

# superDimension Navigation System to help diagnostic sampling of peripheral lung lesions

Medtech innovation briefing

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## Summary

- The **technology** described in this briefing is the superDimension Navigation System. It is used to guide endoscopic tools or catheters during biopsy of mediastinal and peripheral lung lesions.
- The **innovative aspects** are access and biopsy of peripheral lung lesions without the need for pleural puncture. The technique involves real-time navigation into the peripheral lung, without needing ionising radiation.
- The **intended place in therapy** would be as an alternative technique for definitive diagnosis of peripheral lung lesions in people for whom percutaneous or surgical approaches are thought to be too high risk.
- The **main points from the evidence** summarised in this briefing are from 7 studies including a total of 8,359 patients in secondary care. Comparative evidence shows that electromagnetic navigation bronchoscopy-guided biopsy is less effective in terms of diagnostic yield (proportion of definitive diagnoses), but with lower pneumothorax rates than CT-guided trans-thoracic needle aspiration in patients with peripheral lung and mediastinal lesions.

- **Key uncertainties** around the evidence are the different definitions of diagnostic yield used in the meta-analyses of primary studies and no studies were identified in a UK setting.
- The **cost** of using the superDimension Navigation System is estimated by the company to be £1,942 to £2,331 per procedure. The **resource impact** would be greater than standard care, where the estimated average cost of a CT-guided trans-thoracic biopsy procedure is £1,357.

## The technology

The superDimension Navigation System (Medtronic) is used to guide endoscopic tools or catheters during biopsy of mediastinal and peripheral lung lesions. It allows access to peripheral lesions that would not otherwise be reached using conventional bronchoscopes. The superDimension Navigation System consists of computer software, which creates a 3D-reconstruction from CT data of the airway. Conventional bronchoscopes can only reach areas of the lung that are close to the main airways, but the superDimension Navigation System may allow access to more distant regions of the lung when needed, for example for biopsies.

Additional image guidance, such as X-ray fluoroscopy, radial endobronchial ultrasound (rEBUS) or cone beam CT are not compulsory, but are recommended by the company to confirm the intended position of biopsy tools, before sampling, to increase diagnostic yield.

## Innovations

The innovative aspect of the superDimension Navigation System is that it allows localisation, access and biopsy of smaller and more peripheral lung lesions, without the risks of pleural puncture. This allows sampling of distal endobronchial disease, beyond the limits of direct vision with a conventional bronchoscope. Avoiding pleural puncture minimises the risk of pneumothorax, pain and haemothorax for patients.

It offers an alternative technique for patients for whom percutaneous approaches to biopsy (such as CT-guided trans-thoracic needle biopsy, or surgical excision) are thought to be too high risk.

## Current care pathway

People with suspected endobronchial disease may have lesions that have been identified using standard imaging techniques. However, they may need to have a biopsy to diagnose what is causing the lesion(s). Current standard of care in the NHS for sampling solitary lesions is CT-guided trans-thoracic needle biopsy by an experienced radiologist. If there is mediastinal lymph node

involvement, endobronchial ultrasound guidance is used for diagnostic sampling.

If CT-guided trans-thoracic needle biopsy is not suitable, electromagnetic navigation bronchoscopy, radial endobronchial ultrasound and fluoroscopy-guided biopsy may be used, but these have a lower diagnostic sensitivity.

The following publications have been identified as relevant to this care pathway:

- [Lung cancer: diagnosis and management](#) (2019) NICE guideline NG122
- [Lung cancer in adults](#) (2012 updated 2019) NICE quality standard QS17
- [Endobronchial ultrasound-guided transbronchial biopsy for peripheral lung lesions](#) (2010) NICE interventional procedures guidance 337

## Population, setting and intended user

The superDimension Navigation System is intended for use in people with lesions that are further into the lungs than conventional bronchoscopes may be able to reach. It allows clinicians to navigate to the lesions through the bronchial tree, to diagnose or treat them. Once the lesion is reached, the clinician can do a biopsy, insert fiducial markers to guide radiotherapy or brachytherapy catheters, or do lung marking with methylene blue to help surgical resection of small nodules. Only the application of biopsy for diagnostic sampling is in scope of this briefing.

Specific patient populations for the electromagnetic navigation bronchoscopy biopsy procedure include:

- individuals for whom CT-guided trans-thoracic needle biopsy is thought to be high risk, including those with multiple and bilateral lesions or previous pneumonectomy
- individuals in whom CT-guided trans-thoracic needle biopsy is technically not possible.

The safety of the procedure has been shown in high-risk patients with severe chronic obstructive pulmonary disorder (COPD; [Towe et al. 2017](#)). The system is used in secondary and tertiary care in the NHS. Operators may include pulmonologists and thoracic surgeons trained in bronchoscopy and after training in use of the superDimension Navigation System.

## Costs

### Technology costs

The total average cost of using the technology is estimated to be £1,942 (if done outside of an operating theatre) or £2,331 (in an operating theatre) per procedure, based on costs from an unpublished study done in the NHS. This average cost assumes that 79.7% of procedures are done using a general anaesthetic and represents a staff skills mix including consultant, anaesthetist, operating department practitioner, band 5/6 scrub nurse and band 5 recovery nurse.

**Table 1 superDimension navigation system costs**

| Description  | Cost                 | Additional information  |
|--|----------------------|---|
| <b>superDimension system</b>   |                      |   |
| superDimension Navigation System*  | £110,000 to £130,000 | All prices are for financial year 2018 to 2019  |
| superDimension V6.x to V7.1 Upgrade*   | £32,000              | This can be bought to upgrade a version 6 superDimension technology to the latest version (7.1) |
| <b>EDGE Kits and Catheters</b>   |                      |   |
| EDGE Firm Tip Procedure Kit – 180°, 90° or 45° Curve                           | £773                 | –   |
| EDGE locatable guide   | £730                 | –   |
| EDGE 180°, 90°, 45° Firm Tip or straight extended working channel              | £405                 | –   |
| <b>Bronchoscope Adaptors</b>   |                      |   |
| EDGE Bronchoscope adaptor – Olympus 180, Pentax, Fujinon or Olympus 190 Scopes | £86                  | Also available as a box of 10 for £859  |
| <b>Biopsy Tools</b>  |                      |   |
| superDimension Cytology Brush  | £189                 | Box of 10   |
| ArcPoint Pulmonary Needle – 21G  | £848                 | Box of 5  |

|  |      |           |
|--|------|-----------|
| ArcPoint Pulmonary Needle – 18G  | £970 | Box of 5  |
| superDimension Triple Needle Cytology Brush – 10 mm or 15 mm   | £773 | Box of 10 |
| superDimension Needle-tipped Cytology Brush  | £412 | Box of 10 |
| GenCut™ Core Biopsy System   | £250 | –         |
| CrossCountry Trans-bronchial Access Tool   | £250 | –         |
| <b>Markers and Patches</b>   |      |           |
| superLock Fiducial Marker  | £764 | Box of 5  |
| superDimension Marker Delivery Kit   | £361 | Box of 5  |
| superDimension Patient Sensor Patches*   | £189 | Box of 60 |
| Items in multiple box units are individually packaged and sterile.<br>Items marked with an asterisk (*) are not sterile. |      |           |

## Costs of standard care

CT-guided trans-thoracic needle biopsy is the main alternative in the NHS and, where a CT scanner is already installed, there will be no need for additional capital costs (however, this is likely to be over £1 million). Biopsy needles range in price from £8.00 to £27.50 (inc. VAT) on the [NHS Supply Chain catalogue](#). The tariff cost for standard care is £1,357, which captures the costs of image-guided biopsy and full pulmonary function testing.

## Resource consequences

In April 2019, 10 NHS trusts have either bought the superDimension Navigation system, have business cases for funding in process, or have the system under clinical evaluation or trial. Sixteen clinicians are experienced in its use.

Resources needed include costs of the system and training to develop staff skills needed for the electromagnetic navigation bronchoscopy procedure. Training takes place over 2 days and there is on-site support from the company for the operator and team during their first series of patients.

The main barrier to adoption is the capital cost of the system and potential changes to staffing. No changes in facilities or infrastructure are needed because the procedure can be done under sedation (as in conventional bronchoscopy and endobronchial ultrasound in the bronchoscopy suite done by respiratory physicians) or under general anaesthetic (as in the operating theatre if the procedure is being done by thoracic surgeons).

There may be cost savings from fewer surgical biopsies and a shorter inpatient stay. However, there are examples of best practice of standard care in the NHS, using CT-guided trans-thoracic needle biopsy, where the diagnostic yield is high and risk is low, with pneumothoraces managed in an outpatient setting in most cases. The time needed to complete a CT-guided trans-thoracic needle biopsy procedure is short and it is done under local anaesthetic. There may be some patients for whom CT-guided biopsy is too high risk, because of comorbidities. If used in people who are at less risk, then there could be fewer CT-guided biopsies, which would free up radiology resources for other biopsy demand. It should be noted that the procedure kit (catheter and locatable guide) costs more than a CT-guided biopsy needle.

Centres with the infrastructure to provide the recommended additional fluoroscopy and radial endobronchial ultrasound for optimal diagnostic yield will be best placed to adopt this technology.

## Regulatory information

The superDimension Navigation System is a CE-marked class IIa medical device with class I (sterile) accessories.

The following manufacturer field safety notices or medical device alerts for this technology have been identified.

- [Medicines and Healthcare products Regulatory Agency \(MHRA\) 2012/007/004/081/001 \(July 2012\)](#). A pre-Medtronic company [field safety corrective action letter](#) was issued for superDimension systems sold under product code AAS00016-xxx, operating Software Version 4.0-4.9, relating to a failure to recognise the locatable guide and incorrect error message display.

## Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

No equality issues were identified. The technology will be used to investigate people who may have lung cancer. People with cancer are considered disabled under the equality act.

## Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the [interim process and methods statement](#). This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technologies. Further information about how the evidence for this briefing was selected is available on request by contacting [mibs@nice.org.uk](mailto:mibs@nice.org.uk).

## Published evidence

Seven studies are summarised in this briefing: 4 systematic reviews with meta-analyses, 1 randomised controlled trial (RCT), 1 retrospective comparative cohort study and 1 prospective single-armed global cohort study. The total number of patients in the selected studies is 8,359. However, this figure includes unquantifiable instances of multiple-counting of patients in the systematic reviews.

Table 2 summarises the clinical evidence as well as its strengths and limitations.

## Overall assessment of the evidence

The body of evidence for superDimension Navigation System is large, with several systematic reviews and meta-analyses including a large number of primary studies and thousands of patients worldwide, although none in a UK setting.

Primary outcomes include diagnostic yield and safety parameters, such as incidence of procedure-related pneumothorax. A common limitation across the meta-analyses is the different definitions of diagnostic yield between the studies.

The published evidence shows a general trend towards improving diagnostic yield over time, and lower incidence of pneumothorax than with CT-guided trans-thoracic needle biopsy. This may reflect both advances in newer versions of the technology and the learning curve of people using the device.

However, definitive RCT evidence is lacking and the place for this technology in the NHS, alongside other guided bronchoscopy techniques, is not yet established. More evidence around the benefit and cost is needed, including a UK-based audit. A multicentre prospective randomised trial could

address the overall risks and benefits of this procedure. The superDimension Navigation System may be suitable for patients for whom CT-guided biopsy is thought to be high risk.

## Table 2 Summary of selected studies

| <u>Deng et al. (2018)</u>       |   |
|---------------------------------|---|
| Study size, design and location | Systematic review with limited meta-analysis (search dates January 2000 to November 2017).<br>n=1,648 ENB cases from 31 selected studies.<br>China.   |
| Intervention and comparator(s)  | ENB biopsy of lesion in lung parenchyma and mediastinal area.<br>CT-guided PTNB biopsy of lesion in lung parenchyma mapped on CT images.<br>EBUS-TBNA biopsy of lesion in subcarinal and bilateral hilar area.<br>Mediastinoscopy biopsy of the lesion or lymph node in the vicinity of the trachea, the subcarinal and the bronchi area.<br>CTC biopsies of tumour cells shed from solid tumour lesion into peripheral blood.  |
| Key outcomes                    | No significant correlation was found between ENB detection rate and number of cases, average age of patients, sex, nodule size, lobar location of nodule, mean distance from pleura to nodule and operation time.<br>ENB complication rate: pneumothorax=5.2% (86/1,648), significantly negatively correlated with nodule size (p=0.018).<br>CT-guided PTNB complication rate: pneumothorax=23.0% (1,111/4,822).  |
| Strengths and limitations       | Large study size with some limited meta-analysis.<br>Outcome measures such as detection rate and diagnostic yield are not adequately defined.<br>There may be double counting of cases in the meta-analysis, because the selection of the 1,648 cases is not reported in a way that can be replicated.<br>At least 1 of the 31 ENB citations is a non-systematic review which simply quotes an earlier primary study; however, both the review and the primary study have been tabulated as separate studies of 932 cases by the authors. |
| <u>Zhang et al. (2015)</u>      |   |



|                                 |  |
|---------------------------------|--|
| Study size, design and location | <p>Systematic review with meta-analysis (search dates 2000 to 2015).</p> <p>n=1,161 lung nodules in 1,106 patients from 19 studies in the systematic review.</p> <p>n=892 patients from 15 studies in the meta-analysis.</p> <p>China.</p>   |
| Intervention and comparator(s)  | <p>superDimension Navigation System.</p> <p>superDimension Navigation System combined with fluoroscopy.</p> <p>superDimension Navigation System combined with radial EBUS.</p> <p>superDimension Navigation System combined with ROSE.</p>   |
| Key outcomes                    | <p>ENB alone; pooled values (95% CI):</p> <p>Sensitivity=0.82 (0.79 to 0.85)</p> <p>Specificity=1.00 (0.98 to 1.00)</p> <p>PLR=18.67 (9.04 to 38.55)</p> <p>NLR=0.22 (0.15 to 0.32)</p> <p>DOR=97.36 (43.75 to 216.69)</p> <p>Summary ROC AUC=0.9842 (SE=0.0113)</p> <p>Complication rate: 40 pneumothorax in 681 procedures=5.9%.</p> <p>ENB plus ROSE (6 studies):</p> <p>Sensitivity range=85 to 92%</p> <p>Specificity range=96.5 to 100%.</p> |
| Strengths and limitations       | <p>Well-reported large study with clinically relevant diagnostic outcomes.</p> <p>Limited comparative data, as none of the included studies compared ENB to surgery as a gold standard. Some minor inconsistencies in reported results in tables in the paper, versus narrative.</p>   |
| <u>Gex et al. (2014)</u>        |  |
| Study size, design and location | <p>Systematic review with meta-analysis (search date March 2012).</p> <p>n=1,033 lung nodules or masses in 971 patients from 15 studies.</p> <p>Switzerland.</p>   |

|                                  |   |
|----------------------------------|---|
| Intervention and comparator(s)   | <p>ENB (14/15 studies used the superDimension Navigation System).</p> <p>ENB combined with fluoroscopy.</p> <p>ENB combined with radial EBUS.</p> <p>ENB combined with ROSE.</p>  |
| Key outcomes                     | <p>Rate of successful navigation=97.4% (95% CI 95.4 to 98.5).</p> <p>ENB alone; pooled values (95% CI):</p> <p>Sensitivity for malignancy=71.1% (64.6 to 76.8)</p> <p>Accuracy for malignancy=78.6% (72.8 to 83.4)</p> <p>Diagnostic yield=64.9% (59.2 to 70.3)</p> <p>Diagnostic accuracy=73.9% (68.0 to 79.2)</p> <p>NPV=52.1% (43.5 to 60.6).</p> <p>Complication rate: 32 pneumothorax in 1,033 procedures=3.1% (95% CI 2.1 to 4.3).</p> <p>Combined procedures:</p> <p>ENB combined with fluoroscopy: diagnostic yield=56.3%</p> <p>ENB combined with ROSE: sensitivity=80.2%.</p> |
| Strengths and limitations        | <p>Well-reported large study with clinically relevant diagnostic outcomes. Issues of variable definitions of diagnostic yield across the constituent primary studies are addressed by study selection criteria.</p> <p>Limited comparative data, because none of the included studies compared ENB with surgery as a gold standard.</p>   |
| <u>Wang Memoli et al. (2012)</u> |   |
| Study size, design and location  | <p>Systematic review with meta-analysis (search date up to October 2010).</p> <p>n=3,052 lesions in 3,004 patients from 39 studies.</p> <p>US.</p>  |
| Intervention and comparator(s)   | <p>ENB.</p> <p>Virtual bronchoscopy.</p> <p>Radial EBUS.</p> <p>Ultrathin bronchoscope.</p> <p>Guide sheath.</p>  |

|                                 |  |
|---------------------------------|--|
| Key outcomes                    | <p>Diagnostic yield (inverse variance weighted, with 95% CI values):</p> <p>ENB=67.0% (62.6 to 71.4)</p> <p>Virtual bronchoscopy=72.0% (65.7 to 78.4)</p> <p>Radial EBUS=71.1% (66.5 to 75.7)</p> <p>Ultrathin bronchoscope=70.0% (65.0 to 75.1)</p> <p>Guide sheath=73.2% (64.4 to 81.9)</p> <p>Overall=70.0% (67.1 to 72.9).</p> <p>Complication rate: pneumothorax=1.5% (range 0.0 to 7.5).</p> |
| Strengths and limitations       | <p>Well-reported large study with clinically relevant diagnostic outcomes.</p> <p>Heterogeneity of diagnostic yield results across the constituent primary studies is acknowledged and discussed, with subgroup analysis between the different technology types reported.</p>  |
| <u>Eberhardt et al. (2007)</u>  |  |
| Study size, design and location | <p>Dual centre RCT between January 2003 and August 2006.</p> <p>n=120 patients.</p> <p>Germany and US.</p>   |
| Intervention and comparator(s)  | <p>ENB (superDimension/Bronchus system)</p> <p>EBUS.</p> <p>ENB with EBUS.</p>   |
| Key outcomes                    | <p>ENB:</p> <p>Overall diagnostic yield=59%</p> <p>Pneumothorax rate=5%.</p> <p>EBUS:</p> <p>Overall diagnostic yield=69%</p> <p>Pneumothorax rate=5%.</p> <p>ENB/EBUS combined procedure:</p> <p>Overall diagnostic yield=88%</p> <p>Pneumothorax rate=8%.</p>  |

|                                 |  |
|---------------------------------|--|
| Strengths and limitations       | <p>Well-reported RCT with clear definitions of all baseline characteristics and outcome measures. 118/120 patients had confirmed histological findings (from either the bronchoscopy, or, if this was non-diagnostic, from a follow-up, gold standard, surgical biopsy) and were included in the analyses, giving robust data for diagnostic yield.</p> <p>The biopsy technique using bronchoscopy was standardised to forceps therefore avoiding confounders from alternatives such as needle, brush or washing biopsies.</p> <p>This is a relatively small RCT, with 40 patients randomised to each arm.</p> |
| <u>Bhatt et al. (2018)</u>      |  |
| Study size, design and location | <p>Retrospective comparative cohort between 2013 and 2015.</p> <p>n=150 biopsies in 146 patients with ENB-guidance.</p> <p>n=150 biopsies in 149 patients with CT-guidance.</p> <p>US.</p>   |
| Intervention and comparator(s)  | <p>ENB-guided biopsy using the superDimension system.</p> <p>CT-guided biopsy.</p>   |
| Key outcomes                    | <p>ENB-guided biopsy:</p> <p>Overall diagnostic yield=66.0% (99/150)</p> <p>Any pneumothorax=4.0% (6/150)</p> <p>Pneumothorax needing chest tube / admission=2.7% (4/150)</p> <p>Any haemorrhage=3.3% (5/150)</p> <p>Symptomatic haemorrhage=2.0% (3/150).</p> <p>CT-guided biopsy:</p> <p>Overall diagnostic yield=86.0% (129/150)</p> <p>Any pneumothorax=28.7% (43/150)</p> <p>Pneumothorax requiring chest tube/admission=1.3% (2/150)</p> <p>Any haemorrhage=16.7% (25/150)</p> <p>Symptomatic haemorrhage= 1.3% (2/150).</p>   |
| Strengths and limitations       | <p>Clinically relevant, patient level data presented, comparing ENB with standard care.</p> <p>The authors highlight a lack of statistical power as a possible limitation.</p>   |

|   |  |
|---|--|
| Folch et al. (2019)   |  |
| Study size, design and location   | Prospective, single-armed, multicentre global, pragmatic cohort study from April 2015 to August 2016 (12-month results from the NAVIGATE study).<br>n=976/1,215 patients with 12-month results from 29 sites (of 37 sites in total).<br>US.  |
| Intervention and comparator(s)  | ENB using the superDimension navigation system, version 6.0 or higher.<br>n=1,157/1,215 with ENB-guided lung lesion biopsy, 258/1,215 ENB with fiducial placement, 23/1,215 ENB with plural dye marking and/or 30/1,215 ENB with lymph node biopsy.<br><br>Biopsy tools include aspirating needles, biopsy forceps, cytology brushes, core biopsy, and bronchoalveolar lavage.   |
| Key outcomes  | Pneumothorax needing hospitalisation or intervention (CTCAE grade 2 or greater)=2.9% (35/1,215)<br>Any grade pneumothorax=4.3%<br>Navigation success rate=94.4% (1,092/1,157)<br>Diagnostic yield ((TP+TN)/all attempted biopsies)=72.9% (768/1,053)<br>Excluding 104/1,157 deferred cases, for malignancy:<br>Sensitivity=68.8% (484/704)<br>Specificity=100% (284/284)<br>PPV=100% (484/484)<br>NPV=56.3% (284/504). |
| Strengths and limitations   | Well-reported, large study with clear definitions of baseline characteristics, outcome measures and data flow diagrams.<br><br>Pragmatic, 'real-world' study gives heterogeneous patient pathways, including some ENB combined procedures.   |
| Abbreviations: AUC, area under the curve; CI, confidence interval; CT, computed tomography; CTC, circulating tumour cell; CTCAE, Common Terminology Criteria for Adverse Events; DOR, diagnostic odds ratio; EBUS, endobronchial ultrasonography; ENB, electromagnetic navigation bronchoscopy; NLR, negative likelihood ratio; NPV, negative predictive value; PLR, positive likelihood ratio; PPV, positive predictive value; PTNB, percutaneous trans-thoracic needle biopsy; RCT, randomised controlled trial; ROC, receiver operating characteristic; ROSE, rapid on-site cytological evaluation; SE, standard error; TBNA, trans-bronchial needle aspiration; TN, true-negative for malignancy; TP, true-positive for malignancy. |  |

## Recent and ongoing studies

- [NAVIGATE: Clinical Evaluation of superDimension Navigation System for Electromagnetic Navigation Bronchoscopy](#). ClinicalTrials.gov identifier: NCT02410837. Status: active, not recruiting. First 1,000 patients 1-month results, 1,215 patients 12-month results and separate subgroup analyses of fiducial marker placement and COPD populations published. Due to complete December 2019. Indication: lung lesion(s) needing evaluation. Device: Medtronic superDimension Electromagnetic Navigation Bronchoscopy.
- A company-sponsored economic study in the NHS, based on a model developed by York Health Economics Consortium, is intended for submission to academic publication by October 2019.

## Specialist commentator comments

Comments on this technology were invited from 4 clinical specialists. The comments received are individual opinions and do not represent NICE's view.

Three specialists were familiar with or had used this technology before. The fourth specialist was invited to comment on the patient pathway from an oncology perspective.

## Level of innovation

Specialists agreed that the technology is an innovative development for bronchoscopy. Although it has been used internationally for many years, the technology has not gained substantial uptake in the NHS, most likely because of the cost and a perceived lack of widespread need. One specialist emphasised that this is a completely novel approach, moving from the percutaneous, radiation-based technique of CT-guided biopsy to one that is endoscopic, does not need skin or pleural puncture but makes use of the natural, pre-existing conduits to the lesion through the airway. This specialist added that the next generation superDimension Navigation System uses a short sweep of C-arm fluoroscopy to refine the accuracy of the procedure. Whilst this uses ionising radiation, the risks associated are still considerably lower than CT-guided biopsy, and potentially increases the diagnostic yield for the electromagnetic navigation bronchoscopy procedure.

## Potential patient impact

All 4 specialists agreed that the patient groups most likely to benefit from the technology include those who cannot have surgical biopsies or those for whom CT-guided trans-bronchial needle biopsy is too high risk because of the position of the lesion or comorbidities such as severe chronic

obstructive pulmonary disorder and poor lung function. In patients with suspected cancer, a tissue diagnosis could inform potential treatment with targeted therapies and thereby improve clinical outcomes.

Particular sub-groups who may benefit from the technology include patients with multiple, especially bilateral, lung lesions and patients with only 1 lung (after pneumonectomy). Individuals having linear endobronchial ultrasound staging of the mediastinum, where diagnosis from the peripheral lesion is also needed, can benefit by avoiding further biopsy for confirmatory diagnosis later.

Two specialists agreed that the technology allows more patients, with more distal disease, to have endobronchial biopsy for diagnostic tissue sampling. Another specialist further considered that the technology should be used instead of percutaneous biopsy to reduce risk from pleural puncture (pneumothorax, pain, haemothorax), even in patients for whom the procedure is low risk. The fourth specialist considered that the main benefit to patients would be through placing fiducials to guide surgeons or clinical oncologists (for novel radiotherapy techniques), or with therapeutic procedures such as cryotherapy. Minimising radiation exposure for patients was a further benefit mentioned by 2 specialists.

However, given the low negative predictive value seen in the evidence base, 1 specialist expressed concern that individuals having a negative biopsy with this technology should be considered for another mode of biopsy, to confirm.

## Potential system impact

Specialists generally agreed that the technology would shorten the current pathway by allowing tissue diagnosis and mediastinal staging in 1 biopsy, so that, where needed, the correct treatment can be started within a few days. If done as a day case, the procedure uses fewer hospital resources than an inpatient stay and takes less time than an invasive surgical biopsy. It can also free up radiology resources for other patient workloads. The quoted average cost per procedure may be reduced in a scenario with just sedation and normal bronchoscopy staff in a bronchoscopy suite.

However, 1 specialist considered that the technology will have limited system impact, being a very niche indication at a high cost. It has been available for over 10 years, but has not gained much traction, compared with the widespread uptake of endobronchial ultrasound in the NHS. Another specialist expressed concern about upgrade costs. Because there have been 7 software/firmware upgrades of superDimension Navigation System, this could potentially mean high maintenance costs and should be included if appropriate in the cost effectiveness.

## General comments

As with most new technologies, the studies in the evidence base are done by expert users. Diagnostic yields are likely to be lower for newly trained users.

The latest unpublished efficacy data from conferences suggest that electromagnetic navigation bronchoscopy should be used with radial endobronchial ultrasound, or fluoroscopy. Hence the cost of setting up a diagnostic service should include all additional technology costs.

Also, it will be interesting to see the full results of NAVIGATE study, but so far it looks very promising and this trial is probably most relevant to the current version of the technology.

Most of the systems bought in the UK recently are for thoracic surgery departments who use the technology for both diagnosis and intraoperative localisation (to help find small, difficult-to-feel lesions). The latter is an unmet need and current solutions are high risk, inaccurate, costly and disruptive to both the radiology department and operating theatres. The technology may be best limited to adoption in specialist bronchoscopy centres, with procedures subject to registry data collection, audit and adherence to a quality standard.

## Specialist commentators

The following clinicians contributed to this briefing:

- Dr Malcolm Lawson, consultant respiratory physician, Mid Essex Hospital Services NHS Trust, did not declare any interests.
- Dr Shahzeena Aslam, consultant clinical oncologist, Bedford Hospital NHS Trust, declared support from Astra Zeneca, Pfizer and Roche to attend conferences (includes 12 months before).



- Mr Kelvin Lau, consultant thoracic surgeon, Barts Health NHS Trust, declared the following interests:
  - Medtronic. consultant, proctor and mentor, received honorarium, travel and accommodation for lectures.
  - Philips. education and research grant for the use of hybrid theatre and cone beam CT in thoracic surgery, received honorarium, travel and accommodation for lectures.
  - Intuitive. consultant, received honorarium, travel and accommodation for lectures.
- Dr Neal Navani, consultant in thoracic medicine, University College London Hospitals NHS Foundation Trust, declared support from Astra Zeneca, Takeda, Oncimmune and Pfizer to attend conferences. Honoraria paid when possible to UCLH Charity.

## Development of this briefing

This briefing was developed by Newcastle External Assessment Centre. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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