Wessex Academic Health Science Network

NHS

Independent Evaluation of a pilot of Electromagnetic Navigation Bronchoscopy (ENB) in the detection of lung cancer at University Hospitals Southampton NHS Foundation Trust

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Disclaimer

This report presents the findings of an independent evaluation of a pilot of Electromagnetic Navigation Bronchoscopy (ENB) in the detection of lung cancer at University Hospitals Southampton NHS Foundation Trust (UHS). The findings of this independent evaluation are those of the authors and do not necessarily represent the views of UHS. For information governance purposes this report contains analysis with small number suppression. Any figures relating to patients that have less than seven data points have been replaced with an asterisk.

Declaration of interest statement

Wessex AHSN supports innovators to bring their innovations to the NHS as well as provide an evaluation service more broadly to our members and others. On occasion, we evaluate innovations that we have also supported. Whilst these evaluations are independent, for transparency we disclose our dual role where applicable. In this report we note that Wessex AHSN was initially involved in supporting UHS to adopt the innovation by assisting with funding bids and supporting the pilot team to develop the pilots' plans. Wessex AHSN was not involved in the implementation of the innovation and its only role since has been as the independent evaluator.

Acknowledgements

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List of Abbreviations

AHSN – Academic Health Science Network

CT – Computerised tomography

ENB – Electromagnetic navigational bronchoscopy

EBUS - Endobronchial Ultrasound-guided Transbronchial Needle Aspiration

IMD – Indices of multiple deprivation

MDT – Multidisciplinary Team

NICE – National Institute for Health and Care Excellence

NOLCP – National optimal lung cancer pathway

PACS - Picture archiving and communication system

PAS – Patient administration system

TLHC - Targeted Lung Health Check

UHS – University Hospital Southampton NHS Foundation Trust

Glossary of Terms

Ablation - A treatment that involves an application of either heat or extreme cold to destroy localised cells. The cells die and the treated area slowly shrinks and becomes scar tissue.

Biopsy - A medical procedure that involves taking a small sample of body tissue so it can be examined under a microscope.

Bronchoscopy – A medical procedure to look inside the airways in the lungs using a thin, lighted tube (bronchoscope).

Brushing – An alternative procedure to biopsy in which cells are taken from the inside of the lungs via a bronchoscope. A small brush is inserted through the bronchoscope to capture cells on the inner surface of the lung.

Hybrid operation theatre room: A specialised operation theatre room which allows interventional radiology and surgical procedure to occur. The CT machine can produce live imaging during the operation.

Medtech Innovation Briefings - An initiative commissioned by NHS England to support NHS and social care commissioners and staff who are considering using new medical devices and other medical or diagnostic technologies for patient care and treatment, diagnosis, monitoring, and improvement of people's health.

Pneumothorax – A collapsed lung due to air leaking into the space between the lung and chest wall.

superDimension™ Navigation System – A visual navigational device from the Medtronic company for displaying images of the lung to aid clinicians in guiding the bronchoscope through a patient's lung.

Targeted Lung Health Check – An NHS initiative to offer lung health check to people in certain area of England, aged between 55 and 74 and who are current or former smokers. It is designed to identify signs of cancer at an early stage when it is much more treatable, ultimately saving more lives.

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EXECUTIVE SUMMARY

Background

Electromagnetic Navigation Bronchoscopy (ENB) is a minimally invasive procedure which supports earlier diagnosis of lung cancer. Patients whose lung lesions cannot be diagnosed through standard procedures would normally go onto a computerised tomography (CT) observation (watch and wait) pathway. Using ENB these patients may have a chance of receiving an earlier definitive diagnosis. ENB's unique innovation is the ability to access with live visual guidance, a nodule more accurately that is not accessible with other diagnostic techniques. It is less invasive for patients than CT guided biopsy (entry is through the chest wall) and reduces the risk of pneumothorax. ENB procedure requires a general anaesthetic, whilst CT guided biopsy requires a local anaesthetic. ENB provides an alternative to the computerised tomography (CT) observation (watch and wait) pathway with some patients undergoing repeated CT observation.

University Hospital Southampton NHS Foundation Trust (UHS) ran a pilot of a new ENB pathway, alongside the CT observation and guided biopsy pathways. As of the 15 April 2023, the pilot has run for 15 months and performed the ENB procedure on 83 patients. The Wessex Cancer Alliance has funded the pilot.

Wessex Academic Health Science Network (AHSN) was asked to undertake an independent evaluation of this pilot to understand:

- What has enabled or hindered the implementation of ENB at UHS?
- Does ENB contribute to earlier diagnosis of lung cancer in Wessex?
- Does the ENB pathway change the diagnostic experience for patients in Wessex?
- What impact has the introduction of ENB had on other pathways at UHS?

This evaluation sought to address this through a comparison of patients on the ENB pathway (newly implemented for the pilot at UHS), with patients on the existing CT observation (watch and wait) pathway. In addition, gather information to understand implementation factors of integrating the ENB procedure and patient experience.

Methods

Patient experience of the ENB pathway was collected via a survey. The experience and perceptions of staff either directly or indirectly involved in delivering ENB were also collected via survey and interview. A selection of quantitative data was gathered from routine data collections at UHS. This evaluation looked at data from the 83 patients who had an ENB procedure within the pilot period 01 January 2022 to 31 March

2023 and this was analysed alongside patient data from the existing CT observation pathway identified from the Nodule multidisciplinary team (MDT) list. This list is made up of suspected cancer patients with a suspicious nodule; patients in our sample were those with lung nodules.

Quantitative descriptive analysis resulted in the calculation of several indicators to evaluate the ENB pilot including:

- Time between
    - Referral
    - MDT
    - Pathology
    - Diagnosis
    - Discharge
- Diagnosis rate
- Diagnosis stage proportions
- Discharge rate
- Indices of multiple deprivation (IMD) decile proportions and other patient demographics.
- Activity – volume and time.

Descriptive statistics were used to analyse survey data and themes were created from the synthesis of this data with the interview data.

Findings

The evaluation findings demonstrated that the ENB pathway has potential to change the diagnostic experience for patients in Wessex. The adjusted minimum average referral to diagnosis time for ENB would be 77.6 days and for CT observation 137.25 days. Survey findings indicate patients' experience is overall positive, and they felt well informed. ENB was only problematic if the ENB procedure was delayed or cancelled, or their diagnosis delayed. Staff perceptions of patient experience also indicated their view that ENB was more positive and less invasive for patients. Four key factors and three themes were identified in the staff interviews and survey factors that indicate both enablers and barriers to the successful implementation of ENB at UHS during this pilot.

Operational factors such as access to a day surgery bed, a hybrid theatre and availability of suitably trained clinicians increases the complexity of care in the lung cancer diagnostic pathway. These are also key requirements to provide ENB. The fourth, an inhibiting factor, although this did not stop the ENB procedure, was the imaging interface between UHS IT and the ENB superDimension™ navigation system. It is currently not optimal due to the manual transfer of images. Themes identified were:

- Complexity of lung cancer diagnostic processes and decisions
- Challenges to implementation and embedding of ENB into the lung cancer pathway
- Potential use and application of the ENB.

Staff have gained additional skills and ENB provides another diagnostic option for both patients and clinicians given the challenges in the complex diagnosis of lung cancer. This is particularly to access peripheral nodules less invasively with live visual guidance to reach the suspected area with accuracy not offered with other diagnostic techniques. The anticipated benefit is potentially an earlier diagnosis and better outcome for the patient. However, diagnosis is not always possible. Finally, staff interviewed discussed the potential use and application of ENB and these views seemed polarised by those that see a future for ENB as a treatment option (ablation) and those that felt if ENB did not provide a diagnosis it was an additional step for patients in the lung cancer pathway.

Key activity data findings were stage of lung diagnosis, average pathway times and number of episodes by patient.

Stage of lung cancer diagnosis:

Proportion of Lung Cancer diagnosis by stage	ENB	England (2020)
Stage 1	55.4%	20.0%
Stage 2	5.4%	6.6%
Stage 3	3.6%	17.7%
Stage 4	8.9%	46.0%

Average pathway times and proportions of patients receiving a definitive diagnosis/discharge:

Measure	ENB	CT observation
Referral to MDT	24.4 days	12.2 days
MDT to Diagnosis	30.1 days	26.6 days
Diagnosis to Discharge	10 days	NA
Diagnosed	85.4%	40.0%
Discharged	40.0%	0.0%

Average activity (number of episodes per patients):

		ENB	CT observation
Count	**Diagnostic**	0.68	2.35
	Inpatient	1.02	0.23
	Outpatient	1.68	1.98
Duration (hours)	**Diagnostic**	0.2	0.6
	Inpatient	18.3	12.5
	Outpatient	0.6	0.5

Conclusions

This evaluation of the ENB procedure pilot indicates the potential for providing another option for clinicians managing complex cancer diagnosis challenges. Implementation of ENB in the lung cancer pathway was not without difficulty due to typical healthcare operational factors but there were also challenges with the ENB superNavigation system not operating optimally. Both patients and staff were positive about their experience of receiving or using ENB. Nevertheless, some dissent was also reported on cost, over diagnosis and viability.

There is reasonable evidence that indicates the ENB pathway may contribute to earlier lung cancer diagnosis in Wessex. An adjusted minimum average referral to diagnosis time was shown for ENB as 77.6 days and for CT observation 137.3 days. Over half of those patients involved in the pilot were diagnosed at Stage 1 (55.4%) compared to the national average (20.0%). However, there were limitations associated with the availability and quality of the quantitative data made available by UHS to this evaluation. Conclusions drawn here need to consider these limitations and their impact on the evaluation. These are detailed throughout the report.

The data received indicates that diagnosis rates for patients going through the ENB pathway appear higher than that of a historic CT observation pathway sample. Discharge rates also appear higher for the ENB pathway patients.

Looking at changes to activity, the ENB pathway patients show on average having fewer CT scans than those on the CT observation pathway. However, ENB patients on average spend more time as an inpatient. Some ENB patients required further diagnostic activity following their ENB procedure before they could be discharged. Further evaluation could provide more definitive findings on a larger cohort of patients.

Recommendations for future evaluations

To address the limitations in data availability and quality for future monitoring and evaluation moving forward, we recommend:

- Data capture and data governance are improved to allow better definition of patient pathways.
- There is continued observation to increase the number of completed patient records to improve reliability of future analysis.
- Acceptance criteria are refined to will improve definitions of patient cohorts but also target the ENB procedure at those patients who cannot get a diagnosis through standard methods.

We also recommend continued monitoring of the proportions of ENB patients in the lowest two deciles of the Index of Multiple Deprivation (IMD) due to the drop in proportions observed in descriptive analysis of the routine UHS data. An opportunity to gain an in-depth understanding of patient experience, choice and involvement in decision making within this cancer pathway would be valuable. This should also include a better understanding of the experience patients categorised in the Core20PLUS5 receive whilst under the ENB pathway compared to those who remain under CT observation would be beneficial as ENB becomes embedded in the lung cancer pathway.

At the time of this report there was an outstanding issue with the ENB superDimension™ system and its interoperability with local NHS systems. This relates to the transfer and production of a 3D image. A further evaluation of a fully functioning ENB system could provide more definitive findings for further adoption and spread of ENB beyond UHS.

1 BACKGROUND

1.1 ELECTROMAGNETIC NAVIGATION BRONCHOSCOPY (ENB)

ENB is a minimally invasive approach to support earlier diagnosis of lung cancer. It utilises a special type of image guided approach to reach lesions and enable biopsy or highlight the location of the lesion for further treatments (Folch et al 2022). ENB guides endoscopic tools by mapping the lungs using the superDimension™ Navigation System from the medical device company Medtronic (NICE, 2019). A small biopsy sample of the nodule can be taken for diagnostic purposes. When a tissue biopsy cannot be obtained, then a brushing technique is done that collects superficial tissue fragments of the nodule.

Implemented across multiple sites throughout the United States and Europe, the ENB procedure has shown reasonable success, with a diagnostic yield of 67.8% (Folch et al 2022). The National Institute for Health and Clinical Excellence (NICE) has developed a Medtech Innovation Briefing (MIB) for a 'superDimension™ Navigation System to help diagnostic sampling of peripheral lung lesions' (NICE, 2019).

The uniqueness of ENB is described as the ability to access peripheral nodules with live visual guidance to reach the nodule area with an accuracy that is not possible using other diagnostic techniques. ENB is less invasive than CT guided biopsy as the lung nodules are accessed internally through the bronchus rather than via external incision. ENB reduces the risk of pneumothorax by removing the need to create an external incision to the lung, which is required in a CT guided biopsy. Otherwise, the patient risks associated with ENB are no different from any other procedure involving bronchoscopy and general anaesthesia.

In existing lung cancer detection pathways, the computed tomography (CT) guided biopsy procedure allows the radiologist to accurately locate the best place to access the lung nodule for tissue sample collection. The sample is obtained by externally inserting a needle into the lung through the chest wall whilst the patient is under local anaesthetic. The is usually a day case procedure, but it may require hospital admission for further monitoring.

Standard procedures used for lung biopsy/diagnosis may not be suitable for several reasons so, under existing pathways, patients in Hampshire and Isle of Wight might be placed onto CT observation.

On this pathway, these patients have regular CT scans to track the change in their condition. One alternative to this CT observation pathway is Electromagnetic Navigation Bronchoscopy (ENB).

1.2 UNIVERSITY HOSPITAL SOUTHAMPTON NHS FOUNDATION TRUST (UHS) PILOT

University Hospital Southampton NHS Foundation Trust (UHS) ran a pilot of a new ENB pathway for the early detection of lung cancer. Wessex Cancer Alliance funded the pilot which ran for 15 months from January 2022 to April 2023. During this time, the pilot team performed the ENB procedure on 83 patients. Wessex AHSN was approached by the Wessex Cancer Alliance to support this pilot following the involvement of their jointly funded cancer innovation programme who had supported the UHS team to apply for grant funding. This led to the request that the Insight team at Wessex AHSN provide an independent evaluation on the pilot to demonstrate its impact.

The pilot was open to patients reviewed by multi-disciplinary teams (MDTs) from eight hospitals across Wessex. The initial aim was to see patients who have lung lesions that are too small, too deep, or critically

centred for a reliable biopsy by one of the existing diagnostic procedures (CT-guided biopsy or routine bronchial biopsy), or patients for whom surgical/percutaneous approaches are too high risk.

The UHS pilot originally sourced its patients from the CT observation pathway (Limitations, section 2.2), including patients identified at a Targeted Lung Health Check, and new cases referred by primary care.

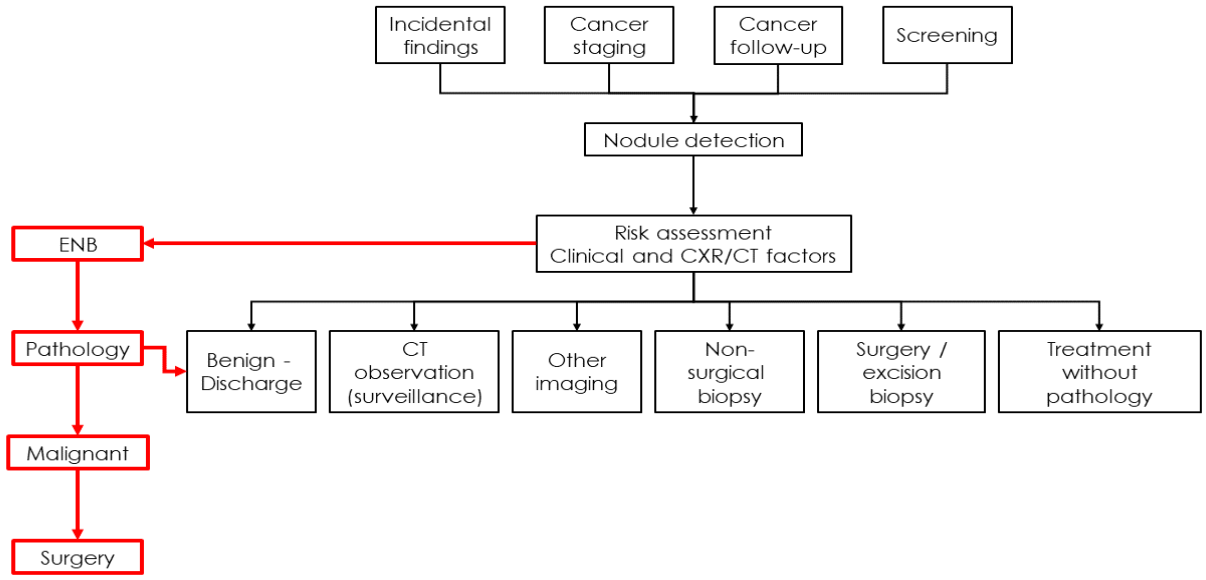

Figure 1 - Proposed inclusion of ENB pathway to existing UHS lung cancer detection pathway. Abbreviations: chest x-ray (CXR); computerised tomography (CT); Electromagnetic navigational bronchoscopy (ENB).

The pilot team believe ENB offers an alternative to the inconvenience and anxiety often caused by regular attendances for CT observation or an invasive biopsy. ENB was conducted as a day case procedure in a hybrid theatre. For those cases with a definitive non-cancer pathology, the patients received appropriate treatment and follow-up by CT until their condition was resolved and they could be discharged from secondary care.

With this pilot, UHS became the second NHS trust to implement ENB in a hybrid theatre. Barts Health NHS Trust used ENB for four years and remain the only other NHS trust using ENB in day case surgical procedures in a designated hybrid theatre.

The ENB pilot was run by the UHS thoracic team, led by a consultant cardiothoracic surgeon and the associate care group manager for Cardiovascular and Thoracic.

1.3 INDEPENDENT EVALUATION

The ENB pilot team approached Wessex AHSN's Insight team in September 2021 to evaluate the pilot with the aim to inform commissioners' decisions on the future of the service once the pilot funding ended.

The purpose of the evaluation activity was to investigate ENB implementation and impact on patients and the service.

2 METHODS

Both quantitative and qualitative methods were used to answer questions about ENB implementation and impact. The following sets out the evaluation approach.

2.1 EVALUATION DESIGN

2.1.1 LOGIC MODEL

To inform the design of the evaluation, a logic model (Appendix 1) was developed by Wessex AHSN using information provided by the pilot team. The logic model highlighted resources allocated to the pilot, the activities expected during the pilot and the expected outcomes from these activities. This identified measurable outcomes to provide evidence for the expected impacts of this new pathway. The model helped define the evaluation questions for this project.

2.1.2 EVALUATION QUESTIONS

The evaluation questions were developed collaboratively by Wessex AHSN and UHS and underpinned a detailed evaluation specification produced by Wessex AHSN to describe and explain the evaluation activities.

The mixed methods approach agreed with the ENB pilot team involved obtaining Trust routine activity data (quantitative metrics) and qualitative data via a patient survey, staff survey and staff interviews. Table 1 shows the **planned** data collection to answer the pre-specified evaluation questions. The observation of

MDTs was not considered practical by the UHS team and therefore key MDT informants were invited to interview as an alternative.

Evaluation question	Proposed Evaluation methodology and metrics
1. What has enabled or hindered the implementation of the ENB pathway at UHS?	The evaluation team will consider the MDT's criteria for selecting patients for the ENB pathway on initial assumptions from the pilot team that there will be more eligible patients than slots available. Data collection of staff perceptions of the enablers and barriers to implementing ENB such as integration of the ENB pathway into existing pathways at UHS. This will be done via staff questionnaire, key informant interviews.
2. Does ENB contribute to earlier diagnosis of lung cancer in Wessex?	Data collection and analysis of: a) Number of cancers detected on the ENB pathway as a proportion of lung cancers detected in Wessex. b) Stage of diagnosis of cancers detected on the ENB pathway. c) Number of days from referral to MDT and from referral to diagnosis/pathology result.
3. Does the ENB pathway change the diagnostic experience for patients in Wessex?	Data collection and analysis of: a) Number of appointments and procedures for patients on the ENB pathway compared with the number of appointments and procedures for ENB-eligible patients placed on the CT observation pathway. b) Number of ENB patients requiring alternative diagnostics following an inconclusive pathology result. Type and frequency of alternative diagnostic e.g., alternative sampling or surgical resection. Data collection via patient questionnaires to capture their experience of the ENB pathway. Wessex AHSN will explore the availability of comparison data – see Qualitative Data Summary below.
4. What impact has the introduction of ENB had on other pathways at UHS?	Data collection and analysis of: a) Number of cases reviewed at MDT per month for the ENB eligible pathway

Evaluation question	Proposed Evaluation methodology and metrics
	b) Reduction in CT demand - number of cases and average time for CT for ENB eligible patients, by pathway (ENB versus CT observation) To explore if ENB frees up capacity for other pathways, the evaluation team will compare the average time for lung cancer cases to complete the pathway and the number of CT scans per patient, split by pathway type. Data collection on the perceptions of UHS staff of the ENB pathway, including any changes or adaptations to practice caused by the ENB pathway. This will be done by an online staff survey and key informant interviews.

Table 1 - Evaluation questions, methodology and metrics as outlined in the evaluation specification

2.2 LIMITATIONS

2.2.1 NON-CT OBSERVATION PATHWAYS

As the ENB pilot progressed, the acceptance criteria for patients on the ENB pathway evolved. This resulted in the inclusion of patients from a non-CT observation pathway - the surgical biopsy pathway. While comparator data was available for the CT observation pathway, no comparator data was available for the other pathways included in the pilot.

The inability to accurately identify the different patient pathways within UHS routine data meant that assumptions were made (see below, section 2.2.2). This impacted the reliability of statistical analysis. Therefore, findings for this evaluation only report descriptive analysis of the available quantitative data.

2.2.2 QUANTITATIVE DATA ASSUMPTIONS

As no historic comparator data was available for surgical biopsy patients, we needed to filter the ENB sample to focus on those patients who would have gone on the CT observation pathway had ENB not been available. As we were unable to identify these patients from the routine data alone, the proportions were

estimated by the clinical lead. They estimated that roughly half of the patients who had an ENB procedure during the pilot would have otherwise been placed on the CT observation pathway.

Following confirmation from the clinical lead, it was assumed that patients with lower pathway times are more likely to be these patients. Therefore, here we take the 50% of ENB patients with lower pathway times as the patients who would have been placed on the CT observation pathway in the absence of ENB.

2.2.3 QUALITATIVE DATA

Patient and staff surveys along with staff interviews provided views from both regarding their experience of receiving or delivering ENB. The sample was representative for both, that is, nearly 50% of patients in pilot and most staff likely to be involved or have knowledge of the ENB pathway. The original plan included observation of MDTs to gain an understanding of ENB pathway decisions however, for this pilot it was not a good use of a limited resource because the proportion of ENB eligible patients at any single MDT would be low. Interviews were conducted with those attending MDT meetings as an alternative.

2.3 DATA COLLECTION AND PROCESSING

2.3.1 ROUTINE UHS DATA

A detailed data requirement was co-developed between Wessex AHSN and UHS. A data set relating to 83 ENB patients and 58 historic CT observation pathway patients was collected from the different available data sources at UHS. This data gave some information on patient demographics, MDT details, patient pathway, and activity.

Data validation was performed to account for transcription errors and extreme outliers. Following this the historic data was filtered to match the time frame of the ENB pilot. This worked out to be a referral period of 408 days and an activity period of 515 days.

	ENB	Historic
First referral	01/01/2022	05/10/2020
Last referral	13/02/2023	17/11/2021
Last activity	01/04/2023	03/01/2022

Table 2 - date range for routine UHS data

Following this date range filtering, 72 ENB patients and 58 historic patients remained for further analysis.

From the ENB patients the median (50th percentile) pathway length was calculated as 171 days. This was used as the threshold to divide the ENB data into CT observation pathway (those below the threshold) and non-CT observation pathway (those at or above the threshold). The pathway length here is pathway to date and includes non-discharged patient activity up to the last activity definition (01/04/2023).

2.3.2 INTERVIEW DATA ANALYSIS

Key clinical staff involved in the delivery of the pilot ENB pathway were invited to interview to explore their experience and views about the ENB pathway. Interviews were audio recorded and transcribed verbatim for data accuracy. Participants were allocated unique identification codes and any information identifiable to individuals was removed from transcription to ensure confidentiality and anonymity. The transcripts were uploaded to qualitative data analysis software NVivo (version 1.7.1) for coding and reflexive thematic analysis. The analysis followed Braun and Clarke's (2021) process for data engagement, coding, and theme development. The process involved:

1) data familiarisation and writing familiarisation notes
2) systematic data coding
3) generating initial themes from coded and collated data
4) developing and reviewing themes
5) refining, defining, and naming themes.

2.3.3 SURVEY DATA ANALYSIS

Key clinical staff and patients who had undergone the ENB pathway were invited to complete an online evaluation survey using Microsoft Forms. Survey data from both patients and staff were processed separately using Microsoft 365 Excel (version 2304) for numerical, quantitative data and NVivo (version 1.7.1) for free text, qualitative data. The quantitative data was processed for descriptive statistics (frequency distribution of the data set) using pivot tables within Excel. The qualitative data, in particular the free text responses, were processed and analysed in the same approach as the interview data analysis.

3 FINDINGS

Findings for all data collected are presented below by each evaluation question.

3.1 STAFF AND PATIENT SAMPLE CHARACTERISTICS

3.1.1 PROFILE OF SURVEY RESPONDERS AND INTERVIEW PARTICIPANTS

The following synthesised findings are based on survey responses (from patients and staff) and key staff interviews. Patient survey responses were collected from 38 patients during October 2022 and April 2023. Staff survey responses were collected from a total of 24 staff, of which eight responses were collected at timepoint one (between October 2022 and February 2023; noted as "Pre-March" group) and 16 responses were collected at timepoint 2 (between March and April 2023; noted as "post-March" group). It is understood this represents most staff currently involved in the ENB pathway. Key staff interviews were completed with eight participants during September 2022 and February 2023. ENB and CT observation pathway activity data is also presented to address each question as outlined in section 2.1.2 12.

Patient surveys (*n*=38) did not capture data characterising the profile of the individuals, however quantitative data did, shown in section 3.1.2. The main defining category for the patients was whether their ENB procedure was their first diagnostic procedure (*n*=33) or not (*n*=5).

Staff survey responses (*n*=24) were completed by a range of healthcare professionals shown on Table 3. Staff survey responders either had direct experience of providing ENB care (*n*=7) or have the knowledge only of the ENB pathway (*n*=17).

Job titles	Number of respondents (n)
Respiratory consultant	8
Consultant oncologist	6
Specialist nurse	2
Nurse case manager	2
Thoracic surgeon	2
Interventional radiographer	1
Consultant radiologist	1

Job titles	Number of respondents (n)
Consultant nurse	1
Doctor	1
Total	**24**

Table 3 - Job titles of staff survey respondents

3.1.2 PATIENT CHARACTERISTICS

Routine data regarding certain patient characteristics was analysed – the results are shown below.

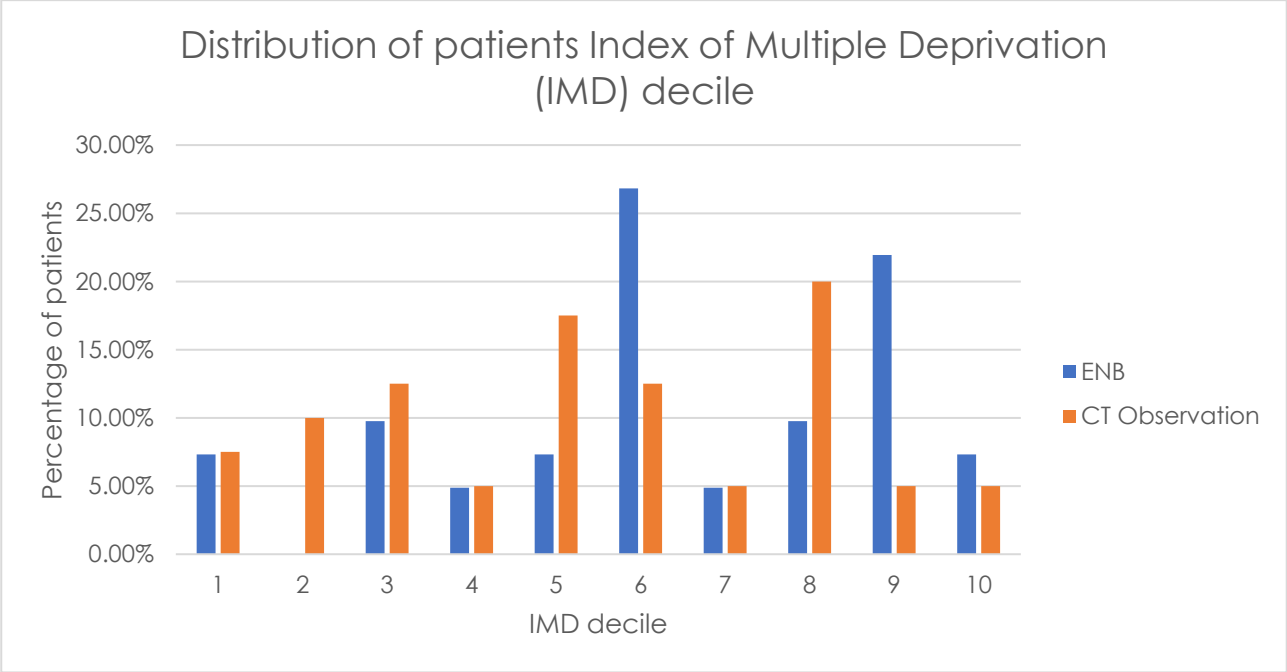

Figure 2- Distribution of index of multiple deprivation decile (national), derived from patients' address, the associated Lower Layer Super Output Area (LSOA) IMD values. Shown for the ENB and CT observation pathway samples.

	CT Observation	ENB
Index of Multiple Deprivation (IMD) in lowest 20%	17.50%	7.32%

Table 4 - Percentage of patients from each pathway sample with IMD scores in the lowest two national deciles

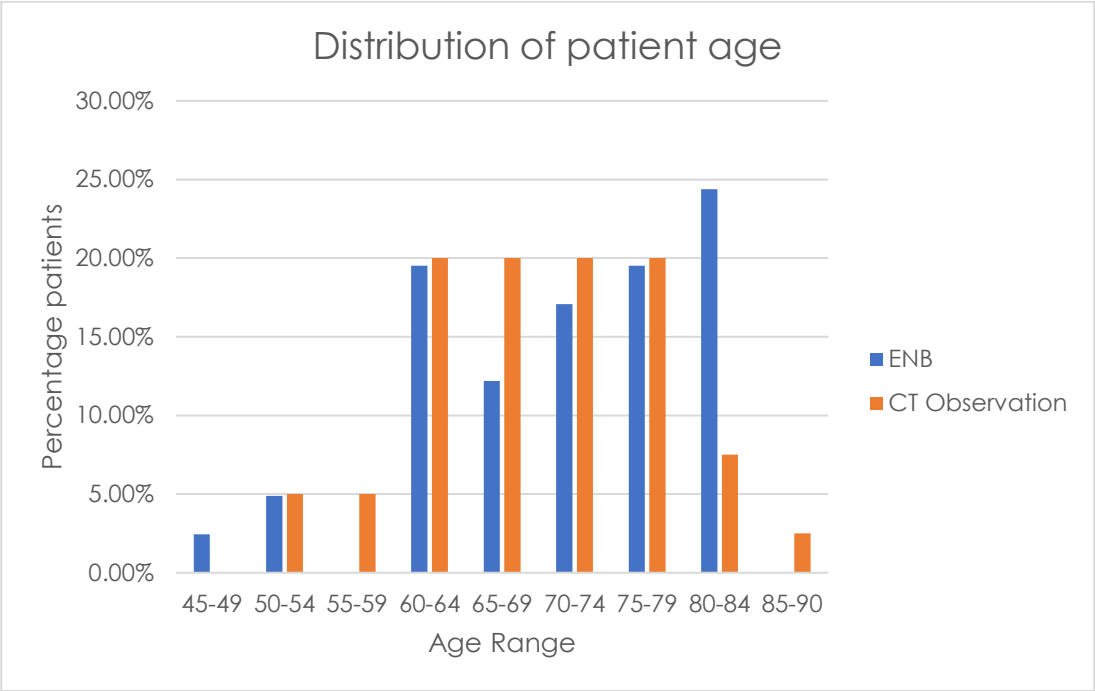

Figure 3 - distribution of patient ages for the ENB and CT observation pathway samples

Row Labels	CT observation	ENB
Female	57.5%	61.0%
Male	42.5%	39.0%

Table 5 - Reported gender proportions for ENB and CT observation pathway samples

3.2 WHAT HAS ENABLED OR HINDERED THE IMPLEMENTATION OF THE ENB PATHWAY AT UHS?

The findings from the surveys and interviews have informed the detailed pathway diagram in Figure 4. This diagram depicts the real-world implementation pathway in contrast to the planned pathway in Figure 1. The pathway diagram was generated based on the information obtained in the staff interviews and surveys. It is not suggested that it is definitive as it represents perspectives of those staff at the time of their

interview. The national faster diagnosis standard which applies to the pathways discussed here aims to achieve a definitive diagnosis within 28 days of the initial referral for suspected cancer. Further information on time from referral to diagnosis is presented in section 3.3.3., which indicates longer timeframes for both pathways. The pathway diagram outlines the processes involved that might hinder patients' progress through the ENB and CT lung cancer pathways at UHS. These are described more fully below.

In summary, operational logistics (bed, theatre and clinician availability) and technical issues (managing the ENB imaging interface and failed sample collection) can create a patient loop back to the MDT for re-referral to either ENB or the CT observation pathway.

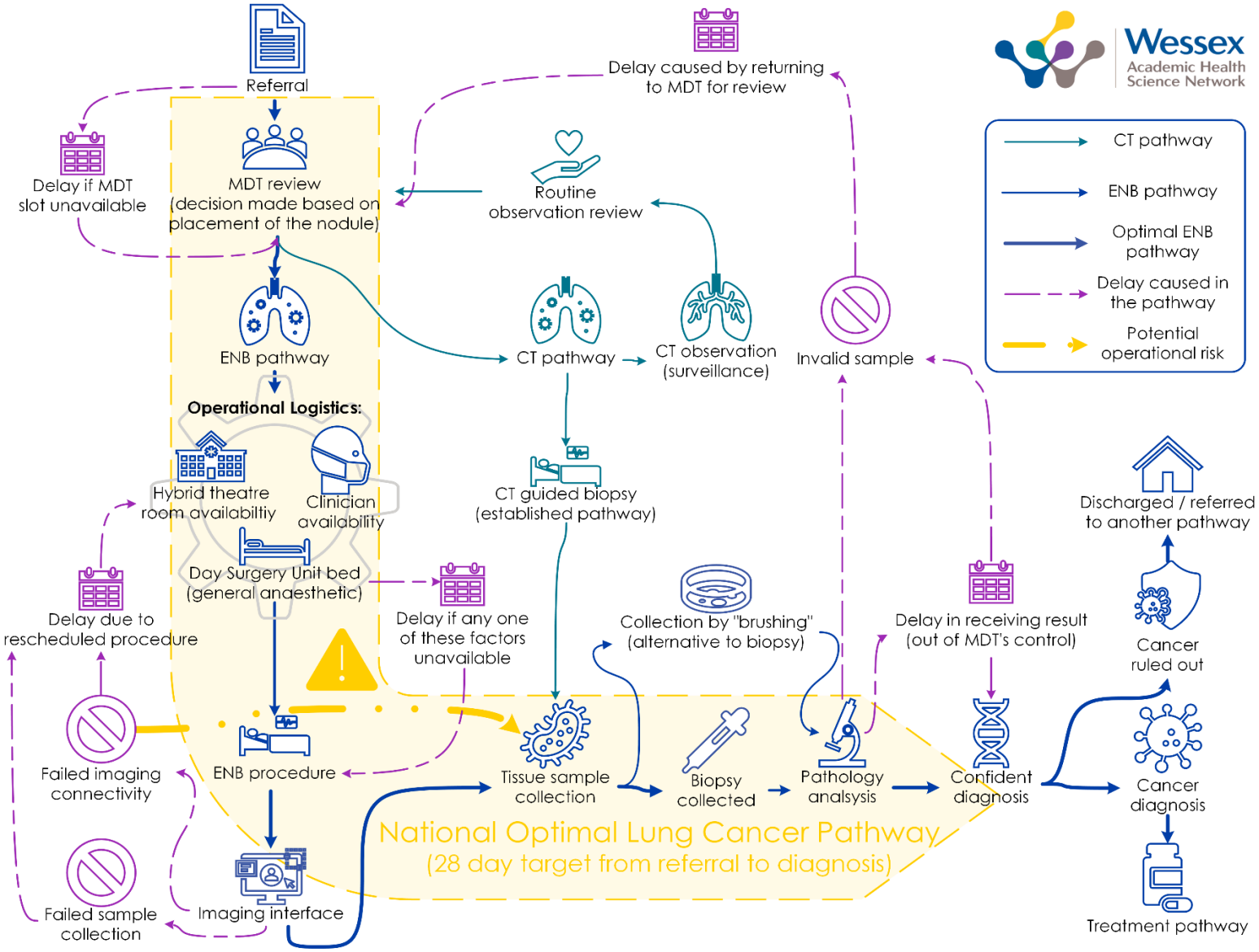

Figure 4 - Visualisation of ENB and CT observation pathway factors reported in staff survey and interviews

3.2.1 FACTORS THAT ENABLE OR HINDER THE IMPLEMENTATION OF THE ENB PATHWAY

Staff survey responses and interview responses describe the operational factors that either enabled or hindered the success of ENB within the lung cancer pathway. These four factors were the availability of the hybrid operation theatre room, the relevant clinicians required for the operation, the surgical day unit bed and the imaging interface functionality.

The **availability of hybrid operation theatre room** is perceived as both an enabler and barrier in the pathway. The prerequisite for the ENB procedure to occur is access to the specialist theatre room where both interventional radiology (i.e., ability to take live CT scan) and thoracic surgery (bronchoscopy and biopsy) can occur in one setting. The availability of such space was the key determinant of whether a procedure would go ahead or not and thus impacting on both patient and pathway management.

> "So, it's got to be done in the hybrid theatre… where there's the CT scanner. We were not getting access to that very often, so initially… we were only getting access to that theatre probably once or twice a month." Nurse case manager

The next factor was ensuring **the availability of the highly specialised and experienced clinicians** required to conduct the procedure successfully. For ENB procedures, key clinicians included a radiographer (to operate imaging interfaces), thoracic surgeon (to conduct bronchoscopy), anaesthetist (to administer general anaesthetic), and other healthcare professionals are also needed in the theatre room for the procedure to be performed.

> "[ENB is] expert dependent procedures, so you have to have experienced people [clinicians] doing it. An experienced team overall so those people [clinicians], so you have to have a surgeon. I have an interventional [surgeon]... To do this, you need a radiographer who knows how to operate the hybrid theatre." Thoracic surgeon

A third factor was the **bed capacity of the surgical day unit** to accommodate ENB patients because the procedure is conducted under general anaesthetic. The availability of a bed space before and after the procedure determined whether it could go ahead on the day or had to be postponed to another day.

> "[for ENB procedure], you want a [surgical day unit] bed for the patient to come into before the procedure and to afterwards go back before going home. So, if there's no day care space available… you struggle to get… the throughput of the patient." Thoracic surgeon

The final factor for success is the **transfer of the patient's lung CT image to the ENB device** so that the electromagnetic visual guidance can be mapped on to a screen for the surgeon to navigate and access the lung nodule accurately. However, we found the interface between CT imaging and ENB did not always

connect successfully. At the beginning of the pilot phase, the interface experienced unpredictable connectivity and incompatibility. This required the UHS picture archiving and communication system (PACS) team to investigate the compatibility between CT images stored in PACS and the ENB device. The connectivity seemed variable, and the technical issues have yet to be fully resolved. Interview participants consistently reported the unreliability of the imaging interface, with one participant highlighting the safety risk to patients.

> "…patient is laying in an electromagnetic field [emitted by ENB] and we use a previous CT to create the [3D] model. But to do this we need to transfer the [CT] images which is time consuming. We have to ask somebody to do it. We have to go and plug a gadget. So, I think that's a very big point and it happened before that on the day you don't see the image although it was there like last Friday. The two cases I switched the machine and I couldn't see it. So plugged in and out with the Internet cable and suddenly it appeared. But this is like gambling… I think there's no good solution….. so that's clearly a difficulty. And not the safe practice… You cannot use it, so that's it. Then it's a blind old fashioned thing that you put your catheter [bronchoscope] and you pray that it goes into the right place." Thoracic surgeon

The first three factors (availability of the hybrid theatre, clinicians, and day case bed) are implementation challenges to address in order to operationalise the ENB procedure as intended at UHS. These are highlighted in Figure 4 as 'operational logistics' and act as the major cog to ensure the ENB procedure happens. The fourth factor, the imaging interface, is deemed as an innovation issue which needs to be addressed for the ENB device to function as intended. The imaging interface process is also highlighted in Figure 4, where it acts as a key determinant to whether the procedure can proceed or be rescheduled. This stage is a crucial step in the pathway as the interoperability of the imaging system cannot be assessed until the patient is sedated on the theatre bed, ready for the procedure to occur. If the imaging interface is unsuccessful at this point, it poses a potential risk to the patient, which is highlighted in Figure 4 with the warning triangle icon. If any of these factors are not available or functioning as intended, the procedure would need to be rescheduled, adding time to the pathway and the patients. These potential delays in the pathway are highlighted in Figure 4 by the dotted purple lines, diverting against the flow of the National Optimal Lung Cancer Pathway, which is outlined in yellow angled track. Any delay caused by these factors will negatively impact on achieving the National Optimal Lung Cancer Pathway target (ensuring patients have cancer ruled out or diagnosed within 28 days of referral for diagnostic test).

> "If [one of the surgeons] is away on holiday, there may be two weeks when there's no one here who can do it... You're putting someone into [a diagnostic pathway], but that pathway isn't fully mature, therefore has time restraints and capacity restraints that actually can make the patient journey worse……" Consultant radiologist

However, availability of ENB raises expectations with the patient and a combination of factors adds delay and increases patient anxiety, with the added risk of unsuccessful procedure;

> "….if it happens that [one of the surgeons] is away for two weeks and then he comes back and there's no space in the lab [hybrid theatre room] for two weeks, then you've got a patient who's expecting a procedure. And actually, you've introduced a delay of four weeks and an anxiety, and you don't know whether that procedure is going to be successful or not, so you may end up then with a patient at the end of the day, he's waited six weeks for an unsuccessful procedure. With a lot of anxiety and related psychological distress, as well as breaching on our pathway commitments. Just because you, you're putting them into a new programme that's not quite fully up and running, so I think that's the major disadvantage." Consultant radiologist

3.2.2 STAFF EXPERIENCES OF WORKING ON THE ENB PATHWAY

Staff who participated in the online survey were asked whether they agreed or disagreed to four statements based on their understanding or experience of the impact of the ENB pathway on ways of working in cancer pathways. The four statements included the impacts related to staff gaining additional skills, improving their confidence, improving their ways of working in the ENB cancer pathway and reducing their time in comparison to the usual pathway.

Most staff from both groups (pre-March, 87.5%; post-March, 81.3%) agreed to the statement 'the ENB pathway has provided staff additional skills.' All those who did not agree from the pre-March group stated disagree (12.5%) whilst all from the post-March group stated no difference (18.8%).

Reponses	Pre-March Group	Post-March Group	Total
Agree	87.5%	81.3%	83.3%
Disagree	12.5%	0.0%	4.2%
No difference	0.0%	18.8%	12.5%

Table 6 - Staff response to the statement 'The ENB pathway has provided staff additional skills'

Staff responses to the statement 'ENB pathway has improved staff confidence' showed a shift from the pre-March group majority noting disagree (50%) with 37.5% agree and 12.5% no difference to the post-March group majority responding no difference (68.8%) with 31.3% agree and no one disagreeing.

Responses	Pre-March Group	Post-March Group	Group Total
Agree	37.5%	31.3%	33.3%
Disagree	50.0%	0.0%	16.7%
No difference	12.5%	68.8%	50.0%

Table 7 - Staff response to the statement 'The ENB pathway improved staff confidence'

Most of both pre-March and post-March staff groups agreed (75%) that 'The ENB pathway improved ways of working in the cancer pathway'; more from the pre-March group (12.5%) compared to the post-March group (6.3%) disagreed to the same statement and 12.5% of the pre-March group and 18.8% from the post-March group noted no difference.

Responses	Pre-March Group	Post-March Group	Group Total
Agree	75.0%	75.0%	75.0%
Disagree	12.5%	6.3%	8.3%
No difference	12.5%	18.8%	16.7%

Table 8 - Staff responses to the statement 'The ENB pathway improved ways of working in the cancer pathway'

Finally, most of the pre-March staff group disagreed (75.0%) that the ENB pathway has reduced their time (whilst 12.5% agreed and 12.5% stated no difference) compared to half of the post-March group (50%) stated no difference, 31.3% agreed and 18.8% disagreeing.

Responses	Pre-March Group	Post-March Group	Group Total
Agree	12.5%	31.3%	25.0%
Disagree	75.0%	18.8%	37.5%
No difference	12.5%	50.0%	37.5%

Table 9 - Staff responses to the statement 'The ENB pathway has reduced staff time in comparison to the usual pathway'

In summary, compared to the pre-March staff group, the post-March staff group felt little or no change to the ENB pathway providing additional skills amongst staff nor improvement in the cancer pathway. As the team progressed on with the pilot ENB pathway, the post-March staff responses seemed to shift opinions on improved staff confidence and reduction in staff time from disagreement to neutrality. It is worth noting that the sample size for the pre-March group was eight, half of the post-March group sample (*n*=16).

3.2.3 A THEMATIC SYNTHESIS OF THE STAFF INTERVIEW AND STAFF SURVEY DATA

A thematic analysis of the staff interview and staff survey data was undertaken to draw out key elements that hindered or enabled implementation of ENB in the lung cancer pathway at UHS.

The following themes, supported by quotes from the interviews, demonstrate issues to note in this pilot:

- Complexity of lung cancer diagnostic processes and decisions
- Challenges to implementation and embedding of ENB into the lung cancer pathway
- Potential use and application of the ENB.

3.2.3.1 COMPLEXITY OF LUNG CANCER DIAGNOSTIC PROCESSES AND DECISIONS

There are complexities in diagnosing and identifying patients who are suitable for ENB. Patients may have a nodule or area of lung that requires investigation, but due to its location or patient history, the patient may not be suitable for CT observation or referral for biopsy. The ENB procedure may be a viable alternative for such patients as the uniqueness of ENB is the ability to access peripheral nodules less invasively and with live visual guidance to reach the suspected area with accuracy that are not offered with other diagnostic techniques. The anticipated benefit is potentially an earlier diagnosis and better outcome for the patient. Given the complexity of diagnosis, clinicians have access to an additional diagnostic option.

Nevertheless, diagnosis is not straightforward, and clinicians remain unsure of identifying the right patients for an ENB procedure;

> "But it's early days, you know, and I think we need to have a better feel for which patients are going to be appropriate, which ones are going to be successful? Which ones aren't. So, I think I think exactly where it fits into the pathway is going to take a bit of time." Consultant radiologist

The use of diagnostic tools such as CT biopsy and ENB may still be unable to confirm or disconfirm a cancer diagnosis.

> "it's just a less invasive the […] taking [of] some samples. Yes, it's the quality [ENB] is not as good as biopsy you know, but at least you try to attempt to establish a diagnosis. But we have to emphasise that not [..] all lung lesions are malignant, so [.] sometimes I fear that [..] did not confirm the diagnosis of cancer. So, was this successful? Then the next question was does this patient have cancer at all. I think it's they don't know, so I think we have to clarify really, that OK if we diagnose cancer that's good, but if we don't, there's still the biopsy. Maybe was good quality, but the patient does not have cancer [but] has an inflammatory process, some scarring or previous TB. So, I think that's really important that the result goes back to the MDT saying that OK, ENB happened. It did not confirm cancer." Thoracic surgeon

There remains the need to have confidence in the diagnostic capability of ENB.

> "What percentage of patients are they getting an appropriate sample in order to make the diagnosis?" Nurse case manager

3.2.3.2 CHALLENGES TO IMPLEMENTATION AND EMBEDDING OF ENB INTO THE LUNG CANCER PATHWAY

Multiple challenges were identified when adding an alternative diagnostic option in the lung cancer pathway with the ENB procedure. A postponement of the ENB procedure can lead to step back in the pathway (see Figure 4). If a definitive diagnosis is not obtained this may also loop the patient back onto the CT observation pathway following an MDT review. These delays add a risk to the national faster diagnosis standard (ensuring patients have cancer ruled out or diagnosed within 28 days of referral for diagnostic tests). Other challenges involved delays in pathology results, training, and access to staff.

Comments around "*long delay to investigation and results*" (consultant cancer nurse, staff survey response) caused by ENB operational logistics were consistently noted in the staff survey responses. For example, a comment from a consultant oncologist noted:

> "At times (due to theatre capacity or operator availability) there have been major delays in ENB being performed which has had a potential impact on patient care (in the context of known or suspected cancer awaiting tissue diagnosis before definitive treatment)." Consultant oncologist (staff survey response)

Another consultant oncologist noted a suggestion to minimise potential delay to patients getting a diagnosis:

> "It needs to be clearer how long the waiting list is likely to be so that other options for biopsy can be considered, if available." Consultant oncologist (staff survey response).

These implementation challenges seem to have been addressed over time, as a case nurse manger mentioned in the interview:

> "Another challenge was we only had one consultant who was able to do the procedure and… wasn't very robust because if he was off sick or on study leave or on annual leave, the [ENB] programme would stop. But actually, we now got a second consultant who's also doing the procedure now… it's a more robust service now." Nurse case manager

An additional consultant surgeon joining the ENB programme meant that the pathway improved its delivery,

> "In safer ways, better that it relies on not on one surgeon, but at least two." Thoracic surgeon

ENB requires technical training resource to support the steep learning curve for a surgeon with bronchoscopy experience to be confident in the procedure:

> "…a big learning curve for the actual [ENB] operator. And I think that shouldn't be underestimated. This isn't a procedure they [thoracic surgeons] used to doing. So actually, the person doing it needs a lot of mentorship. And I think it's probably a very steep learning curve. Which will be an interesting point going forwards." Consultant radiologist

At the start of the pilot, there was only one thoracic surgeon who could deliver the procedure. If the surgeon was unavailable, then the operation was delayed. Although the surgeon can deliver in-house training to fellow thoracic surgeons with bronchoscopy experience, the current team is still looking for appropriate clinicians to join the programme and expand their capability.

> "So, in house training for this is very possible. And it's just a matter of continuing with it so that we don't need…. training centres elsewhere in the UK and in Europe, ……I think that is not as much

needed now because the local experience is adequate for them to learn how to do this. And we just need to find a medic and radiographer in the house." Thoracic surgeon

One participant expressed the view that it was a steep "learning curve" (consultant radiologist) not only for the bronchoscopist but also for the whole MDT. There was a need to learn and build experience overtime to understand the optimum process from patient referral to shared decision making with patients to determine appropriate treatment plans.

> "It requires training up new people in new techniques and breaking preconceived boundaries. So, they're always challenged in trying to introduce something new to the NHS, but I don't think that there are any more challenges to this pathway than [anywhere] else, particularly." Consultant radiologist

> "And there's also a learning curve for the MDT. In…terms of understanding the results. Yeah, so you know if [a surgeon has] done 1,000 of these. […] we know from audit that all of his negative ones have been truly negative at five years' time. Then the MDT can say well, we know [the] negative ones… don't we. I think at the moment we're not confident of that. But that's something that comes with time and experience. You know that that's not a criticism. That's just part of the process of doing something new." Respiratory medicine consultant

UHS provides regional tertiary care and so receives patient referrals from a wide area across Hampshire and the Isle of Wight. Referrals from other trusts need refinement to ensure a smooth, "*streamlined pathway*" (Respiratory medicine consultant) as it is anticipated that the demand for ENB pathway will *"increase and more people [patients] would be suitable for it."* Thoracic surgeon.

> "We have a big referral territory, so they are more and more aware of this option, and I think we are. It's more common…" Thoracic surgeon

3.2.3.3 POTENTIAL USE AND APPLICATION OF THE ENB

The future of ENB seems to be polarised amongst clinicians; clinicians with a positive perception have expressed ENB's potential as an ablation treatment and its suitability amongst other lung cancer detection pathways to contribute to the target for patients.

> "*And of course, we only talked about the diagnostic pathway and what we all should think about is the therapeutic aspect of it because the next stage of development of course is to actually do the endobronchial ablation of the lesion. So that is quite exciting*." Thoracic surgeon

> "And then once they've selected for the procedure. I think they should be listed. ASAP…so that they are not disadvantaged by going to ENB compared to other sampling, so whatever waiting times to get biopsies, bronchoscopy or CT scan they should try to be similar, if not better waiting times and which means that you [need a] good number of places available on regular basis well, patients to go on to…to get their procedure." Thoracic surgeon

On the other hand, some clinicians take a more cautious stance on ENB stating that it is "early *days"* (consultant radiologist) to determine whether ENB provides any benefit to lung cancer detection and whether it adds unnecessary complexity to the existing pathway:

> "…if we prove that it's safe and efficacious, then I think it will find a routine place in the pathway. If, on the other hand. It's a nice idea, but in reality, it doesn't give us results often enough or that there are major complications in getting those results. Then I think it'll probably atrophy quite quickly… I think we probably need…. the preliminary results. And then it should find its natural place in the order of investigations we do." Consultant radiologist

If the ENB procedure has resulted in confident and positive diagnosis of a cancerous nodule, then the process to decide treatment options can commence with the patient. However, if the result did not confirm cancer, then the result returns to the MDT for further discussion to establish whether the tissue sampling was successful (thus avoiding Type 2 error of falsely rejecting the case of cancer) or whether it requires further investigation:

> "But we have to emphasise that not necessary all lung lesions are malignant, so in sometimes I fear that ohh, did not confirm the diagnosis of cancer. So, was this successful [procedure to obtain quality tissue sample]? Then the next question was this patient have cancer at all so. I think if they don't know, so I think we have to clarify really, that OK if we diagnose cancer that's good, but if we don't, that's still the biopsy." Thoracic surgeon

> *"So, I think if you do ENB and you get a cancer diagnosis then yes, you're confident with it. If you get if you do ENB and you and you don't get to cancer diagnosis, then I think there's situations where we haven't been entirely confident, and we've decided to do another CT scan to see if the if the so……"* Respiratory medicine consultant

On a final point, one clinician suggested there were implications for earlier diagnosis to consider and that lung cancer screening programmes could lead to unnecessary treatment:

> "… what is the benefit? Of diagnosing some of these cancers more quickly. […] That's a bigger issue, one that's being debated a lot at the moment, so we are particularly [thinking about] lung cancer screening programmes. We're turning up a lot of little nodules. … that ww are operating on and taking

out…. an early lung cancer, which is fine, but actually we don't know whether those cancers would have had any impact upon that patient at all. And there's a suspicion that some of these cancers would have actually just sat there for many years without having any impact upon patient who might well have died from something completely different. In which case, actually, you've inflicted an unnecessary procedure on the patient." Consultant radiologist

3.3 DOES ENB CONTRIBUTE TO EARLIER DIAGNOSIS OF LUNG CANCER IN WESSEX?

Earlier diagnosis in this context refers to both the definitive diagnosis being made at an earlier cancer stage (size and spread of the growth) or a reduced time between the initial referral for suspected cancer and receiving a definitive diagnosis.

3.3.1 NUMBER OF CANCERS DETECTED ON THE ENB PATHWAY AS A PROPORTION OF LUNG CANCERS DETECTED IN WESSEX

Using the published NHSE cancer standards data (NHSE, 2023), we are able to show the number of ENB cancer diagnosis as a proportion of total suspected lung cancer diagnosis in Wessex acute trusts (Dorset County Hospital NHS Foundation Trust, Hampshire Hospitals NHS Foundation Trust, Isle of Wight NHS Trust, Portsmouth Hospitals University NHS Trust, University Hospital Southampton NHS Foundation Trust, University Hospitals Dorset NHS Foundation Trust). This shows that 2.10% of suspected lung cancers were detected by the UHS ENB pathway during the pilot period. This is broken down monthly in Figure 5.

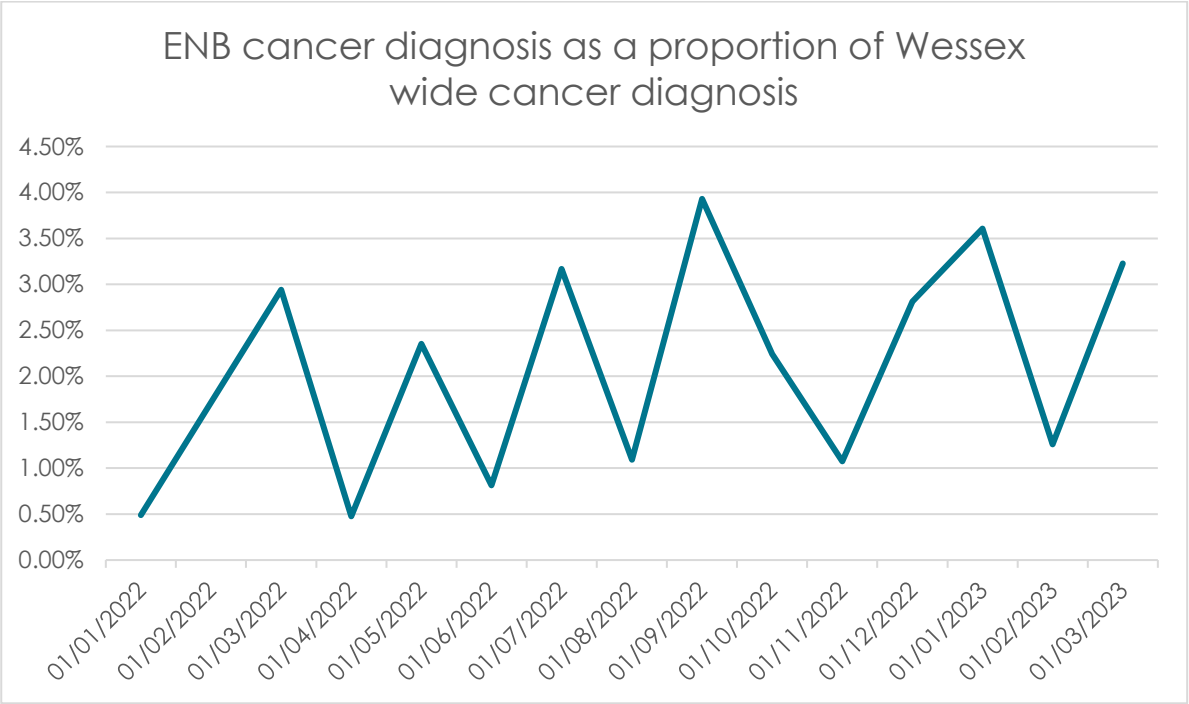

Figure 5 - the percentage of suspected lung cancer diagnosis in Wessex that were identified by the ENB procedure at UHS by month of diagnosis.

3.3.2 STAGE OF DIAGNOSIS OF CANCERS DETECTED ON THE ENB PATHWAY

Of the 83 patients, 27 had no lung cancer detected. From the remaining 56 patients, the stage at which their lung cancer was detected is shown as proportions in Figure 6. This is also shown in comparison against the English national proportions for stage of diagnosis of lung cancer, taken from 2020 NHS Digital figures.

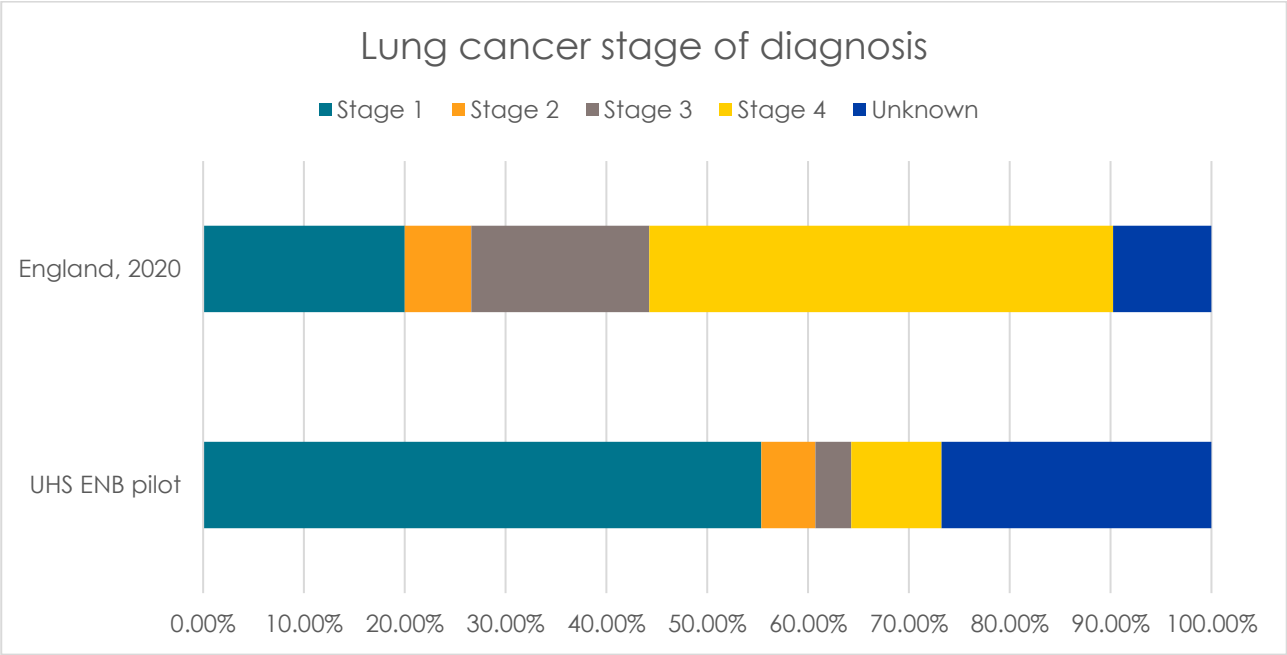

Figure 6 - Lung cancer proportions of stage at diagnosis. Results shown for England in 2020 and for the UHS ENB pilot. All ENB patients from UHS data – no filtering for internal pathway comparison.

Most referrals came from Southampton General Hospital, Queen Alexandra Hospital and Salisbury District Hospital. Only a small number came from other hospitals and the Targeted Lung Health Clinic (TLHC).

Referral Source	Grand Total
Dorset County Hospital	*
Lymington New Forest Hospital	*
Poole Hospital	*
Queen Alexandra Hospital	14
Royal Bournemouth and Christchurch Hospital	*
Royal Hampshire County Hospital	*
Salisbury District Hospital	11
Southampton General Hospital	26
St Mary's Hospital IOW	*
TLHC	*
Grand Total	**72**

Table 10 - Number of diagnoses during ENB pilot split by referral source

3.3.3 TIME TAKEN TO REACH KEY EVENTS ON THE SUSPECTED LUNG CANCER PATHWAYS - ENB/CT OBSERVATION

The time taken between key events was calculated for both the ENB pathway and the CT observation pathway. The average times are displayed in figure 7. The average referral to diagnosis time for the ENB pathway sample was 54.5 days and for the CT observation pathway sample was 38.8 days.

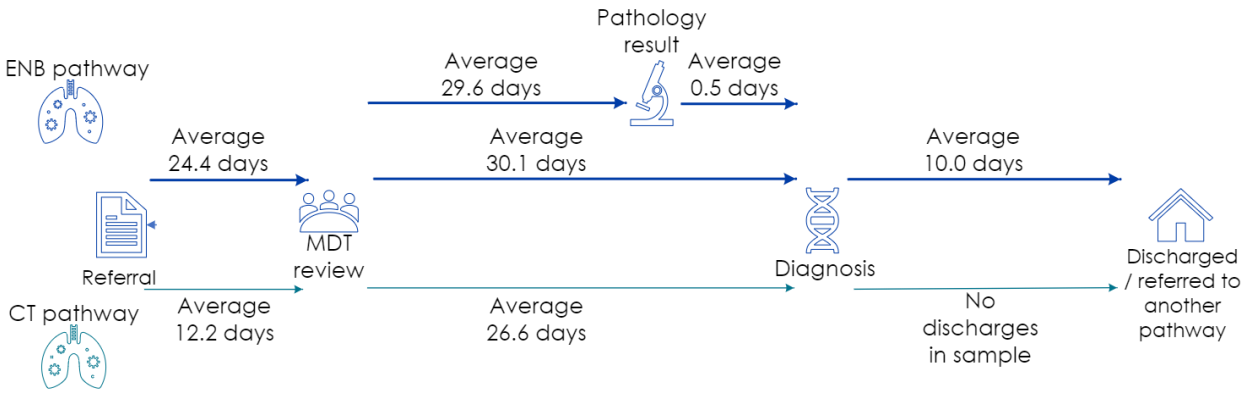

Figure 7 - Diagram of key events on the ENB and CT observation pathways including average times between events

For the sake of comparability, we calculated pathway lengths as the time to discharge or in the absence of a discharge, the time to the end of the sample period. This information is shown in figure 8.

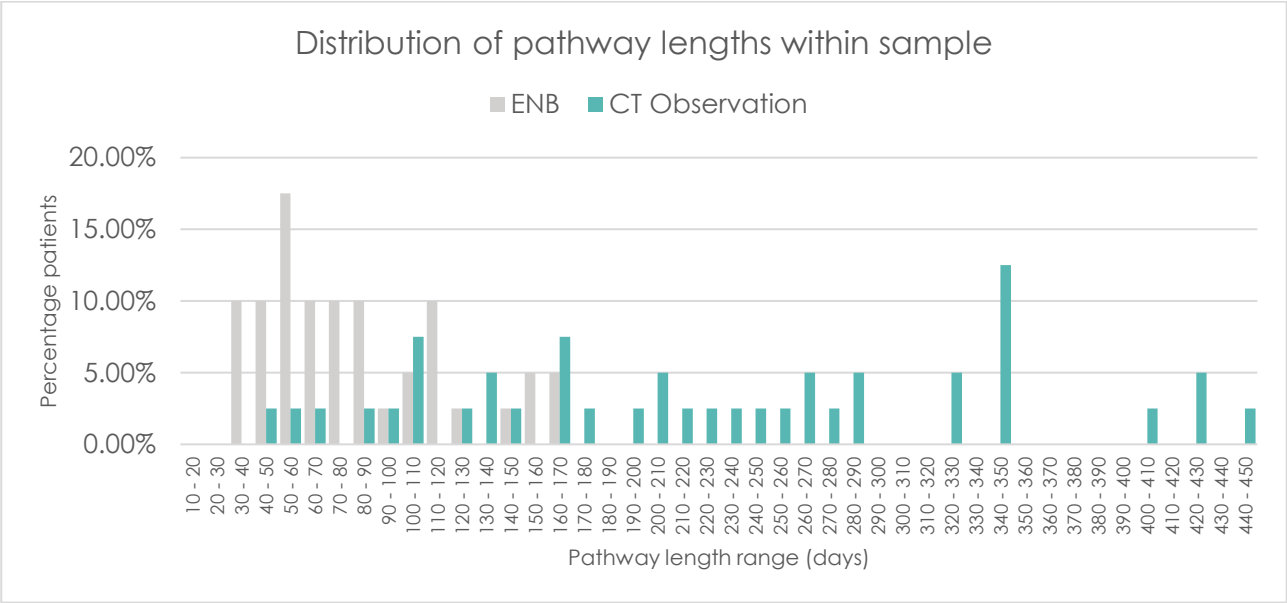

Figure 8 – Distribution of pathway lengths for the ENB and CT observation pathway samples

3.4 DOES THE ENB PATHWAY CHANGE THE DIAGNOSTIC EXPERIENCE FOR PATIENTS IN WESSEX?

3.4.1 DIAGNOSIS AND DISCHARGE RATES

We used the routine data collections to calculate the percentage of patients receiving a diagnosis and those receiving a discharge. This information is presented in table 11. We also show these as cumulative trends in figure 9.

	Diagnosed	Discharged
ENB	85.4%	68.3%
CT observation	40.0%	0.0%

Table 11 - Percentage of patients diagnosed and discharged

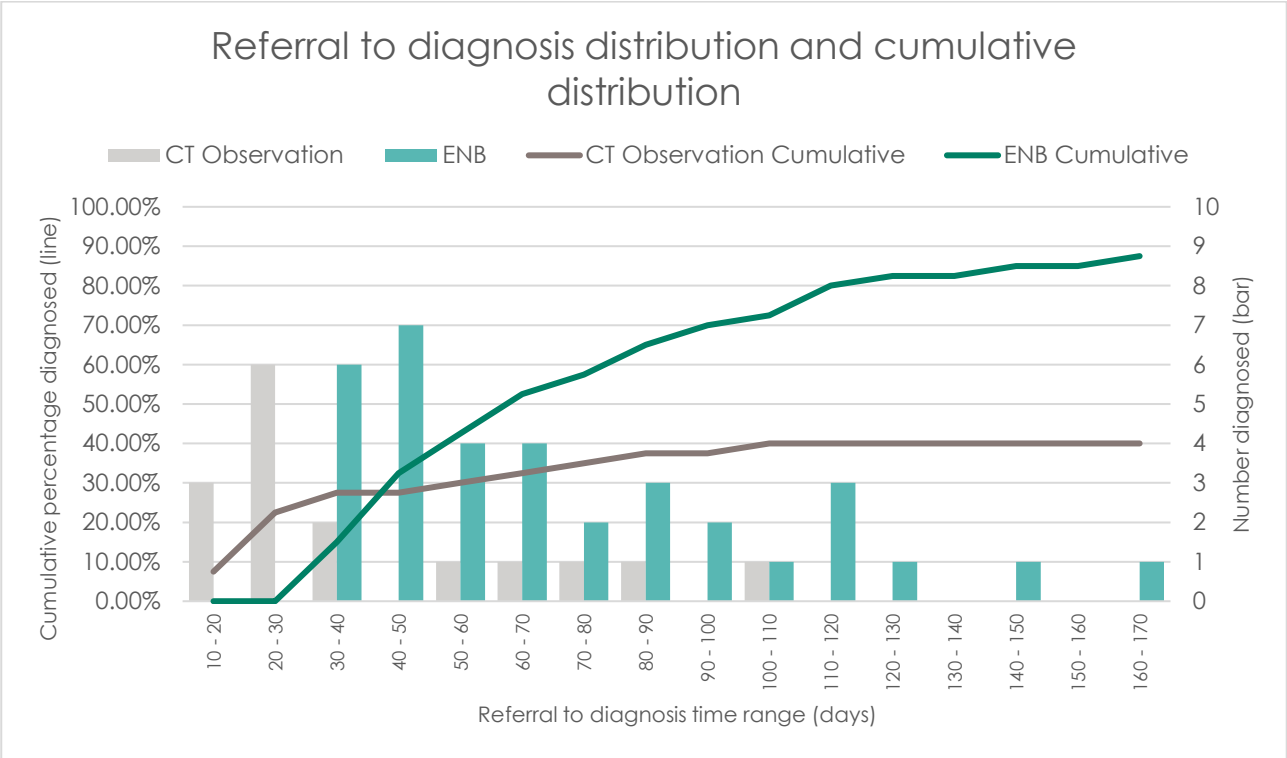

Figure 9 - Distribution and cumulative distribution of referral to diagnosis time for the ENB pathway and CT observation pathway samples

If we consider the incomplete patients within the data, we can calculate a minimum - average diagnosis time for the two different pathways by setting the diagnosis date as the end date of the sample period. In other words, we make an adjustment so that patients without a diagnosis date are given a diagnosis date - which allows us to visualise the impact from incomplete patients as well as complete patients. This information is shown in Figure 10. The adjusted minimum - average referral to diagnosis time for ENB would be 77.6 days and for CT observation 137.25 days.

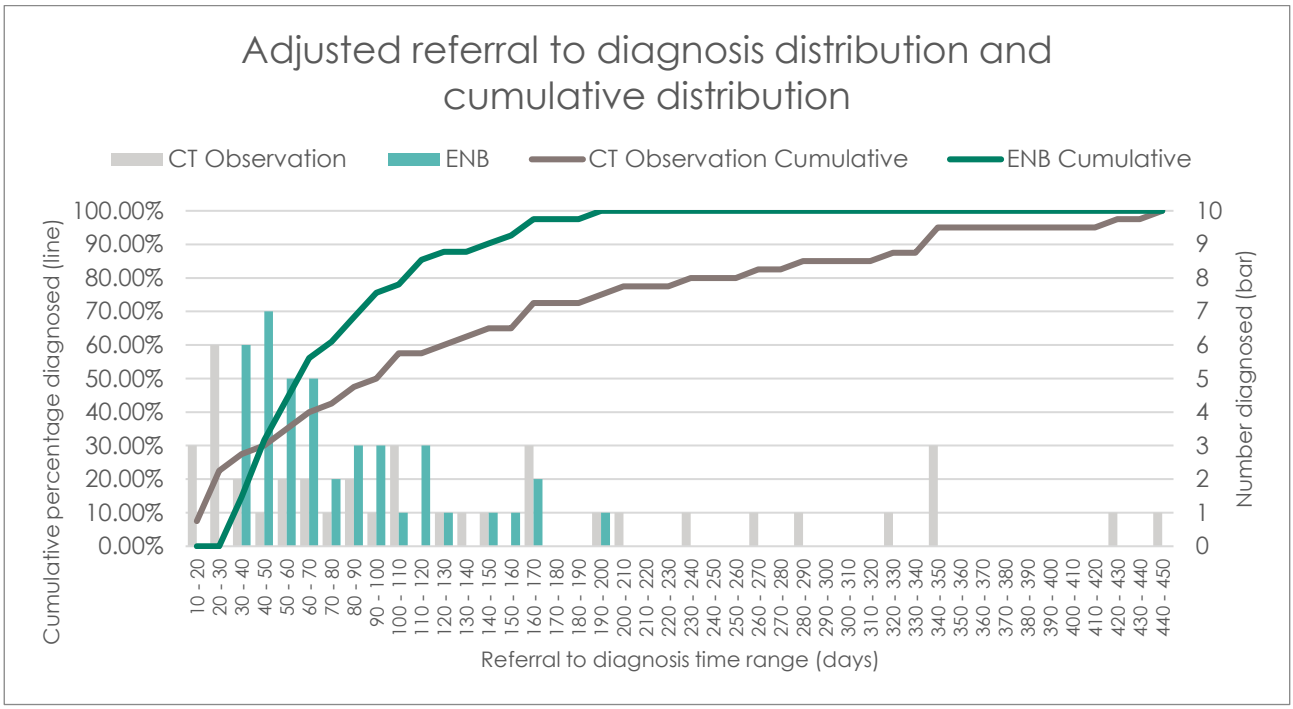

Figure 10- Distribution and cumulative distribution of referral to diagnosis time for the ENB pathway and CT observation pathway samples. Adjustment = patients without diagnosis date are assigned a diagnosis date equal to the sample period end date.

3.4.2 NUMBER OF ENB PATIENTS REQUIRING ALTERNATIVE DIAGNOSTICS FOLLOWING AN INCONCLUSIVE PATHOLOGY RESULT

From the routine data collections, we identified activity that came after an ENB procedure. Following an ENB procedure 14 patients had further diagnostic activity before they were discharged. This activity is detailed in table 12.

Row Labels	Count of Activity after ENB
Computerised Tomography (CT)	8
Positron Emission Tomography (PET)	*
X-Ray	7

Table 12 - Diagnostic activity of ENB patients following an ENB procedure and prior to discharge

3.4.3 STAFF PERCEPTIONS OF PATIENTS' EXPERIENCES ON THE ENB PATHWAY

The staff reported the ENB pathway to offer "*a positive experience for patients*" (nurse case manager). The procedure is perceived as "*very much less invasive, less traumatic, less painful [for the patients] and it can be done as a day case*" (nurse case manager). ENB does not involve external incision, thus less risk of complication (e.g., pneumothorax), and collects tissue sample accurately without disrupting surrounding tissue too much. The ENB procedure is done as day case and usually the patients are sent home on the same day. If the sample has been successfully collected and confidently diagnosed, then patients are expected to spend less time waiting for a definitive diagnosis, reducing their level of worry, anxiety, stress, and uncertainty of their future.

> "If they're just having repeated CT compared to having an answer much quicker with the ENB. Again, that with the families might address and help them so plan better for the care of their care or the care of the family member… I think that's the main positive impact." Thoracic surgeon

Because of these benefits, in comparison to CT guided biopsy, once the diagnosis is decided as either cancerous or benign, patients can be put onto an appropriate pathway swiftly.

> "Traditionally, we wouldn't have progressed on to a biopsy because it was too dangerous or not felt to be beneficial, and those patients would have just gone into a sort of holding pattern where we observe them every three months for a while we watch [the nodule] grow or not. Now, I think we're in a position where we can actually give those patients a positive diagnosis more quickly [with ENB]." Consultant radiologist

3.4.4 PATIENTS' EXPERIENCES OF THE ENB PATHWAY

Patients' feedback from the survey was positive, highlighting that they were "*very well informed throughout the whole process*," that it was "*straightforward,*" smooth and quick procedure. There were a few comments highlighting delays, and failed sample collection. For example, one response noted that the patient's procedure was cancelled and then when the procedure happened, a sample could not be obtained. Few patients noted that they could not take in all the information about ENB as they were worried about the procedure or the outcome, or they did not understand all the information given about ENB.

The patients' survey included 33 responses noting that ENB was their first experience of a diagnostic procedure and 5 patients noting that ENB was not their first experience of diagnostic procedure. Of those with previous diagnostic experience (*n*=5), the number of previous procedures ranged from one to 11. Compared to their previous experiences, the ENB procedure was noted as quicker for two patients and two patients responded that they preferred ENB compared to their previous experience. Two patients noted that they were not happy to consent. Both these patients reported that they were not happy with the overall care received or the time it took to complete the procedure. In addition, one response in the staff survey noted that ENB may not be preferable for some patients as "*patients are often anxious about having a 'camera test' so some may opt for CT* observation *if given a choice*" (nurse specialist, staff survey response).

3.5 WHAT IMPACT HAS THE INTRODUCTION OF ENB HAD ON OTHER PATHWAYS AT UHS?

3.5.1 NUMBER OF CASES REVIEWED AT MDT PER MONTH FOR THE ENB ELIGIBLE PATHWAY

From Routine UHS data we calculated the number of patients per month who were placed on the ENB pathway. This is shown in figure 11.

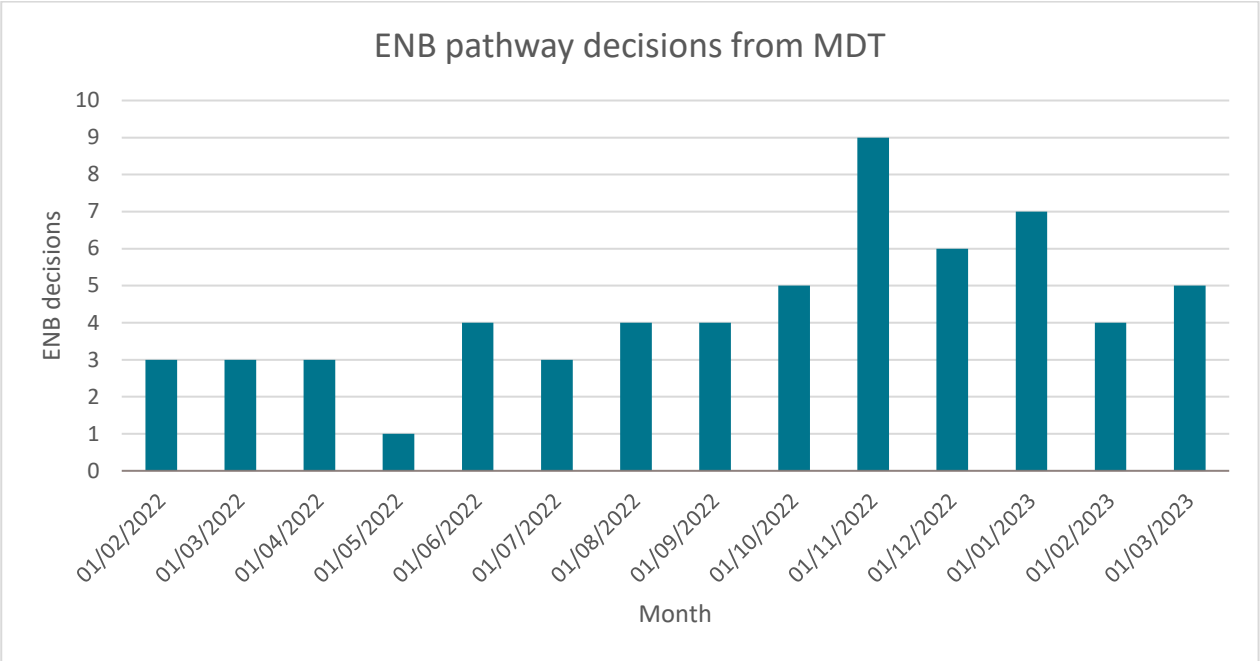

Figure 11- Number of patients per month placed on the ENB pathway following MDT review

3.5.2 CHANGE IN ACTIVITY DEMAND – VOLUMES AND TIME TAKEN

The various types of activity that happened under the lung cancer pathways was captured from UHS routine data. The average volume of activity per patient was calculated to account for the difference in the number of patients in the pathway samples. Table 13 shows these figures displayed by type and sub-type.

	CT Observation	ENB	Variance
Diagnostic	**2.35**	**0.68**	-1.67
Computerised Tomography (CT)	1.35	0.32	-1.03
Positron Emission Tomography (PET)	0.60	0.22	-0.38
Targeted Lung Health Clinic CT	0.33	0.00	-0.33
X-Ray	0.08	0.15	0.07
Inpatient	**0.23**	**1.02**	0.80
Bronchoscopy	0.03	0.00	-0.03
ENB	0.00	0.98	0.98

	CT Observation	ENB	Variance
Left VATS Segmentectomy	0.03	0.00	-0.03
Left VATS Trisegmentectomy	0.03	0.00	-0.03
Left VATS Wedge Resection	0.03	0.00	-0.03
Lobectomy	0.08	0.02	-0.05
Lobectomy & Flexible Bronchoscopy	0.00	0.02	0.02
Radiosurgery	0.03	0.00	-0.03
Right VATS Wedge Resection	0.03	0.00	-0.03
Outpatient appointment	**1.98**	**1.68**	-0.29
Oncology	0.05	0.15	0.10
Respiratory	1.65	0.34	-1.31
Thoracic	0.28	1.20	0.92

Table 13 - Average volumes of activity per patient on the ENB pathway and the CT observation pathway

The length of time utilised for the different activities was also captured from routine data. The average time spent per patient on these activities was calculated and is presented in Table 14.

	CT Observation	ENB	Variance
Diagnostic	**0.59**	**0.19**	-0.41
CT	0.23	0.05	-0.17
PET	0.30	0.11	-0.19
TLHCCT	0.05	0.00	-0.05
X-Ray	0.01	0.02	0.01
Inpatient	**12.47**	**18.29**	5.82
Bronchoscopy	0.07	0.00	-0.07
ENB	0.00	13.83	13.83
Left VATS Segmentectomy	1.29	0.00	-1.29
Left VATS Trisegmentectomy	4.36	0.00	-4.36
Left VATS Wedge Resection	1.47	0.00	-1.47
Lobectomy	4.51	2.47	-2.04
Lobectomy & Flexible Bronchoscopy	0.00	1.99	1.99
Radiosurgery	0.00	0.00	0.00

	CT Observation	ENB	Variance
Right VATS Wedge Resection	0.77	0.00	-0.77
Outpatient appointment	**0.50**	**0.55**	0.04
Oncology	0.01	0.05	0.04
Respiratory	0.40	0.09	-0.32
Thoracic	0.09	0.41	0.33

Table 14- Average time per patient in different activities for the ENB pathway and CT observation pathway samples. Shown as number of hours.

Some staff feedback suggested that patients might incur an additional step, if the ENB procedure was not successful and they were transferred to the CT observation pathway.

Some interviewees expressed views on the balance of cost benefit in comparison to other existing diagnostic procedures (CT guided biopsy, Endobronchial Ultrasound-guided Transbronchial Needle Aspiration, EBUS). The factors to consider included:

- sample accuracy of ENB (quality of sample collected to provide confident diagnosis or the "*hit rate*")
- overall cost saving of ENB against the conventional CT observation follow-up scans
- potential displacement of other diagnostic procedures
- whether every suspected lung nodule should be subject to investigational operations.

> "I think it depends on what you do with the patient afterwards, so if they get an operation, then that's value for money because they get the operation they need, they get it sooner. The chance of having spread is lower and it reduces them coming back for scans in three months, nine months, and 24 months…." Respiratory medicine consultant

> "…..money has to be spent on this to get it right. That's the downside to it, [ENB] is not cheap. It's not free. I think that that's the number one… issue…. Again, it is just ... costs. You know manpower and you know, consumables to get it going… But the observation is that a lot of people now who have a nodule……. which they didn't have two years ago… the spell of care and for ENB and cost of the spell of care for CT, repeated CT, repeated appointment. CT biopsy at some point. …. [have ENB], I think that's where the comparison can be made." Thoracic surgeon

> "I mean, we know it's quite an expensive procedure, so it's gonna cost a lot more to do than a CT guided biopsy. So, if you can do a CT guided biopsy, do a CT guided biopsy. But if you can't do it…. then ENB may or may not be beneficial depending on your downstream savings…. if you diagnose one patient in 10 with an early-stage cancer, that saves us lots and lots of money. That may be enough, who knows. So, I think the jury's out." Consultant radiographer

These personal reflections by clinicians indicate some concerns over cost versus benefit based on the diagnostic benefit of the patient receiving treatment sooner and how best that benefit can be measured.

4 CONCLUSIONS

4.1 WHAT HAS ENABLED OR HINDERED THE IMPLEMENTATION OF THE ENB PATHWAY AT UHS?

A number of factors which enabled or hindered the implementation of the ENB pathway at UHS were identified. ENB requires a surgical day bed as an additional requirement, this will be subject to hospital bed capacity. It also requires the availability of a hybrid theatre. Other operational factors such as clinician availability are common across all similar care pathways. Decisions at the MDT following referral are complex based on diagnostic factors such as location of a nodule. Once the patient is on the ENB pathway and undergoing ENB examination, there remain issues with the manual transfer of images and the need to ensure the surgeon has access to a CT scan. If the ENB procedure is successful in obtaining a sample and providing a definitive diagnosis this is considered a beneficial to patients, however, if unsuccessful, the patient may revert to CT observation or biopsy and so adds an additional step.

4.2 DOES ENB CONTRIBUTE TO EARLIER DIAGNOSIS OF LUNG CANCER IN WESSEX?

The evaluation revealed conflicting evidence regarding whether the ENB pathway is faster at reaching a diagnosis than the existing CT observation pathway.

The average referral to diagnosis time for the ENB pathway sample using complete records (patients who have received a diagnosis) was 54.5 days and for the CT observation pathway sample was 38.8 days. We also show that for these complete records, the average time from MDT to diagnosis for the ENB pathway sample was 30.1 days and for CT observation was 26.6 days (3.3.3 figure 7).

This comparison is obscured firstly due to limitations within the data (2.2 - Limitations), but more importantly by the percentage of patients diagnosed. The ENB pathway sample had a diagnosis rate of 85.4% whereas the CT observation pathway sample had a diagnosis rate of only 40.0% (3.4.1 table 11). We show that if we account for undiagnosed patients by adding in their minimum time to diagnosis (by assuming this is the end date of the sample period), then the average referral to diagnosis time for the ENB sample would be 77.6 days and for the CT observation sample would be 137.25 days (3.4.1 figure 10).

We have also shown that when compared to national data, the ENB pathway sample patients show a higher proportion are receiving a cancer diagnosis at an earlier stage. Nationally only 20.0% of patients are diagnosed at Stage 1, for the ENB pathway over half (55.4%) were diagnosed at stage 1 (3.3.2 figure 5).

4.3 DOES THE ENB PATHWAY CHANGE THE DIAGNOSTIC EXPERIENCE FOR PATIENTS IN WESSEX?

From the routine data collected by UHS, we present some evidence suggesting that changes resulting from the ENB pathway have occurred.

Changes that may improve patient experience - diagnosis and discharge rates appear higher looking at the ENB pathway sample compared to the CT observation pathway (3.4.1 Table 11). Also, we have shown that it appears the ENB pathway may have fewer CT episodes (3.5.2 table 13).

Changes that may decrease patient experience - the amount of time patients spend in the hospital as an inpatient has increased (3.5.2 table 14). We have also shown that there is evidence to suggest several NB procedures failed. Several patients required further diagnostic activity following their ENB procedure before they could be discharged (3.4.2 table 12). It is unclear how the changes in time from referral to diagnosis have impacted patient experience from the quantitative data alone. Qualitative data shows that staff think that ENB is a less invasive procedure compared with surgical biopsy. They also believe it is less painful and that patients can potentially receive an earlier diagnosis allowing for treatment options to start sooner. For some patients they will avoid repeated CT observation appointments. The patient experience of the ENB process was mostly positive because it was quick and straight forward. Some patients experienced delay or cancellation increasing anxiety as well as were overwhelmed by the procedure and its potential outcome.

4.4 WHAT IMPACT HAS THE INTRODUCTION OF ENB HAD ON OTHER PATHWAYS AT UHS?

We have shown from routine UHS data that during the pilot, 83 patients had an ENB procedure and that numbers of patients being placed on the ENB pathway have increased slowly as the pilot has progressed (3.5.1 figure 11).

Quantitative data suggests that for the ENB pathway sample, the number of CT scans decreased (per patient – 2.35 down to 0.68, 3.5.2 table 13) and in so doing, the amount of time patients spend utilizing that resource has also decreased (per patient – 14hrs 10min down to 4hrs 34min, 3.5.2 table 14) when

compared to the CT Observation sample. This suggests that there may be unused CT resource which can be redeployed to other tasks within UHS. Additional data relating to the potential re-use of this unused resource was not available to evaluators, therefore we are unable to translate this potentially unused capacity into any units relating to re-use.

Inpatient activity, both volume and time appear to be higher in the ENB pathway sample compared to the CT observation sample (3.5.2 table 13 and 14). This is supported by the planned pathway for ENB patients which centres around the ENB procedure being performed as an inpatient episode, whereas previous activity on the CT observation pathway was held in an outpatient setting.

Outpatient appointment comparison between the ENB pathway sample and CT observation pathway sample appears to be relatively similar. There is an indication that on the ENB pathway patients are having fewer but longer appointments. However overall, the resource requirement remains similar. There does appear to have been a shift within the outpatient activity. Respiratory appointments have dropped whereas thoracic appointments have increased.

From the staff perspective the introduction of the ENB pathway, alongside the CT observation pathway, created more complexity within the whole lung cancer diagnostic pathway. This is because ENB is more challenging to operationalise. It relies upon access to a hybrid theatre, availability of an experienced team of clinicians, and an available surgical day unit bed. Whilst ENB can provide a diagnosis that shortens the patient's need to remain on the CT observation pathway, a definitive result is not guaranteed. This may be due to a failed sample collection or failed imaging connectivity. If either of these were to happen, the patient may be moved to a different pathway. Nevertheless, some patients may benefit and gain an earlier diagnosis. In addition, there is potential for ENB to be used as treatment as well as a diagnostic option. It is noted that lung cancer diagnosis is complex due to the positioning of potentially cancerous nodules in the lung and so ENB provides an additional diagnostic tool for the clinician.

5 RECOMMENDATIONS TO ENABLE FUTURE MONITORING AND EVALUATION OF THE ENB PATHWAY

5.1 IMPROVED DATA CAPTURE/GOVERNANCE

One of the main limitations on this evaluation was the ability to identify and source comparator data that was compatible with the ENB sample data. Once the evaluation was underway, difficulties were encountered by UHS in identifying and extracting data related to specific cancer pathways, that had not been foreseen. We therefore recommend improving data capture and storage to enable easier extraction of pathway specific data for this type of analysis moving forward. The central UHS patient administration

systems (PAS) are set up for recording referrals and associated activity so it may be challenging to include a pathway level identifier within them. Instead UHS management may wish to look at improving governance of localised data collections.

5.2 CONTINUED OBSERVATION

Another limiting factor on the quantitative analysis for this evaluation was the number of complete records (i.e., patients who had finished their pathway) that were able to be included within the evaluation timeframe. Without a larger number of completed records we had to make assumptions about the potential time to diagnosis (minimum – average time from referral to diagnosis). A longer study can gather the evidence to understand the true impact from the undiagnosed/incomplete patient pathways. This will increase the reliability of any future analysis of impact.

Future evaluations can explore more fully the challenges patients experience in their care on the lung cancer pathway and their involvement in decision making. The patient survey provided some indicative feedback on experience, generally positive, but not the complexities of diagnosis some patients might experience.

5.3 REFINE AND FORMALISE ENB ACCEPTANCE CRITERIA

Although the analysis of completed records for referral to diagnosis time suggested that it was slower than the existing CT observation pathway, the views of staff suggested that the benefits of increased diagnosis rate (along with other benefits including lower stage at diagnosis) may be worth the trade-off for those patients who cannot expect a diagnosis through standard methods. For example, staff described the complexity of diagnosis and difficulties in obtaining samples from parts of the lung requiring some patients to remain under observation. Patients are focussed on relieving their anxiety and gaining a diagnosis. Formalising acceptance criteria for ENB would enhance future evaluations by defining and identifying patient cohorts for analysis. Future evaluations may benefit from understanding MDT decision making and criteria used to refer patients on to the ENB pathway.

5.4 HEALTH INEQUALITY

Initial descriptive analysis of patient demographics showed that the patients selected for the ENB pilot had a lower proportion from the most deprived locations (3.1.2 table 4). We recommend that the service

continues to monitor this metric to observe if this is an ongoing issue, and to inform service decisions about how to address the source of any inequality. In addition, understanding better the experience of patients from different backgrounds receiving ENB and those who remain under CT observation would be beneficial as ENB becomes embedded in the lung cancer pathway.

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APPENDIX 1 – LOGIC MODEL

UHS ENB LOGIC MODEL

Wessex Academic Health Science Network

A In this **CONTEXT**

led by the Thoracic team, UHS will run a 12 month pilot of Electromagnetic Navigation Bronchoscopy (ENB) from January 2022. The pilot team plans to see approximately five patients per month, with a requirement to see 70 patients

The purpose of ENB is to enable earlier diagnosis and therefore intervention/discharge for patients who would otherwise remain on a CT observation pathway due to the placement/size of their lesion.