

Table 1: Quality indicators used to assess EBUS performance in the staging and diagnosis of lung cancer.

Quality indicator	Source	Target (if stated) or for reporting only	Comments
Staging EBUS performance			
Prevalence of N2/3 disease	UK service specification ³	Reporting only	For evaluation of sensitivity and NPV
Overall sensitivity for N2/3 disease	UK service specification ³	Dependent on N2/3 prevalence	
Overall NPV for N2/3 disease	UK service specification ³	Dependent on N2/3 prevalence	
Adequate for molecular analysis (non-squamous NSCLC)	UK service specification ³	>90%	
Diagnostic EBUS performance			
Pathological confirmation (%)	UK service specification ³	>90%	
NSCLC-NOS (%)	UK service specification ³	<10%	
Sufficient tissue for molecular analysis (non-squamous NSCLC)	UK service specification ³	>90%	
Proportion of cases requiring repeat sampling due to insufficient tissue	UK service specification ³	<10%	
Pathway-related			
EBUS performed ≤ 7 days from referral	UK service specification ³ New Zealand standards of service provision ⁴	85% 95%	
Pathology report ≤ 3 days from EBUS	Australian optimal care pathway ⁶	Reporting only	Target % compliance not stated
Pathology report ≤ 5 days from EBUS	UK service specification ³	85%	
Pathology report ≤ 7 days from EBUS	New Zealand standards of service provision ⁴	95%	
Pathology report, including molecular analysis, ≤ 10 days from EBUS (non-squamous NSCLC)	UK service specification ³	85%	
Pathology report, including molecular analysis, ≤ 14 days from EBUS (non-squamous NSCLC)	Australian optimal care pathway ⁶	Reporting only	Target % compliance not stated
Total pathway time: pathology report (including molecular analysis) ≤ 14 days from referral (non-squamous NSCLC)	UK service specification ³	Reporting only	Target % compliance not stated
Safety/adverse events			
Major/minor complications	UK service specification ³	<3% major	

Abbreviations: EBUS = endobronchial ultrasound; NPV = negative predictive value; NSCLC-NOS = non-small cell lung cancer not otherwise specified.

Table 2: Characteristics of subjects undergoing staging and diagnostic EBUS for lung cancer.

	Staging EBUS		p	Diagnostic EBUS		p
	Phase 1 n (%)	Phase 2 n (%)		Phase 1 n (%)	Phase 2 n (%)	
N	69	46		76	41	
Age						
Median, years (IQR)	73 (67–80)	72 (66–79)	0.59	70 (60–75)	70 (63–80)	0.18
Sex						
Female	36 (55)	26 (60)	0.54	40 (55)	21 (52)	0.98
Ethnicity						
European	49 (75)	32 (74)	0.8	43 (59)	26 (65)	0.84
Māori	4 (6)	4 (9)		7 (10)	5 (13)	
Pacific peoples	1 (1.5)	0		7 (10)	4 (10)	
Asian	9 (14)	7 (16)		14 (19)	5 (13)	
MELAA	1 (1.5)	0		2 (3)	0	
Other	1 (1.5)	0		0	0	
Status at time of EBUS						
Outpatient	66 (96)	43 (93)	0.68	49 (64)	25 (60)	0.71
ACCP group						
A	0	0	0.76	18 (24)	7 (17)	0.41
B	54 (78)	38 (83)		0	0	
C	14 (20)	7 (15)		0	0	
D	1 (2)	1 (2)		0	0	
Or metastatic disease	0	0		58 (76)	34 (83)	
EBUS for detection of N2/3 disease^a						
True positive for N2/3 disease	33 (48)	23 (50)		75 (99)	38 (93)	
True negative for N2/3 disease				-	-	
EBUS stage N0	20 (29)	18 (39)		-	-	
EBUS stage N1	11 (16)	2 (4)		-	-	
False negative for N2/3 disease				1 (1)	3 (7)	
EBUS stage N0 to surgical stage N2	4 (6)	2 (4)		-	-	
EBUS stage N1 to surgical stage N2	1 (1)	1 (2)		-	-	
False positive for N2/3 disease	0	0		0	0	

^a Based on further pathologic sampling or 6-month clinical-radiological follow-up. See Table 3 for associated sensitivity and negative predictive value.

Abbreviations: ACCP = American College of Chest Physicians; IQR = interquartile range; MELAA = Middle Eastern/Latin American/African.

Table 3: Summary of EBUS performance metrics (per procedure) in the staging of lung cancer.

Quality indicator	Target (%)	Staging EBUS		p
		Phase 1 n/N (%)	Phase 2 n/N (%)	
Prevalence of N2/3 disease		38/69 (55)	26/46 (57)	n/a
Sensitivity for N2/3 disease	>85	33/38 (87)	23/26 (88)	>0.99
NPV for N2/3 disease	>85	31/36 (86.1)	20/23 (87)	>0.99
Adequate for molecular analysis ^a	>90	29/31 (94)	21/22 (95)	>0.99
LN sampled per procedure, mean (SD)		1.6 (0.7)	1.9 (0.85)	0.03
LN sampled per procedure				0.19
1		36/69 (52)	17/46 (37)	
2		27/69 (39)	19/46 (41)	
3 or more		6/69 (9)	10/46 (22)	
N2/3 LN sampled per procedure, mean (SD)		1.1 (0.71)	1.5 (0.72)	<0.01
N2/3 LN sampled per procedure				0.06
0/N1 node only		13 (19)	3 (7)	
1		37 (54)	21 (46)	
2		18 (27)	19 (41)	
3		1 (1)	3 (7)	

^a Only applicable to those with non-squamous non-small cell lung cancer confirmed with EBUS during the study period.
Abbreviations: LN = lymph node; NPV = negative predictive value; SD = standard deviation.

Table 4: Summary of EBUS performance metrics (per procedure) in the diagnosis of lung cancer.

Quality indicator	Target (%)	Diagnostic EBUS		p
		Phase 1 n/N (%)	Phase 2 n/N (%)	
Pathological confirmation	>90	75/76 (99)	38/41 (93)	0.12
NSCLC-NOS ^a	<10	1/59 (2)	3/29 (10)	0.1
Adequate for molecular analysis ^b	>90	44/48 (92)	22/24 (92)	>0.99
Repeat sampling required due to insufficient tissue ^c	<10	3/76 (4)	1/41 (2)	>0.99

^a NSCLC-NOS rate among those with NSCLC diagnosed from EBUS.

^b Applicable to those with non-squamous NSCLC confirmed with EBUS during the study period.

^c Repeat sampling for more tissue for either immunohistochemical characterisation or molecular analysis.

Abbreviations: NSCLC-NOS = non-small cell lung cancer not otherwise specified.

Table 5: Pathway times for EBUS and pathology results, and safety data (per procedure).

	Target (%)	Staging EBUS		p	Diagnostic EBUS		p
		Phase 1	Phase 2		Phase 1	Phase 2	
Overall wait time, median (IQR)							
Referral to EBUS		4 (2–6)	5 (3–7)	0.04	2 (1–3)	3 (1–6)	0.14
EBUS to pathology report ^a		4 (2–5)	3 (2–4)	0.05	4 (2–5)	3 (2–5)	0.34
Referral to pathology report ^a		8 (6–9)	8 (6–11)	0.44	6 (4–8)	7 (5–9)	0.33
Performance indicator, % (n/N)							
EBUS ≤7 days from referral	85–95	93 (64/69)	83 (38/46)	0.09	93 (71/76)	93 (38/41)	>0.99
Pathology report ≤3 days from EBUS ^a	ns	42 (29/69)	57 (26/46)	0.13	42 (32/76)	51 (21/41)	0.35
Pathology report ≤5 days from EBUS ^a	85	90 (62/69)	98 (45/46)	0.14	89 (68/76)	85 (35/41)	0.56
Pathology report ≤7 days from EBUS ^a	95	100 (69/69)	100 (46/46)	>0.99	99 (75/76)	100 (76/76)	>0.99
Pathology (including molecular analysis) ≤10 days from EBUS ^b	85	21 (6/29)	38 (8/21)	0.18	18 (8/44)	36 (8/22)	0.10
Pathology (including molecular analysis) ≤14 days from EBUS ^b	ns	69 (20/29)	81 (17/21)	0.34	73 (32/44)	82 (18/22)	0.41
Total pathway time: pathology (including molecular analysis) ≤14 days from referral ^b	ns	34 (10/29)	38 (8/21)	0.79	34 (15/44)	45 (10/22)	0.37
Safety data, % (n/N)							
Serious adverse events	<3	1.4 (1/69)	0	>0.99	1.3 (1/76)	0	>0.99

Table 5 (continued): Pathway times for EBUS and pathology results, and safety data (per procedure).

Bleeding							
Mild	ns	0	2 (1/46)		0	2 (1/41)	
Moderate		3 (2/69)	0	0.24	3 (2/76)	0	0.23
Severe		0	0		0	0	

Serious adverse events: severe bleeding, cardiac arrhythmia, seizure, myocardial infarct/pulmonary oedema, pneumothorax requiring intervention, over-sedation requiring reversal agent, unplanned hospitalisation, admission to critical care unit, death.

Bleeding classification: mild = continued suctioning, bleeding stops spontaneously; moderate = requiring adrenaline or cold saline; severe = requiring bronchus blocker, fibrin sealant, resuscitation, blood products.

^a Pathology report including tumour subtyping and relevant immunohistochemistry.

^b Molecular analysis performed in those with non-squamous NSCLC during this study period, and with sufficient sample.

Abbreviations: EBUS = endobronchial ultrasound; NSCLC = non-small cell lung cancer; ns = not stated; PET/CT = positron emission tomography.