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Original Article

Biomarker-Guided Oncology Practice in Non–Small Cell Lung Cancer: Utilization Patterns, Turnaround Time, and Sector-Associated Access Barriers

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ABSTRACT

Background: Biomarker-guided therapy has become standard in advanced non-small cell lung cancer (NSCLC), yet real-world implementation varies across healthcare sectors. Objective: To evaluate biomarker utilization, turnaround time, and structural access barriers among oncology clinicians and to assess whether public-sector practice is associated with higher implementation burden. Methods: A cross-sectional survey of 125 oncology professionals assessed utilization of five NSCLC biomarkers, turnaround time for single-gene and next-generation sequencing testing, and the frequency and severity of access barriers. A composite Barrier Burden Score was calculated, and sector-based comparisons were performed using ANOVA. Results: EGFR testing in at least 50% of eligible patients was reported by 64.8%, PD-L1 by 68.8%, and KRAS by 53.6%. NGS turnaround exceeded 21 days in 57.6% of respondents. Patient affordability (61.6%) and absence of reimbursement (52.0%) were the most frequently reported barriers. Public-sector clinicians demonstrated significantly higher Barrier Burden Scores compared with private-sector clinicians (17.96 ± 5.82 vs. 12.23 ± 5.23; mean difference 5.73; $p = 0.003$). High biomarker utilization, defined as at least 4 of 5 markers tested in at least 50% of eligible patients, was observed in 40.8%. Conclusion: Biomarker utilization was moderate and sectorally variable, with higher cumulative barrier burden associated with public-sector practice. Financial and infrastructural constraints correspond with implementation disparities and warrant targeted system-level interventions.
Keywords: Precision oncology, NSCLC, biomarker utilization, implementation barriers, molecular diagnostics, healthcare disparities.

INTRODUCTION

Precision oncology has fundamentally transformed the management of non-small cell lung cancer by enabling treatment stratification based on tumor-specific molecular alterations rather than histologic classification alone. The identification of actionable driver mutations and immune biomarkers, including epidermal growth factor receptor (EGFR) mutations, anaplastic lymphoma kinase (ALK) rearrangements, ROS proto-oncogene 1 (ROS1) fusions, Kirsten rat sarcoma viral oncogene homolog (KRAS) mutations, and programmed death-ligand 1 (PD-L1) expression, has facilitated the development and clinical application of molecularly targeted therapies and immune checkpoint inhibitors that have substantially improved progression-free and overall survival in eligible patient populations.

The evolution of molecular testing in NSCLC has progressed from single-gene assays targeting individual mutations to multiplexed next-generation sequencing panels capable of simultaneously detecting multiple actionable alterations, thereby reducing tissue exhaustion and optimizing diagnostic yield. However, the operational complexity of NGS, including requirements for specialized laboratory infrastructure, trained bioinformatics personnel, extended turnaround time, and adequate reimbursement policies, has created practical implementation challenges in many healthcare systems.

Multiple implementation barriers to biomarker-guided oncology have been identified globally. Financial toxicity and inadequate reimbursement coverage represent dominant obstacles, while additional barriers include prolonged turnaround time, limited local laboratory capacity, tissue sample inadequacy, administrative approval delays, insufficient clinician familiarity with evolving biomarker landscapes, and unclear institutional testing pathways. Structural disparities between public and private healthcare sectors may further exacerbate inequitable access to precision medicine.

Pakistan presents a unique context for evaluating precision oncology implementation. Its healthcare system includes public government hospitals, private facilities, mixed-sector institutions, and charitable trust hospitals operating under different financing models, infrastructure capacities, and regulatory environments. The present study was designed to quantify biomarker utilization, characterize turnaround times, and identify structural and financial barriers affecting implementation across these settings.

MATERIALS AND METHODS

This cross-sectional observational study was conducted at Shalimar Hospital, Lahore, Pakistan, to evaluate real-world implementation of biomarker-guided oncology practice among clinicians involved in cancer management across the Pakistani healthcare system. The study population comprised oncology professionals actively engaged in the diagnosis, treatment, or pathological evaluation of patients with cancer across Punjab, Pakistan.

Participants were recruited using a non-probability convenience sampling strategy through institutional oncology networks and regional professional oncology associations. Electronic invitations containing the survey link were distributed to an estimated sampling frame of 310 oncology professionals between March and August 2024, yielding 125 completed responses and a response rate of 40.3%.

Data were collected through a structured, self-administered electronic questionnaire developed on the basis of published implementation science frameworks in precision oncology. The instrument underwent expert content validation and pilot testing among oncology professionals not included in the final analytic sample. Internal consistency for the 12-item barrier severity subscale was acceptable, with Cronbach's alpha of 0.74.

Biomarker utilization was operationalized as the self-reported proportion of eligible advanced NSCLC patients undergoing testing for each biomarker, categorized into ordinal response options of 0%, 1–24%, 25–49%, 50–74%, and 75–100%. High utilization was defined a priori as testing in at least 4 of 5 key biomarkers in at least 50% of eligible patients. Turnaround time categories were predefined for single-gene testing and NGS panels.

Barrier burden was quantified using a two-stage composite scoring methodology. Respondents first selected all barriers experienced in clinical practice from a predefined list of 12 implementation barriers and then rated the perceived severity of each selected barrier on a 5-point Likert scale. The Barrier Burden Score was calculated as the unweighted sum of severity ratings across all selected barriers.

Statistical analyses were conducted using IBM SPSS Statistics version 28.0 and R version 4.3.1. Descriptive statistics were reported as frequencies and percentages for categorical variables and as mean ± standard deviation and median with interquartile range for continuous variables. Chi-square tests, one-sample

proportion tests with false discovery rate correction, one-way ANOVA, and Games-Howell post hoc comparisons were applied as appropriate. Ethical approval for this study was obtained from the Institutional Review Board of the University of Lahore, Lahore, Pakistan (Approval Reference: IRB-UOL-2024/0312).

RESULTS

A total of 125 oncology professionals from Punjab, Pakistan completed the survey. Medical oncologists comprised the largest specialty group, followed by radiation oncologists and pathologists. Public/government and private sectors were represented in comparable proportions, whereas mixed-sector and charity/trust institutions constituted the remainder. While 72.0% of respondents reported access to in-house pathology services, only 36.8% had in-house molecular testing capability.

Table 1. Participant and Practice Characteristics (n = 125)

Variable	Category	n	%	95% CI
Specialty	Medical oncologist	74	59.2	50.4–67.5
	Radiation oncologist	21	16.8	11.2–24.2
	Pathologist	18	14.4	9.3–21.6
	Surgical oncologist	7	5.6	2.7–11.1
	Pulmonologist	4	3.2	1.3–7.9
	Other	1	0.8	0.1–4.3
Healthcare sector	Private	48	38.4	30.3–47.2
	Public/Government	46	36.8	28.8–45.6
	Mixed	19	15.2	9.9–22.7
	Charity/Trust	12	9.6	5.6–15.9
Years in practice	<2 years	13	10.4	6.2–17.0
	2–5 years	31	24.8	18.0–33.1
	6–10 years	35	28.0	20.8–36.5
	11–15 years	22	17.6	11.9–25.4
	>15 years	24	19.2	13.2–27.1
Cancer patients/month	<10	14	11.2	6.8–17.9
	10–25	45	36.0	28.1–44.7
	26–50	40	32.0	24.4–40.7
	>50	26	20.8	14.5–28.8
In-house pathology	Yes	90	72.0	63.5–79.3
	No	35	28.0	20.7–36.5
In-house molecular testing	Yes	46	36.8	28.8–45.6
	No	79	63.2	54.4–71.2

Turnaround time for single-gene biomarker testing clustered predominantly within the 7–14 day range, while more than half of respondents reported NGS turnaround beyond 21 days. Both single-gene and NGS turnaround time distributions were significantly associated with healthcare sector.

Table 2A. Typical TAT for Single-Gene Testing (EGFR/KRAS)

TAT Category	n	%	95% CI	Cramér's V	p-value
<7 days	12	9.6	5.6–15.9		
7–14 days	59	47.2	38.6–56.0		
15–21 days	33	26.4	19.5–34.7		
>21 days	17	13.6	8.7–20.7		
Don't know	4	3.2	1.3–7.9	0.24	0.038

Table 2B. Typical TAT for NGS Panel

TAT Category	n	%	95% CI	Cramér's V	p-value
<14 days	6	4.8	2.2–10.1		
14–21 days	38	30.4	23.0–38.9		
22–28 days	43	34.4	26.7–42.9		
>28 days	29	23.2	16.7–31.2		
Don't know	9	7.2	3.8–13.1	0.27	0.021

Among the five NSCLC biomarkers assessed, PD-L1 demonstrated the highest proportion of clinicians reporting at least 50% utilization, followed by EGFR, whereas KRAS showed the lowest utilization and did not significantly differ from the 50% benchmark.

Table 3. Utilization of NSCLC Biomarkers: Summary Indicators (n = 125)

Biomarker	75–100%	≥50%	0%	95% CI (≥50%)	p-value	FDR p
PD-L1	44.8%	68.8%	4.0%	60.1–76.4	0.008	0.020
EGFR	42.4%	64.8%	1.6%	56.0–72.7	0.018	0.030
ALK	44.0%	62.4%	2.4%	53.5–70.6	0.032	0.040
ROS1	32.0%	62.4%	3.2%	53.5–70.6	0.032	0.040
KRAS	19.2%	53.6%	5.6%	44.8–62.2	0.430	0.430

Table 4. Full Utilization Distribution for EGFR Testing in Eligible NSCLC Patients (n = 125)

Testing Proportion	n	%	95% CI	Cumulative %
0%	2	1.6	0.4–5.6	1.6
1–24%	20	16.0	10.6–23.4	17.6
25–49%	16	12.8	8.0–19.8	30.4
50–74%	28	22.4	15.9–30.5	52.8
75–100%	53	42.4	34.1–51.1	95.2
Not applicable	6	4.8	2.2–10.1	—

Table 5A. Barrier Frequency (Multi-Select; n = 125)

Barrier	n	%	95% CI	Rank
Patient affordability	77	61.6	52.8–69.7	1
No reimbursement/coverage	65	52.0	43.2–60.6	2
Long turnaround time	63	50.4	41.8–59.0	3
Limited access to targeted therapy	53	42.4	34.1–51.1	4
No local lab / limited capacity	47	37.6	29.7–46.2	5
Insufficient tissue / sample inadequacy	46	36.8	28.8–45.6	6
Administrative approval delays	42	33.6	25.9–42.2	7
Difficulty interpreting reports	37	29.6	22.3–38.1	8
Uncertainty which test to order	37	29.6	22.3–38.1	8
Unclear guidelines / no pathway	36	28.8	21.6–37.3	10
Logistics/transport	34	27.2	20.2–35.6	11
Uncertainty when to test	21	16.8	11.2–24.2	12

Table 5B. Barrier Severity Among Those Selecting Each Barrier (Likert Scale 1–5)

Barrier	Selected (n)	Mean Severity	Median	Mean × Freq	Severity Rank
Uncertainty which test	37	3.68	4	136.2	1
No local lab	47	3.55	4	166.9	2
Patient affordability	77	3.43	4	264.1	3
Limited targeted therapy	53	3.42	4	181.3	4
Long TAT	63	3.38	3	212.9	5
Insufficient tissue	46	3.37	4	155.0	6
Admin approval delays	42	3.33	3	139.9	7
No reimbursement	65	3.29	3	213.9	8

High biomarker utilization was observed in 40.8% of respondents. Mean Barrier Burden Score across all respondents was 15.22 ± 5.98. One-way ANOVA revealed a statistically significant difference in barrier burden across the four healthcare sectors, with the public sector demonstrating the highest scores.

Table 6A. Distribution of High Utilization and Barrier Burden Score (n = 125)

Indicator	Result	95% CI
High utilization (≥4/5 biomarkers in ≥50% patients)	51/125 (40.8%)	32.6–49.6
Barrier Burden Score, mean ± SD	15.22 ± 5.98	14.16–16.28
Barrier Burden Score, median (IQR)	15 (11–19)	—
Number of barriers selected, mean ± SD	4.6 ± 2.1	4.2–5.0
Mean severity per barrier, mean ± SD	3.38 ± 0.72	3.25–3.51

Table 6B. Barrier Burden Score by Healthcare Sector (One-Way ANOVA with Post-Hoc Comparisons)

Sector	Mean ± SD	Median	95% CI (Mean)	ANOVA	Effect Size
Public/Govt (n = 46)	17.96 ± 5.82	17	16.23–19.69		
Mixed (n = 19)	16.37 ± 5.04	18	13.94–18.80		
Charity/Trust (n = 12)	14.83 ± 5.80	14.5	11.15–18.52		
Private (n = 48)	12.23 ± 5.23	13	10.71–13.75	F(3,121) = 4.89, p = 0.003	η^2p = 0.108

Table 6C. Games-Howell Post-Hoc Pairwise Comparisons for Barrier Burden Score

Comparison	Mean Diff.	95% CI (Diff.)	Cohen's d	p-value
Public vs. Private	5.73	2.98–8.48	1.04	<0.001
Public vs. Mixed	1.59	−2.14–5.32	0.29	0.679
Public vs. Charity	3.13	−1.45–7.71	0.54	0.284
Mixed vs. Private	4.14	0.78–7.50	0.81	0.011
Charity vs. Private	2.60	−1.99–7.19	0.47	0.452
Mixed vs. Charity	1.54	−3.68–6.76	0.28	0.863

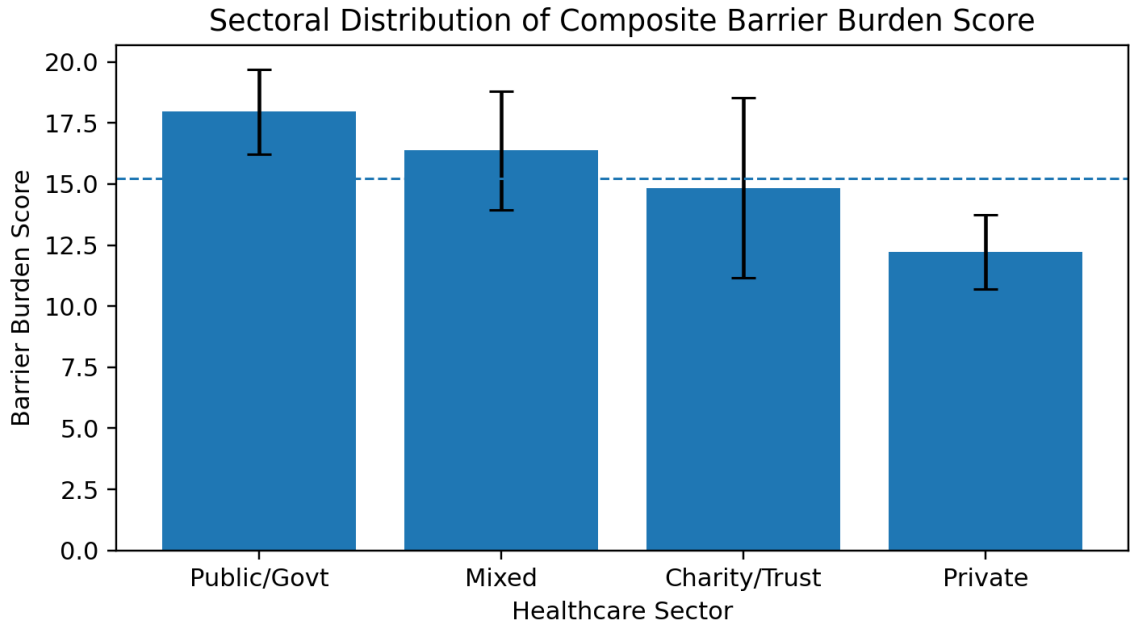

Figure 1. Sectoral Distribution of Composite Barrier Burden Score in Biomarker-Guided Oncology Practice Among Clinicians in Pakistan (n = 125)

Bars represent mean Barrier Burden Score ± 95% confidence interval by healthcare sector. The dashed horizontal line indicates the overall cohort mean of 15.22. ANOVA: F(3,121) = 4.89, p = 0.003; partial η^2 = 0.108. The primary pre-specified contrast was public versus private sector (mean difference 5.73, 95% CI 2.98–8.48, Cohen's d = 1.04, p < 0.001).

DISCUSSION

The primary hypothesis, that clinicians practicing in public-sector settings would report higher composite barrier burden scores than those in private-sector settings, was supported. Public-sector respondents demonstrated a mean Barrier Burden Score of 17.96 ± 5.82 compared with 12.23 ± 5.23 in the private sector, corresponding to a mean difference of 5.73 points. This represents a clinically meaningful differential in implementation burden across sectors.

Utilization of individual biomarkers demonstrated heterogeneity. EGFR and PD-L1 testing reached moderate levels, whereas KRAS testing remained less consistently adopted. These findings suggest that

biomarker adoption in the present cohort is meaningful but still below levels typically reported in better-resourced systems.

Turnaround time patterns further contextualized implementation capacity. Although nearly half of respondents reported single-gene testing within 7–14 days, 57.6% indicated that NGS results required more than 21 days. This likely reflects structural bottlenecks in laboratory capacity, referral pathways, and administrative processing rather than clinician reluctance alone.

Financial barriers were prominent throughout the analysis. Patient affordability and absence of reimbursement were the most frequently reported barriers, and patient affordability showed the greatest population-weighted impact when frequency and perceived severity were combined. Public-sector practice was associated with higher cumulative barrier burden, but the cross-sectional design permits only association and not causal inference.

Several limitations should be acknowledged. Practice patterns were self-reported and therefore subject to recall and social desirability bias. Geographic heterogeneity was not formally stratified, and the composite Barrier Burden Score, although internally consistent, was not externally validated against standardized implementation indices. One inconsistency in the source manuscript also requires correction: the discussion states that the response rate was not captured, although the methods and results clearly report a response rate of 40.3%.

Despite these limitations, the study provides an integrated assessment of utilization intensity, turnaround time, and structural barriers within a single analytical framework. The quantified difference in burden between public and private sectors may inform policy prioritization, particularly regarding laboratory expansion, reimbursement reform, and standardized molecular testing pathways.

CONCLUSION

Biomarker-guided oncology practice in this cohort demonstrates moderate utilization with statistically significant sectoral variation. Higher cumulative barrier burden was associated with public-sector practice, and financial constraints, reimbursement gaps, and laboratory capacity limitations were frequently reported. These findings support targeted system-level interventions aimed at improving equitable access to molecular diagnostics and optimizing precision oncology implementation pathways.

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