions, both at an operational and educational level, that can be carefully tailored to the specific needs and challenges of each program or region to optimize success. Nevertheless, health service research has shown that multidisciplinary meetings can help decrease variations in lung cancer care,[46] and the widespread adoption of coordinated multidisciplinary care can reduce test redundancy, improve compliance with clinical pathways, and positively impact patient satisfaction.[47] In addition to streamlining of diagnostics and therapeutics, communication and collaboration between different stakeholders are important components of multidisciplinary care, leading to improvements in clinical decision-making.[46] Indeed, results from a systematic review of 37 studies reported that multidisciplinary cancer teams changed cancer management in 2 percent to 52 percent of cases.[48] There is also evidence that effective communication of decisions within the multidisciplinary team improves the patient journey and ensures smooth

transition between services.[46] Consequently, it would appear that the multidisciplinary team approach is increasingly being used in the care of patients with NSCLC in the U.S.; results from a survey reported that 57 percent of pathologists and 65 percent of pulmonologists from the U.S. routinely had discussions with a multidisciplinary team.[17] Furthermore, the majority of pathologists and pulmonologists reported consulting with oncologists (92 percent and 85 percent, respectively).[17] The establishment of multidisciplinary tumor boards to facilitate coordinated care across all disciplines, together with a concerted effort to improve education and communication on the importance of biomarker testing, for example at formal venues such as multidisciplinary tumor boards, could further improve overall care practices and potentially improve collaboration.[33]

This survey has a few limitations. There was an absence of cognitive interviews with a demonstrative cohort prior to study initiation. All survey data were self-reported and therefore could not be validated. In addition, the survey did not demonstrate an association between the multidisciplinary teams involving pathologists and pulmonologists and clinical care delivery and outcomes. Therefore, further studies are required to validate this self-reported data and explore the association between patient outcomes and cancer care delivery. However, to the best of our knowledge this is the largest and most robust health-based survey performed among U.S. cancer programs across diverse healthcare-delivery settings.

This survey, which provides an overview of decision-making processes, functioning, and barriers to optimal care for patients with stage III/IV NSCLC from the perspective of pathologists and pulmonologists, can inform process improvement efforts by providing practical solutions for strengthening various facets of care delivery across a diverse array of cancer programs in the U.S. Opportunities to improve the quality of care for patients with stage III/IV NSCLC include reducing barriers to effective screening, improving care coordination and collaboration between healthcare professionals, increasing awareness around diagnostic modalities and current treatment guidelines, enhancing patient-provider communication, and engaging patients through a shared decision-making process.

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