Greater Manchester Cancer

Standard Operating Procedure &

Minimal Standards for Referral for Treatment of Primary Lung Cancer

Written & Published: **June 2020**

Review Date: **June 2023**

NHS
Manchester University
NHS Foundation Trust

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Single point of referral:
Email: **smu-tr.rapidlungsurgery@nhs.net**

To refer to The Christie Clinical Oncology Team

Single point of referral:
Email: **chn-tr.referralsandbookings@nhs.net**

To refer to The Christie Medical Oncology Team

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Email: **MedOncClinicAdmin@christie.nhs.uk**

Objectives of this document

- To optimise patient experience of the referral pathway and treatment assessment process
- To standardise the physiological and diagnostic work up of patients with lung cancer across Greater Manchester
- To streamline the diagnostic work-up in line with the Greater Manchester Optimal Lung Cancer Pathway (Target 14 day diagnostic pathway)
- To reduce unjustifiable delay in the treatment pathway with a particular focus on specific areas e.g. patients with early stage disease but at higher risk from surgery
- To increase treatment rates across Greater Manchester and eliminate variation in treatment e.g. surgical resection rate in early stage disease, multi-modality treatment rates in stage III lung cancer through standardised assessment and efficient pathways
- To potentially improve survival in lung cancer through rapid and efficient pathways
- To inform local pathways & agree regional guidelines to provide clear lines of responsibility that will assist cancer services and trusts in the management of patients
- To provide clear lines of responsibility for the receiving trust in providing a responsive, equitable and high quality regional service

The Greater Manchester Cancer Structure & the need for a referral SOP

Greater Manchester has a population of approximately three million people and there are approximately 2500 new cases of lung cancer per year. Several surrounding areas also use the cancer services within Greater Manchester and including East and Mid-Cheshire Trusts. Wythenshawe Hospital (part of Manchester University NHS Foundation Trust) is the sole Thoracic Surgery Unit for Greater Manchester and surrounding areas and performs approximately 500 lung cancer resections per year, one of the highest volume centres in the United Kingdom. The Christie NHS Foundation trusts the oncological management of lung cancer including radiotherapy and systemic anti-cancer therapy, through its central hospital site and a number of satellite sites across the region. Patients in Greater Manchester often have tests performed at different hospitals during their diagnostic work up with 4 different staging EBUS centres, and three different PET-CT locations. Referrals for lung cancer treatment are received from 10 NHS trusts across GM.

In order to have an efficient and productive treatment consultations and an excellent patient experience for those travelling from around the region, the treating teams require a core set of information & source documents available at the moment of clinical review in order to progress patients care and make timely decisions. This document sets out the standard operating procedure for lung cancer treatment referrals in this region. It will set out what is required of referring teams (basic physiological work-up and staging) as well as the responsibilities of the treating teams.

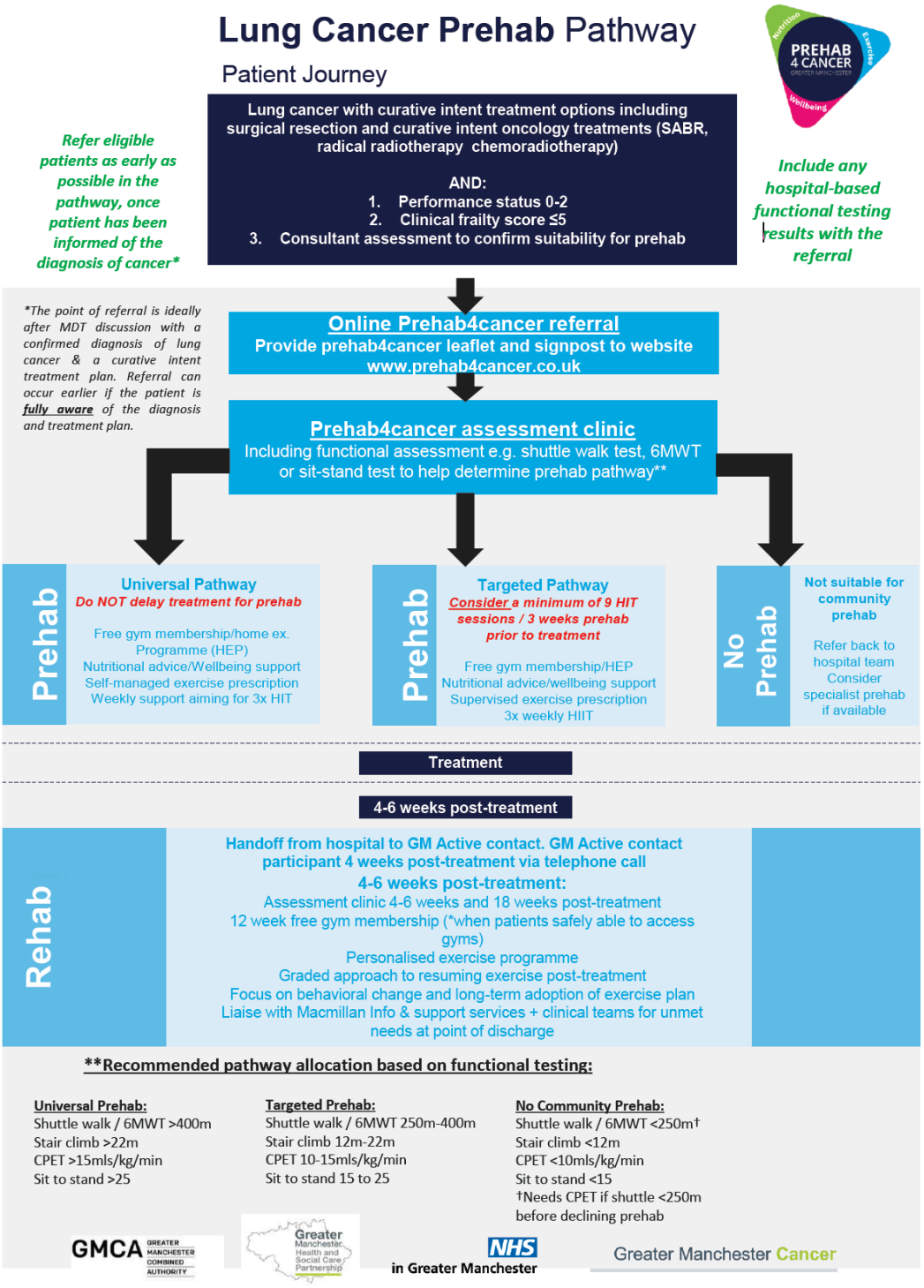
The minimum standards set out in this document may also facilitate early referral for treatment prior to an MDT discussion when the treatment decision is clear cut. Referrals can be accepted prior to MDT discussion as along as they contain all the information set out in these standards. Incomplete referrals could be rejected.

Prehab4Cancer

Prehab4cancer is GM Cancer funded prehabilitation programme that provides patients undergoing curative intent lung cancer treatment with prehabilitation and rehabilitation programmes in local leisure facilities.

All suitable patients should be referred to the programme in line with the pathway below. A single point of referral is provided via an online referral portal http://www.gmactive.co.uk/prehab4cancer.

This is a service Greater Manchester Residents so maybe not apply to some referring trusts such as East & Mid-Cheshire.



1. Referring for thoracic surgery *

1.1 Background

Lung cancer is the single biggest cause of premature death in Greater Manchester. Surgical resection is the best treatment for early stage lung cancer and offers the best possible chance of long term cure. Improving the surgical resection rate in lung cancer is a key priority for Greater Manchester Cancer and will drive its ambitions to ensure more than 2750 additional cancer patients will survive 5 years or more by 2028. However, an ageing population and the co-morbidities frequently present in patients with lung cancer can challenge a patient's ability to withstand thoracic surgery and rehabilitate to an adequate functional status post-operatively. For all patients with potentially resectable lung cancer, a robust and systematic physiological work-up is required to assess their suitability for surgery. This assessment compromises basic physiological testing that can be readily performed in all hospital trusts and in selected cases more advanced physiological work-up, predominantly cardiopulmonary exercise testing, that is often limited to a smaller number of hospitals. The decision to operate in higher risk patients is made by a multi-disciplinary team compromising thoracic surgeons, physicians, thoracic anaesthetists and clinical oncologists (who provide the required information about alternative treatment strategies involving radiotherapy). In addition to the physiological work up, defining the suitability for surgical resection requires a systematic and robust staging pathway to exclude distant metastatic disease and define regional nodal status.

The Greater Manchester Cancer Lung Pathway Board has developed specific algorithms for the diagnostic work up of patients with suspected lung cancer that describe the required basic physiological testing and staging tests in different scenarios based on the initial CT scan appearances (Appendix 1). These algorithms recommend 'test bundles' which should be used whenever possible. Specific points relevant to surgical referrals can be summarised below:

1.2 Basic Physiology in all patients under considerarion for surgery

- All patients require spirometry and diffusion capacity
- All patients require a basic functional assessment: **shuttle walk test is the test of choice** (6 minute walk test or stair climbing test are alternatives)
- All patients require an cardiac examination and ECG
- Patients aged >70yr, or a history of IHD, or a murmur on examination, or an abnormal ECG or where there is the possibility of a pneumonectomy, all require an echocardiogram

1.3. Staging Tests in patients under consideration for surgery

- Where possible, pathological confirmation of lung cancer is recommended (either through nodal sampling or image-guide biopsy)
- All patients under consideration for surgery require FDG PET-CT
- Patients with enlarged (>10mm in short axis) or FDG avid hilar/mediastinal lymph nodes require a staging EBUS
- Patients with clinical stage II disease require contrast enhanced CT scan of brain
- Patients with clinical stage III disease require contrast enhanced MR scan of brain

*This relates to referral for lung resection, not for airway management or diagnostics

1.4 Why is a Staging EBUS needed for any enlarged / FDG avid lymph node?

There is no radiological modality that can accurately stage the mediastinum. Pathological confirmation is required if there is any nodal abnormality on CT or PET as positive predictive value is poor. The only circumstance when pathological nodal staging is not considered necessary is when CT and PET show no nodal abnormality at the hila or mediastinum. In such cases the negative predictive value for absent N2 disease is high (>95%) and therefore pathological sampling in all cases is not required. However, in cases of N1 disease (ipsilateral hilar nodal involvement) even when the mediastinum is normal on CT and PET the risk of occult N2 disease is 25%. In this instance, the identification of N2 disease does not preclude surgical resection but does allow consideration of the different treatment options (that also include chemoradiotherapy) and an opportunity for patients to know accurate staging, prognosis and meet the relevant treating teams when making treatment decisions.

The 2019 NICE guidelines on lung cancer diagnosis & management confirm that any patient with enlarged thoracic lymph nodes (>10mm in short axis) requires a staging EBUS.

1.5 Why is image guided biopsy recommended prior to surgery?

The ideal scenario is to have pathological confirmation of lung cancer prior to embarking on a surgical approach. This is for a number of reasons:

- *It can prevent surgery for benign lesions if a different pathology is identified on image-guided biopsy e.g. tuberculosis*
- *It can prevent the need for an intra-operative frozen section and the extra resource of theatre time, prolonged anaesthesia for the patient and pathological resource whilst the sample is analysed*
- *It can define the surgical approach (lobectomy versus sub-lobar resection). If a non-primary lung cancer or carcinoid tumour is identified pre-operatively it can define the type of surgical resection needed ensuring the best outcomes for the patient*

It is clear there are times when pre-operative pathological confirmation is not possible, for example technical challenges or where the risks may outweigh these benefits, but where it is possible, pre-operative pathological confirmation is recommended.

A regional lung biopsy service is operational at Wythenshawe Hospital. Referrals can be emailed to **thoracicbiopsy@mft.nhs.uk** and the images will be reviewed within 1 working day and an opinion provided as to the feasibility of image guided biopsy and immediate booking for suitable cases. This service will also facilitate access to navigational bronchoscopy at Wythenshawe in cases best suited to this bronchoscopic approach. Please refer as early as possible in the pathway for this service utilising test bundles where appropriate as per the GM diagnostic algorithms.

1.6 Minimum dataset for referral to thoracic surgery for patients with primary lung cancer

All referrals to Wythenshawe for assessment for surgical resection of primary lung cancer require the following information:

Diagnostic test results:

- ✓ Staging CT of the thorax and upper abdomen (source report)
- ✓ PET-CT (source report)
- ✓ Staging EBUS report and pathology results (source reports) – if applicable
- ✓ Image-guided lung biopsy report and pathology results (source reports) – if applicable*
- ✓ Routine blood test results (source report: FBC/renal function/Liver Function Tests)
- ✓ Contrast-enhanced CT/MR brain imaging if stage II/III lung cancer (source report) – if applicable

*Please include reasons if image guided biopsy not possible

Physiological results

- ✓ Spirometry and DLCO (source report)
- ✓ Basic functional assessment (source report or described in referral letter)
- ✓ Echocardiogram (source report) – if applicable
- ✓ Referral to Prehab4Cancer

Referral Letter (a suggested referral letter template has been provided in this document)

- Co-morbidities
- Performance status
- Clinical Frailty Score (Rockwood Score – see appendix 2)
- BMI
- Post-operative predicted lung function
  (see appendix 3 for description of how to calculate post-operative lung function)

1.7 Suggested Referral Letter Template

A suggested referral letter template is provided below with suggested headings to cover all required information within this SOP.

Dear Thoracic Surgeons (Named referral only in highly complex cases) to facilitate rapid pathway

(Every effort will be made to facilitate clinic review by the surgeons serving the MDT)

MDT agreed Staging:

Summary of Investigations

CT:

PET/brain imaging

Staging EBUS: (if not performed, reasons why)

Image guided lung biopsy: (if not performed reasons why)

Physiology

Performance Status:

Clinical frailty Score:

ppo-FEV1:

ppo-DLCO:

BMI:

Basic functional assessment (shuttle/stair climb): (if not performed, reason why)

ECG:

Echocardiogram (if applicable):

Prehab4cancer referral status:

Co-morbidities:

MDT discussion: Including what consideration to the type of surgery and extent of resection required was discussed

Referral details / free text:

1.8 Standard Operating Procedure for surgical referrals

Referral for Surgical resection of proven or suspected primary lung cancer in Greater Manchester

Suspected lung cancer that may be amenable & appropriate for surgical resection

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Diagnostic work-up as per GM Cancer Algorithms

Ensure:

Spirometry and diffusion capacity in all patients
Shuttle walk in all patients (alternative if required)
Echo if >70, IHD, murmur, abnormal ECG or ?pneumonectomy
PET-CT in all patients (+/- brain imaging)
Staging EBUS if any enlarged or FDG avid hilar/mediastinal lymph nodes
Pathological confirmation of lung cancer where possible

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Following all of above

✓ suspected or proven lung cancer that may be amenable & appropriate for surgical resection

Refer to MFT thoracic surgical team

Single point of referral:
Email: smu-tr.rapidlungsurgery@nhs.net

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Referral Checklist:

- ✓ Staging CT of the thorax and upper abdomen (source report)
- ✓ PET-CT (source report)
- ✓ Brain imaging (source report) if applicable
- ✓ Staging EBUS report and pathology results (source reports) – if applicable
- ✓ Image-guided lung biopsy report and pathology results (source reports) – if applicable
- ✓ Lung Function (source report)
- ✓ Basic functional assessment (source report or described in referral letter)
- ✓ Echocardiogram (source report) – if applicable
- ✓ Routine blood tests – FBC,U&Es, LFTs (Source report)
- ✓ Referral letter – including performance status, clinical frailty score, post-operative lung
- ✓ function, BMI, ECG result
- ✓ Prehab4cancer referral

Please include an nhs.net email in the referral to allow timely correspondence from the navigator team

1.8 Triage of Surgical referrals of proven or suspected primary lung cancer in Greater Manchester

Referral received by surgical navigators at Wythenshawe

Checklist reviewed to ensure all appropriate information received:

- ✓ Staging CT of the thorax and upper abdomen (source report)
- ✓ PET-CT (source report) & brain imaging if applicable (source report)
- ✓ Staging EBUS report and pathology results (source reports) – if applicable
- ✓ Image-guided lung biopsy report and pathology results (source reports) – if applicable
- ✓ Lung Function (source report)
- ✓ Basic functional assessment (source report or described in referral letter)
- ✓ Echocardiogram (source report) – if applicable
- ✓ Referral letter – including performance status, post-operative lung function, BMI, ECG result
- ✓ Prehab4cancer referral status

If all information required is present – CARP accepted

If information is missing (and in the absence of clear reasoning why these tests are not able to be performed or are not required described within the referral letter) – CARP will be adjusted and only accepted using a date following the completion of any required additional tests or receipt of source documents. MFT will facilitate expedited investigations and co-ordinate surgical assessment in a single visit, where possible.

Once all information received and CARP accepted the patient will undergo a consultant-led surgical triage that occurs daily (working days). Guidelines for this triage process are in place at Wythenshawe and include ensuring cardiopulmonary exercise testing is organised for patients with a shuttle walk test <250m (Appendix 4). Any patients meeting ANY of the criteria below will also be listed for high risk MDT discussion following the first consultation.

- ✓ ppo-FEV1 <40%
- ✓ ppo-DLCO <40%
- ✓ Shuttle walk <250m
- ✓ V02max <15mls/kg/min
- ✓ Desaturation during exercise - <90% or >4%
- ✓ ThRCRI >=2
- ✓ BMI <20
- ✓ Current smoker
- ✓ Pneumonecotmy
- ✓ Thoracoscore >5%
- ✓ Nottingham 90 day risk >10%
- ✓ Rockwood frailty score >=4

If patients do not proceed with surgery and require radiotherapy, a referral and CARP will be made immediately following this treatment decision.

1.9 Dual referrals to thoracic surgery and joint surgical-oncology clinics

Patients that are a higher risk from thoracic surgery may have an alternative oncological treatment modality and review & discussion with an oncologist is critical in such cases.

Currently, such patients should have a dual referral to thoracic surgery and clinical oncology. A business case for a joint surgical, anaesthetic and oncology clinic is in advanced stages at Wythenshawe hospital which will allow same day review by the required specialists to ensure timely decision making.

Criteria for patient selection for dual referral or to the joint clinic once launched are below:

- Performance status ≥2
- Rockwood Frailty Score ≥4
- ppo-FEV1 or ppo-DLCO ≤40%
- Proposed surgery of pneumonectomy
- Shuttle walk <250 m
- Severe left ventricular dysfunction
- BMI ≤20

1.10 Quality Standards for the referral pathway

It is important that this referral pathway is monitored for performance on a regular basis. Quality standards can be separated to those expected of the referring team and those expected by the receiving team. The following quality standards are in line with the standards set out in the Greater Manchester Optimal Lung Cancer Pathway.

Quality standards for referring teams

- All patients referred for surgical assessment have undergone spirometry and diffusion capacity
- All patients referred for surgical assessment have undergone a basic functional assessment with a shuttle walk test or stair climbing assessment unless there are reasons preventing this assessment (e.g. severe arthritis) and these reasons are documented within the referral
- All patients referred for surgical assessment have undergone a cardiac examination and ECG
- All patients aged >70yr, with IHD, with a murmur or an abnormal ECG have undergone an echocardiogram
- All patients with enlarged or FDG avid hilar/mediastinal lymph nodes have undergone a staging EBUS
- Patients with clinical stage II/III lung cancer have undergone brain imaging
- All patients have had pathological confirmation from either lymph nodes or image guided lung biopsy where the sector MDT has deemed it feasible or reasons why a biopsy has not been performed is documented within the referral
- All referrals contain the required source documents in line with the standard operating procedure

Quality standards for receiving team – MFT thoracic surgery

- Referring teams and patients will be contacted with their appointment time and date within 1 working day of MFT receiving a completed referral. If any source documents are missing or additional tests required, the patient will be informed of next steps, and offered an appointment as soon as the referral is complete. Once complete, the CARP will be accepted.
- Patients will be seen within 5 days of a complete referral being received/CARP accepted
- Referring teams will receive clinic letters within 1 working day of the clinic encounter via NHS. net email
- Those patients accepted for surgery will undergo their operation within a maximum of 14 days of assessment. Referring teams and GPs will receive a discharge and treatment summary post-operatively within 7 working days of discharge via email

Quality standards targets:

Target performance is 85% compliance with quality standards

2. Referring for radical radiotherapy

Referrals for radical radiotherapy are triaged centrally at The Christie. Every effort is made to ensure patients are seen as close to home by the ir local oncologist. However, if there is delay in accessing their local oncologist, patients may be offered an appointment with an oncologist outside of their local area who can see them sooner. The patient will always have the final decision as to whether to accept such an offer but **referring teams must ensure they have discussed this with patients when referring.**

The Greater Manchester Cancer Lung Pathway Board has developed specific algorithms for the diagnostic work up of patients with suspected lung cancer that describe the required basic physiological testing and staging tests in different scenarios based on the initial CT scan appearances (Appendix 1). These algorithms recommend 'test bundles' which should be used whenever possible. Specific points relevant to radiotherapy referrals can be summarised below:

2.1 Basic Physiology in all patients under consideration for radical radiotherapy

- All patients require spirometry and diffusion capacity

2.2 Staging Tests in patients under consideration for radical radiotherapy

- Where possible, pathological confirmation of lung cancer is recommended (either through nodal sampling or image-guide biopsy – see section 1.5)
- All patients under consideration for radiotherapy require FDG PET-CT
- Patients with enlarged (>10mm in short axis) or FDG avid hilar/mediastinal lymph nodes require a staging EBUS – this is especially important for radiotherapy patients who will not have the benefit of pathological nodal staging during surgical resection (see section 1.4)
- Patients with clinical stage II disease require contrast enhanced CT scan of brain
- Patients with clinical stage III disease require contrast enhanced MR scan of brain

2.3 Minimum dataset for referral for radical radiotherapy

All referrals for assessment for radical radiotherapy of primary lung cancer require the following information:

Diagnostic test results:

- ✓ Staging CT of the thorax and upper abdomen (source report)
- ✓ PET-CT (source report)
- ✓ Staging EBUS report and pathology results (source reports) – if applicable
- ✓ Image-guided lung biopsy report and pathology results (source reports) – if applicable*
- ✓ Routine blood test results (source report: FBC/renal function/Liver Function Tests)
- ✓ Contrast-enhanced CT/MR brain imaging if stage II/III lung cancer (source report) – if applicable

*Please include reasons if image guided biopsy not possible

Physiological results

- ✓ Spirometry and DLCO (source report)

Referral Letter (a suggested referral letter template has been provided in this document)

- Co-morbidities
- Performance status
- Clinical Frailty Score (Rockwood Score – see appendix 2)
- BMI

2.4 Suggested Referral Letter Template

A suggested referral letter template is provided below with suggested headings to cover all required information within this SOP.

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Dear Clinical Oncologist

MDT agreed Staging:

Summary of Investigations

CT:

PET/brain imaging

Staging EBUS: (if not performed, reasons why)

Image guided lung biopsy: (if not performed reasons why)

Physiology

Performance Status:

Clinical frailty Score:

BMI:

Co-morbidities:

MDT discussion: Including what consideration to the type of surgery and extent of resection required was discussed

Referral details / free text:

2.5 Standard Operating Procedure for radiotherapy referrals

Referral for radical radiotherapy for primary lung cancer in Greater Manchester

Suspected lung cancer that may be amenable & appropriate for radical radiotherapy

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Diagnostic work-up as per GM Cancer Algorithms

Ensure:

Spirometry and diffusion capacity in all patients
PET-CT in all patients (+/- brain imaging)
Staging EBUS if any enlarged or FDG avid hilar/mediastinal lymph nodes
Pathological confirmation of lung cancer where possible

↓

Following all of above

✓ suspected or proven lung cancer that may be amenable & appropriate for surgical resection

Refer to The Christie Clinical Oncology team

Single point of referral:
Email: chn-tr.referralsandbookings@nhs.net

↓

Referral Checklist:

- ✓ Staging CT of the thorax and upper abdomen (source report)
- ✓ PET-CT (source report) and brain imaging (source report) if applicable
- ✓ Staging EBUS report and pathology results (source reports) – if applicable
- ✓ Image-guided lung biopsy report and pathology results (source reports) – if applicable
- ✓ Lung Function (source report)
- ✓ Routine blood tests – FBC,U&Es, LFTs (Source report)
- ✓ Referral letter – including performance status, clinical frailty score, BMI

Please include an nhs.net email in the referral to allow timely correspondence from the navigator team

2.6 Triage of radiotherapy referrals for primary lung cancer in Greater Manchester

Referral received by surgical navigators at The Christie

Checklist reviewed to ensure all appropriate information received:

- ✓ Staging CT of the thorax and upper abdomen (source report)
- ✓ PET-CT (source report) & brain imaging (source report) if applicable
- ✓ Staging EBUS report and pathology results (source reports) – if applicable
- ✓ Image-guided lung biopsy report and pathology results (source reports) – if applicable
- ✓ Lung Function (source report)
- ✓ Referral letter – including performance status, clinical frailty score, BMI

If all information required is present – CARP accepted

If information is missing (and in the absence of clear reasoning why these tests are not able to be performed or are not required described within the referral letter) – CARP will be adjusted and only accepted using a date following the completion of any required additional tests or receipt of source documents.

Once all information received and CARP accepted the patient will appointed to the next available appointment with the local clinical oncologists. If the time until the next available appointment is beyond 7 days the patient will be offered an earlier appointment outside of the local service

2.7 Quality Standards for the referral pathway

It is important that this referral pathway is monitored for performance on a regular basis. Quality standards can be separated to those expected of the referring team and those expected by the receiving team. The following quality standards are in line with the standards set out in the Greater Manchester Optimal Lung Cancer Pathway.

Quality standards for referring teams

- All patients have undergone spirometry and diffusion capacity
- All patients with enlarged or FDG avid hilar/mediastinal lymph nodes have undergone a staging EBUS
- Patients with clinical II/III lung cancer have undergone brain imaging
- All patients have had pathological confirmation from either lymph nodes or image guided lung biopsy where the sector MDT has deemed it feasible or reasons why a biopsy has not been performed is documented within the referral
- All referrals contain the required source documents in line with the standard operating procedure

Quality standards for receiving team – The Christie Clinical Oncology

- Referring teams and patients will be contacted with their appointment time and date within 1 working day of The Christie receiving a completed referral. If any source documents are missing or additional tests required, the patient will be informed of next steps, and offered an appointment as soon as the referral is complete. Once complete, the CARP will be accepted.
- Patients will be seen within 5 days of a complete referral being received/CARP accepted
- Referring teams will receive clinic letters within 1 working day of the clinic encounter via NHS.net email
- Those patients accepted for radiotherapy will begin their treatment within a maximum of 14 days of assessment. Referring teams and GPs will receive a treatment summary post-treatment within 7 working days of completion via email

Quality standards targets:

Target performance is 85% compliance with quality standards

3. Referral for chemoradiotherapy

The Greater Manchester Cancer Lung Pathway Board has developed specific algorithms for the diagnostic work up of patients with suspected lung cancer that describe the required basic physiological testing and staging tests in different scenarios based on the initial CT scan appearances (Appendix 1). These algorithms recommend 'test bundles' which should be used whenever possible. Specific points relevant to chemoradiotherapy referrals can be summarised below:

3.1 Basic Physiology in all patients under consideration for chemoradiotherapy

- All patients require spirometry and diffusion capacity
- Renal function – creatinine and estimated glomerular filtration rate. **This is critically important for planning treatment and mandated for referral for chemoradiotherapy**

3.2 Staging Tests in patients under consideration for chemoradiotherapy

- Pathological confirmation of lung cancer is required (most commonly through nodal sampling)
- PD-L1 expression should be assessed in tumour samples for patients with non-small cell lung cancer being referred for chemoradiotherapy
- All patients under consideration for chemoradiotherapy require FDG PET-CT
- Patients with clinical stage III disease require contrast enhanced MR scan of brain

3.3 Minimum dataset for referral for chemoradiotherapy

All referrals for assessment for chemoradiotherapy of primary lung cancer require the following information:

Diagnostic test results:

- ✓ Staging CT of the thorax and upper abdomen (source report)
- ✓ PET-CT (source report)
- ✓ Brain Imaging (source report)
- ✓ Pathology results including PDl-1 status (source reports) – if applicable
- ✓ Renal function – both creatinine and estimated glomerular filtration rate (source reports)
- ✓ Routine blood test results (source report: FBC/renal function/Liver Function Tests)

Physiological results

- ✓ Spirometry and DLCO (source report)

Referral Letter (a suggested referral letter template has been provided in this document)

- **Co-morbidities** – include details of any autoimmune disease, its severity and any
- corticosteroid use
- **Smoking status** (never, light, ex-smoker, current smoker)
- **Performance status**
- **Clinical Frailty Score** (Rockwood Score – see appendix 2)
- **BMI**

3.4 Suggested Referral Letter Template

A suggested referral letter template is provided below with suggested headings to cover all required information within this SOP.

Dear Oncologist

MDT agreed Staging:

Summary of Investigations

CT:

PET:

Brain imaging:

Pathology (inc PD-L1):

Physiology

Performance Status:

Clinical frailty Score:

BMI:

Co-morbidities:

Summary of MDT discussion:

Referral details / free text:

3.5 Standard Operating Procedure for chemoradiotherapy

Referral for chemoradiotherapy for primary lung cancer in Greater Manchester

Suspected lung cancer that may be amenable & appropriate for chemoradiotherapy

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Diagnostic work-up as per GM Cancer Algorithms

Ensure:

Spirometry and diffusion capacity in all patients
PET-CT and brain imaging in all patients
Pathological confirmation of lung cancer

↓

Following all of above

✓ suspected or proven lung cancer that may be amenable & appropriate for chemoradiotherapy

Refer to The Christie Oncology team

Single point of referral:
Email: MedOncClinicAdmin@christie.nhs.uk

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Referral Checklist - chemoradiotherapy:

- ✓ Staging CT of the thorax and upper abdomen (source report)
- ✓ PET-CT (source report) and brain imaging (source report)
- ✓ Pathology results (source reports) including PD-L1
- ✓ Lung Function (source report)
- ✓ Echocardiogram (source report) – if applicable
- ✓ Renal function – creatinine and estimated glomerular function rate
- ✓ Routine blood tests – FBC,U&Es, LFTs (Source report)
- ✓ Referral letter – including performance status, clinical frailty score, BMI

Please include an nhs.net email in the referral to allow timely correspondence from the navigator team

3.6 Triage of chemoradiotherapy referrals for primary lung cancer in Greater Manchester

Referral received by chemoradiotherapy navigators at The Christie
Checklist reviewed to ensure all appropriate information received:

- ✓ Staging CT of the thorax and upper abdomen (source report)
- ✓ PET-CT (source report) and brain imaging (source report)
- ✓ Pathology results (source reports) including PD-L1
- ✓ Lung Function (source report)
- ✓ Renal function – creatinine and estimated glomerular function rate
- ✓ Routine blood tests – FBC,U&Es, LFTs (Source report)
- ✓ Referral letter – including performance status, clinical frailty score, BMI

If all information required is present – CARP accepted
If information is missing (and in the absence of clear reasoning why these tests are not able to be performed or are not required described within the referral letter) – CARP will be adjusted and only accepted using a date following the completion of any required additional tests or receipt of source documents.

Once all information received and CARP accepted the patient will appointed to the next available appointment with the oncology team.

3.7 Dual referrals to thoracic surgery and oncology in stage III lung cancer

Optimal treatment for stage III lung cancer is multimodality treatment combining local and distant control. This means there may be multiple treatment options with surgery and with radiotherapy necessitating dual referral to both thoracic surgery and oncology. In such cases, the referral should follow the treatment specific SOP.

In addition, a new treatment pathway has been developed in GM in response to the 2019 NICE guidelines for lung cancer diagnosis & management. This is for trimodality treatment in stage III-N2 lung cancer (chemoradiotherapy followed by surgery). GM have produced a referral pathway for this treatment that includes dual referral to thoracic surgery and oncology (Appendix 5).

The guidance recommends considering trimodality treatment in patients with stage III-N2 that is deemed potentially resectable according to the standardised GM definition and:

- Performance Status 0-1
- Post-operative predicted lung function >40%
- Shuttle walk >400m or VO2 max >15mls/kg/min
- Normal left ventricular function on echocardiogram
- BMI
- >20 Clinical frailty score 1-3

3.7 Quality Standards for the referral pathway

It is important that this referral pathway is monitored for performance on a regular basis. Quality standards can be separated to those expected of the referring team and those expected by the receiving team. The following quality standards are in line with the standards set out in the Greater Manchester Optimal Lung Cancer Pathway.

Quality standards for referring teams

- All patients have undergone spirometry and diffusion capacity
- All patients have a pathological diagnosis of lung cancer plus a PDL1 status in NSCLC
- All patients with clinical II/III lung cancer have undergone brain imaging
- All patients have undergone renal function – creatinine and estimated glomerular filtration rate
- All referrals contain the required source documents in line with the standard operating procedure

Quality standards for receiving team – The Christie Oncology Team

- Referring teams and patients will be contacted with their appointment time and date within 1 working day of The Christie receiving a completed referral. If any source documents are missing or additional tests required, the patient will be informed of next steps, and offered an appointment as soon as the referral is complete. Once complete, the CARP will be accepted.
- Patients will be seen within 5 days of a complete referral being received/CARP accepted
- Referring teams will receive clinic letters within 1 working day of the clinic encounter via NHS.net email
- Those patients accepted for radiotherapy will begin their treatment within a maximum of 14 days of assessment. Referring teams and GPs will receive a treatment summary post-treatment within 7 working days of completion via email

Quality standards targets:

Target performance is 85% compliance with quality standards

4. Referring for palliative systemic anti-cancer therapy (SACT)

The Greater Manchester Cancer Lung Pathway Board has developed specific algorithms for the diagnostic work up of patients with suspected lung cancer that describe the required basic physiological testing and staging tests in different scenarios based on the initial CT scan appearances (Appendix 1). These algorithms recommend 'test bundles' which should be used whenever possible. Specific points relevant to chemoradiotherapy referrals can be summarised below:

4.1 Basic Physiology in all patients under consideration for Systemic Anti-cancer Therapy

- All patients require renal function – creatinine and estimated glomerular filtration rate. This is critically important for planning treatment and mandated for referral for SACT

4.2 Staging Tests in patients under consideration for Systemic Anti-cancer Therapy

- Pathological confirmation of lung cancer is required
- NSCLC requires PDL-1 status
- Non-squamous NSCLC requires EGR, ALK and ROS-1 testing

4.3 Minimum dataset for referral for Systemic Anti-cancer Therapy

All referrals for assessment for SACT for primary lung cancer require the following information:

Diagnostic test results:

- ✓ Staging CT of the thorax and upper abdomen (source report)
- ✓ Pathology results including PDL-1, EGFR, ALK, ROS-1 status (source reports) – if applicable
- ✓ Renal function – both creatinine and estimated glomerular filtration rate (source reports)
- ✓ Routine blood test results (source report: FBC/renal function/Liver Function Tests)

Referral Letter (a suggested referral letter template has been provided in this document)

- **Co-morbidities –** include details of any autoimmune disease, its severity and any
- corticosteroid use
- **Smoking status** (never, light, ex-smoker, current smoker)
- **Performance status**
- **Clinical Frailty Score** (Rockwood Score – see appendix 2)
- **BMI**

4.4 Suggested Referral Letter Template

A suggested referral letter template is provided below with suggested headings to cover all required information within this SOP.

Dear Oncologist

MDT agreed Staging:

Summary of Investigations

CT:

Pathology (inc PD-L1, EGFR, ALK, ROS-1):

Physiology

Performance Status:

Clinical frailty Score:

BMI:

Co-morbidities:

Summary of MDT discussion:

Referral details / free text:

4.5 Standard Operating Procedure for Systemic Anti-cancer Therapy

Referral for SACT for primary lung cancer in Greater Manchester

Suspected lung cancer that may be amenable & appropriate for SACT

↓

Diagnostic work-up as per GM Cancer Algorithms

Ensure:

Pathological confirmation of lung cancer
PDL1, EGFR, ALK, ROS-1 testing completed as indicated
Renal function – creatinine and estimated glomerular filtration rate

↓

Following all of above

✓ suspected or proven lung cancer that may be amenable & appropriate for SACT

Refer to The Christie Oncology team

Single point of referral:
Email: MedOncClinicAdmin@christie.nhs.uk

↓

Referral Checklist - SACT:

- ✓ Staging CT of the thorax and upper abdomen (source report)
- ✓ Pathology results (source reports) including PD-L1, EGFR, ALK, ROS-1
- ✓ Renal function – creatinine and estimated glomerular function rate
- ✓ Routine blood tests – FBC,U&Es, LFTs (Source report)
- ✓ Referral letter – including performance status, clinical frailty score, BMI

Please include an nhs.net email in the referral to allow timely correspondence from the navigator team

4.6 Triage of SACT referrals for primary lung cancer in Greater Manchester

Referral received by SACT navigators at The Christie
Checklist reviewed to ensure all appropriate information received:

- ✓ Staging CT of the thorax and upper abdomen (source report)
- ✓ Pathology results (source reports) including PD-L1, EGFR, ALK, ROS-1
- ✓ Renal function – creatinine and estimated glomerular function rate
- ✓ Routine blood tests – FBC,U&Es, LFTs (Source report)
- ✓ Referral letter – including performance status, clinical frailty score, BMI

If all information required is present – CARP accepted
If information is missing (and in the absence of clear reasoning why these tests are not able to be performed or are not required described within the referral letter) – CARP will be adjusted and only accepted using a date following the completion of any required additional tests or receipt of source documents.

Once all information received and CARP accepted the patient will appointed to the next available appointment with the oncology team.

4.7 Quality Standards for the referral pathway

It is important that this referral pathway is monitored for performance on a regular basis. Quality standards can be separated to those expected of the referring team and those expected by the receiving team. The following quality standards are in line with the standards set out in the Greater Manchester Optimal Lung Cancer Pathway.

Quality standards for referring teams

- All patients have pathological diagnosis of lung cancer
- Patients with NSCLC have a PD-L1 status
- Patients with non-squamous NSCLC have EGFR, ALK, ROS-1 testing
- All patients have undergone renal function – creatinine and estimated glomerular filtration rate
- All referrals contain the required source documents in line with the standard operating procedure

Quality standards for referring teams

- Referring teams and patients will be contacted with their appointment time and date within 1 working day of The Christie receiving a completed referral. If any source documents are missing or additional tests required, the patient will be informed of next steps, and offered an appointment as soon as the referral is complete. Once complete, the CARP will be accepted.
- Patients will be seen within 5 days of a complete referral being received/CARP accepted
- Referring teams will receive clinic letters within 1 working day of the clinic encounter via NHS.net email
- Those patients accepted for radiotherapy will begin their treatment within a maximum of 14 days of assessment. Referring teams and GPs will receive a treatment summary post-treatment within 7 working days of completion via email

Quality standards targets:

Target performance is 85% compliance with quality standards

Summary

This document sets out standards for patients with proven or suspected lung cancer being referred for assessment for treatment in Greater Manchester. These standards are designed to deliver an efficient pathway, minimising unnecessary travel and optimising the patient experience and should help deliver the Greater Manchester Optimal Lung Cancer Pathway. **This ambitious pathway describes a 14 day pathway from treatment decision to commencing treatment.**

Key points for referring teams:

- Ensure the facilities and infrastructure that provide spirometry, diffusion capacity, basic functional assessment (shuttle walk / stair climbing) and ECG as soon as possible within the diagnostic pathway.
- Ensure timely access to echocardiogram for those patients that meet the criteria set out in this document.
- Ensure pathology pathways are in place tyo facilitate reflex testing of lung cancer samples for molecular profiling.
- Ensure the referral checklist is reviewed for all referrals to ensure compliance with minimum referral data set. This will facilitate a prompt assessment and treatment decision. Consequently, CARPs will only be accepted once all required information is received in line with the standards set out in this document.

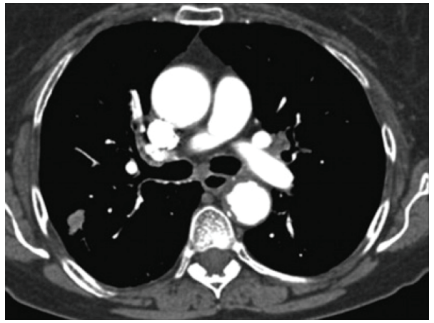
Key points for receiving teams:

- MFT will take responsibility for the advanced physiological testing in surgical referrals in higher risk surgical candidates – predominantly CPET but also including perfusion scintography and dobutamine stress echo when required.
- MFT will facilitate any required tests not performed by the referring team at the time of referral for thoracic surgery, to minimise delay and communicate effectively with the patient (in the absence of clear reasons for tests not being required, described within the referral letter). The referring team will also be notified. A CARP will be adjusted/ accepted once all the required basic physiology and staging tests have been completed and results available in line with the standards set out in this document.
- To ensure the resource and infrastructure to facilitate same-day triage of referrals, clinic listing, and communication in line with the quality standards set out in this document
- To complete annual audit of referrals against the quality standards set out in this document to present to the pathway board.

Appendix 1

Commence prehabilitation and optimisation from first assessment – Ensure the three pillars of prehabilitation are covered:

Treat tobacco addiction	Physical activity	Prevention & management of malnutrition



GROUP 1: Peripheral tumour with normal hilar and mediastinum on staging CT with no disant metastases

For patients deemed suitable and fit enough for investigations and treatment. For those patients deemed unfit for investigations and treatment list straight for MDT discussion and confirm best supportive care decision.

Including: Solid pulmonary nodules ≥8mm diameter / ≥300mm3 volume and BROCK risk of malignancy ≥10% or persistent sub-solid nodules for ≥3 months and solid component ≥5mm

Excluding: Solid nodules <8mm / <300mm3 or BROCK risk <10%, pure ground glass nodules of any size (even if enlarging), and sub-solid nodules with solid component <5mm.
Ground glass nodules do not require further diagnostics and should continue under surveillance. MDTs should exercise extreme caution if considering further investigations or intervention on ground glass nodules.

Diagnostic tests

Option 1: PET first then consider additional investigations dependent upon PET result.
Note – Some MDTs may consider it appropriate to proceed directly to treatment without a biopsy if there is no upstaging on PET and the probability of malignancy is sufficiently high

Option 2: Request diagnostic test bundle

Option 1: PET first
If no upstaging on PET then request additional tests from option 2 diagnostic test bundle
If PET-CT upstages the tumour request additional tests from the appropriate algorithms as per below:
N1 M0 – Group 2
N2-3 M0 – Group 3
N0-3 M1 – Group 5

Option 2: Diagnostic test bundle
(requested in parallel)

PET-CT
Primary tumour biopsy: Percutaneous image-guided biopsy OR bronchoscopic guided biopsy (Fluoroscopy, radial EBUS, navigational bronchoscopy)

Physiology tests
(request simultaneously)

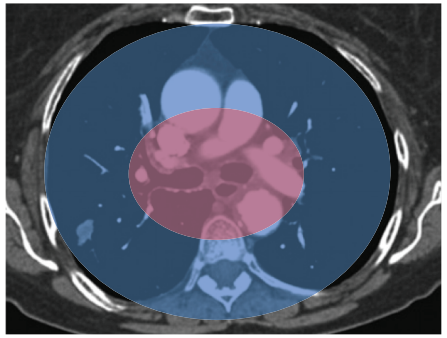
- Spirometry and transfer factor
- Shuttle walk or stair climbing test
- ECG

Request echocardiogram if:

- Heart murmur
- Abnormal ECG
- Known ischaemic heart disease / valvular disease
- Possibility of pneumonectomy

Notes and guidance

Peripheral tumour = positioned in the outer 2/3 of the thorax based on axial CT image (blue area):



Note: Percutaneous image-guided biopsy should be the preferred method of primary tumour biopsy where possible given the higher sensitivity. Bronchoscopic guided biopsy might be considered in cases where image guided is considered high risk (e.g severe emphysema) and /or in the presence of a bronchus sign (a bronchus leading directly into the tumour seen on CT imaging).

Mandatory dataset for MDT discussion:

- **PET-CT results**
- **Performance status, FEV_1 and DLCO, post-operative predicted FEV_1 and DLCO**

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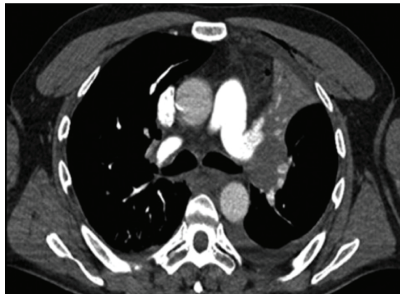
Commence prehabilitation and optimisation from first assessment –
Ensure the three pillars of prehabilitation are covered:

Treat tobacco addiction	Physical activity	Prevention & management of malnutrition



GROUP 2: Central tumour or N1 lymphadenopathy with normal mediastinum on staging CT with no distant metastases

For patients deemed suitable and fit enough for investigations and treatment. For those patients deemed unfit for investigations and treatment list straight for MDT discussion and confirm best supportive care decision.

PET-CT has a 15% false positive rate and 25% false negative rate for N2/3 disease in this category, therefore EBUS is required regardless of PET findings

Prevalence of N2/3 disease in this category is 20-25%

Diagnostic tests

Option 1: PET first then consider additional investigations dependent upon PET result.

Option 2: Request diagnostic test bundle

Option 1: PET first
If no upstaging on PET then request additional tests from option 2 diagnostic test bundle
If PET-CT upstages the tumour request additional tests from the appropriate algorithms as per below:
N2-3 M0 – Group 3
N0-3 M1 – Group 5

Option 2: Diagnostic test bundle
(requested in parallel)

PET-CT
Diagnostic Bronchoscopy (if central tumour for biopsy)
Staging EBUS
(performed simultaneously to diagnostic bronchoscopy)
Contrast enhanced CT brain

Physiology tests
(request simultaneously)

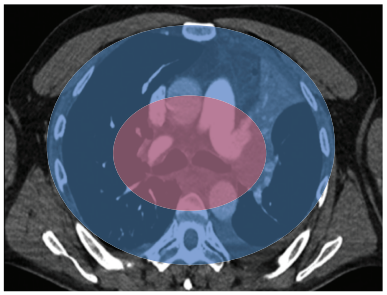
- Spirometry and transfer factor'
- Shuttle walk or stair climbing test
- ECG

Request echocardiogram if:

- Heart murmur
- Abnormal ECG
- Known ischaemic heart disease / valvular disease
- Possibility of pneumonectomy

Notes and guidance

Central tumour = positioned in the inner 1/3 of the thorax based on axial CT image (red area):



A systematic examination of the mediastinal and hilar lymph nodes beginning with N3 stations, followed by N2 stations and finally N1 (a suggested systematic approach is outlined in the table below). Any lymph node measuring >5mm in short axis, based on sonographic measurement, is sampled

N3	N2	N1
Contralateral station 11	Station 7	Ipsilateral station 10
Contralateral station 10	Ipsilateral station 2	Ipsilateral station 11
Contralateral station 4	Ipsilateral station 4	
Contralateral station 2		

Mandatory dataset for MDT discussion:

- **PET-CT, EBUS pathology & CT brain results**
- **Performance status, FEV_1 and DLCO, post-operative predicted FEV_1 and DLCO**

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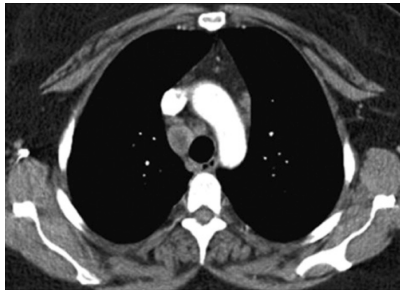
Commence prehabilitation and optimisation from first assessment –
Ensure the three pillars of prehabilitation are covered:

Treat tobacco addiction	Physical activity	Prevention & management of malnutrition



GROUP 3: Primary tumour and discrete mediastinal lymphadenopathy on staging CT with no distant metastases

For patients deemed suitable and fit enough for investigations and treatment. For those patients deemed unfit for investigations and treatment list straight for MDT discussion and confirm best supportive care decision.

PET-CT has a 15% false positive rate and 25% false negative rate for N2/3 disease in this category, therefore EBUS is required regardless of PET findings

Prevalence of N2/3 disease is this category is 60%

Diagnostic tests

Option 1: PET first then consider additional investigations dependent upon PET result.

Option 2: Request diagnostic test bundle

Option 1: PET first
If no upstaging on PET then request additional tests from option 2 diagnostic test bundle
If PET-CT upstages the tumour request additional tests from the appropriate algorithms as per below:
N0-3 M1 – Group 5

Option 2: Diagnostic test bundle
(requested in parallel)

PET-CT
Staging EBUS
Contrast enhanced MR brain

Note: If the CT or PET-CT also shows enlarged or FDG avid supraclavicular lymph nodes then replace EBUS with USS guided lymph node biopsy. EBUS would be needed if neck sampling was negative. If all nodal sampling is negative then biopsy of the primary tumour may be needed.

Physiology tests
(request simultaneously)

- Spirometry and transfer factor
- Shuttle walk or stair climbing test
- ECG
- Creatinine clearance / eGFR

Request echocardiogram if:

- Heart murmur
- Abnormal ECG
- Known ischaemic heart disease / valvular disease
- Possibility of pneumonectomy

Notes and guidance

Discrete mediastinal lymphadenopathy has well defined borders allowing easy measurement and is not conglomerate with other lymph node stations. It is non-bulky (<3cm).

Staging EBUS definition:

A systematic examination of the mediastinal and hilar lymph nodes beginning with N3 stations, followed by N2 stations and finally N1 (a suggested systematic approach is outlined in the table below). Any lymph node measuring >5mm in short axis, based on sonographic measurement, is sampled

N3	N2	N1
Contralateral station 11	Station 7	Ipsilateral station 10
Contralateral station 10	Ipsilateral station 2	Ipsilateral station 11
Contralateral station 4	Ipsilateral station 4	
Contralateral station 2		

Mandatory dataset for MDT discussion:

- **PET-CT results, EBUS pathology results, brain-imaging results**
- **Performance status, FEV_1 and DLCO, post-operative predicted FEV_1 and DLCO, renal function**

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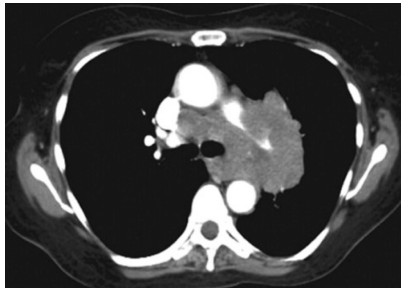
Commence prehabilitation and optimisation from first assessment –
Ensure the three pillars of prehabilitation are covered:

Treat tobacco addiction	Physical activity	Prevention & management of malnutrition



GROUP 4: Conglomerate and invasive nodal malignancy on staging CT with no distant metastases

For patients deemed suitable and fit enough for investigations and treatment. For those patients deemed unfit for investigations and treatment list straight for MDT discussion and confirm best supportive care decision.

Radiology is considered diagnostic for malignancy and pathological confirmation only required
Prevalence of N2/3 disease is this category is 100%

Diagnostic tests

Option 1: PET first then consider additional investigations dependent upon PET result.

Option 2: Request diagnostic test bundle

Option 1: PET first
If no upstaging on PET then request additional tests from option 2 diagnostic test bundle
If PET-CT upstages the tumour request additional tests from the appropriate algorithms as per below:
N0-3 M1 – Group 5

Option 2: Diagnostic test bundle
(requested in parallel)

PET-CT
Diagnostic bronchoscopy with conventional TBNA OR
Diagnostic EBUS
Contrast enhanced MR brain

Note: If the CT or PET-CT also shows enlarged or FDG avid supraclavicular lymph nodes then replace EBUS with USS guided lymph node biopsy. EBUS would be needed if neck sampling was negative.

Physiology tests
(request simultaneously)

- Spirometry and transfer factor'
- Creatinine clearance / eGFR

Notes and guidance

Invasive mediastinal lymphadenopathy has poorly defined borders and cannot be easily measured. It forms conglomerate disease with other nodal stations.

Diagnostic EBUS definition:

Targeted sampling of nodal disease for pathological confirmation, tumour sub-typing and molecular pathology.

Mandatory dataset for MDT discussion:

- **PET-CT results, EBUS pathology results, brain-imaging results**
- **Performance status, FEV_1 and DLCO, renal function**

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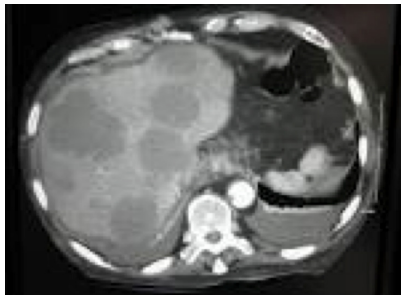
Commence prehabilitation and optimisation from first assessment –
Ensure the three pillars of prehabilitation are covered:

Treat tobacco addiction	Physical activity	Prevention & management of malnutrition



GROUP 5: Distant metastases on staging CT

For patients deemed suitable and fit enough for investigations and treatment. For those patients deemed unfit for investigations and treatment list straight for MDT discussion and confirm best supportive care decision.

Follow this algorithm in cases where there is clear evidence of stage 4 disease on CT. In cases of uncertain findings there may need to additional clarification tests e.g. liver USS/MR, triple phase adrenal wash out CT or PET-CT.

Early referral to specialist palliative care team is recommended regardless of diagnostic pathway or treatment plan

Diagnostic tests

Choose most appropriate sampling technique to yield adequate pathology for tumour sub-typing and targeted therapy assessment:

The core procedures are:
Diagnostic bronchoscopy (including conventional TBNA)
Diagnostic EBUS
Percutaneous image-guided biopsy
These are procedures performed by core lung cancer MDT members aware of the pathological requirements of sampling stage 4 disease

Consider:

Pleural aspiration ± Medical thoracoscopy if symptomatic pleural effusion.

Avoiding bone biopsy (lacking a significant soft tissue component) given time for decalcification and inability to do molecular pathology.

Ensure non-MDT clinicians performing biopsies are informed about tissue requirements for targeted therapy.

Mandatory dataset for MDT discussion:

- **Pathology results**
- **Performance status, renal function**

Physiology tests
(request simultaneously)

- Creatinine clearance / eGFR

Specific Notes

1 - Reflex testing in stage 4 NSCLC is recommended therefore it is critical the pathologist are provided with adequate information, including staging, on request forms.

Non-squamous NSCLC: EGFR, ALK, ROS-1, PDL-1
Squamous NSCLC: PDL1

2 – In patients deemed unfit for invasive investigations or chemotherapy, consider serum EGFR testing to inform role of TKI therapy

Workup of oligometastatic disease

Definition of oligometastatic disease = single metastases in a single organ

In patients that may be suitable for a high grade palliative approach request the following investigations in addition to those performed for Group 5 (either request PET first or request as a diagnostic text bundle):

PET-CT
Contrast-enhanced brain imaging
Staging EBUS
Spirometry and transfer factor
Shuttle walk or stair climbing test
Echocardiogram

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Calculating Post-operative Lung Function

Answer the following questions:

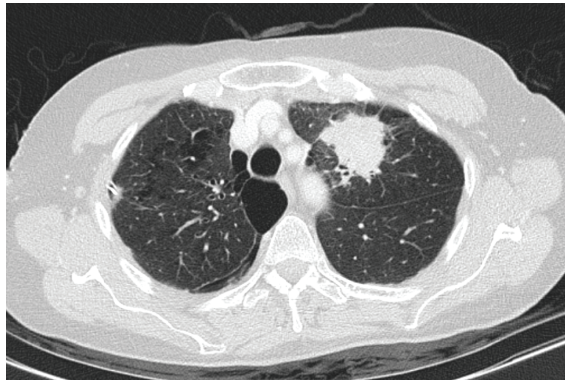
1. Are there any obstructed segments on CT or bronchoscopy?
2. What do you expect will be resected at surgery (assume lobectomy is the standard of care)?

Segments:

Right upper lobe= 3
Right middle lobe= 2
Right lower lobe= 5
Left upper lobe = 5
Left lower lobe = 4
Total = 19

Then calculate:

- Total number of unobstructed segments – number of unobstructed segments to be removed = Answer A
- Answer A ÷ total number of unobstructed segments = Answer B
- Answer B x pre-operative % predicted lung function



Example – patient under assessment for left upper lobectomy, FEV_1 68% predicted – what is the post-operative predicted FEV_1?

There are no obstructed segments on CT or bronchoscopy.

19 – 5 = 14

14 ÷ 19 = 0.75

0.75 x 68 = **50**

Predicted post-operative FEV_1 = 50%

Appendix 3

Clinical Frailty Scale*

1 **Very Fit** – People who are robust, active, energetic and motivated. These people commonly exercise regularly. They are among the fittest for their age.

2 **Well** – People who have **no active disease symptoms** but are less fit than category 1. Often, they exercise or are very **active occasionally**, e.g. seasonally.

3 **Managing Well** – People whose **medical problems are well controlled,** but are **not regularly active** beyond routine walking.

4 **Vulnerable** – While **not dependent** on others for daily help, often **symptoms limit activities.** A common complaint is being "slowed up", and/or being tired during the day.

5 **Mildly Frail** – These people often have **more evident slowing,** and need help in **high order IADLs** (finances, transportation, heavy housework, medications). Typically, mild frailty progressively impairs shopping and walking outside alone, meal preparation and housework.

6 **Moderately Frail** – People need help with **all outside activities** and with **keeping house**. Inside, they often have problems with stairs and need **help with bathing** and might need minimal assistance (cuing, standby) with dressing.

7 **Severely Frail** – **Completely dependent for personal care**, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying (within ~ 6 months).

8 **Very Severely Frail** – Completely dependent, approaching the end of life. Typically, they could not recover even from a minor illness.

9. **Terminally Ill** - Approaching the end of life. This category applies to people with **a life expectancy <6 months**, who are **not otherwise evidently frail.**

Scoring frailty in people with dementia

The degree of frailty corresponds to the degree of dementia. Common **symptoms in mild dementia** include forgetting the details of a recent event, though still remembering the event itself, repeating the same question/story and social withdrawal.

In **moderate dementia**, recent memory is very impaired, even though they seemingly can remember their past life events well. They can do personal care with prompting.

In **severe dementia**, they cannot do personal care without help.

* 1. Canadian Study on Health & Aging, Revised 2008.
2. K. Rockwood et al. A global clinical measure of fitness and frailty in elderly people. CMAJ 2005;173:489-495.

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The purpose of this standardised algorithm for surgical assessment is to provide a consistent framework to assess the risk of surgical resection and describe the magnitude of this risk. This will allow an informed decision making process with each individual patient as well drive up resection rates. Surgery remains the best chance of cure in early stage lung cancer and has been shown to increase survival in high risk patients compared to high risk patients that do not undergo surgery.

RAPID Programme: Thoracic Surgery Triage Pathway (Lung Cancer Patients)

1 **Surgical Triage Step 1 –** review the referral information

- Review the imaging and consider if the disease is resectable and the extent of resection required
- Review the staging investigations and ensure they comply with the minimal standards set out in the Greater Manchester Surgical Referral SOP

☐ Check any patient with enlarged or FDG avid thoracic lymph nodes has undergone pathological nodal staging

☐ Check patients with stage II/ III lung cancer have undergone contrast enhanced brain imaging

☐ If patients don't have pathological confirmation of lung cancer consider whether a percutaneous image guided biopsy should be performed

- Review the physiological investigations performed so far

☐ Calculate predicted post-operative FEV1 and DLCO

☐ Check all patients have undergone a shuttle walk test

☐ Calculate Thoracic Revised Cardiac Risk Index (ThRCRI)

☐ Check patients aged ≥70yrs, IHD, possibility of pneumonectomy, valvular heart disease or ≥2 ThRCRI factors had undergone echocardiogram

2 **Cardiopulmonary exercise testing**

Please request a CPET in patients that have a shuttle walk test of 100-250m

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Supporting Information

Cardiac risk

- Detailed evaluation for coronary artery disease is not needed for patients with an acceptable exercise tolerance and cardiac interventions specifically for thoracic surgery are of **limited value**
- Refer patients for cardiology opinion if they have angina on minimal exertion (<100m or climbing < 2 flights of stairs), breathlessness at rest attributed to cardiac failure, severe aortic stenosis or severe AV conduction defect)
- Non-invasive stress testing (e.g. dobutamine stress echo) are only indicated in those patients with significant limitation to exercise tolerance due to suspected cardiac disease and should be requested at the discretion of the treating cardiologist.

Shuttle walk

- A shuttle walk greater than 40 shuttles (400m) correlates well to a VO2max >15mls/kg/min (100% positive predictive value) however the shuttle walk appears to underestimate VO2max at the lower ranges – 9/17 patients with a shuttle walk <250m had a VO2max >15mls/kg/min (Win et al)
- More recent data demonstrated a shuttle walk of >25 shuttles (250m) has a 90% positive predictive value for VO2max >15mls/kg/min (Benzo&Sciurba)
- Perform CPET in those with a shuttle walk <250m to identify those in a better risk category than suggested by the shuttle walk result

Post-operative predicted lung function

- The ERS/ESTS/ACCP expert consensus opinion is the definition of high risk surgical candidate should be those with a predicted postoperative lung function <30%
- Acceptable mortality and outcomes have been demonstrated using these selection criteria in the context of an acceptable exercise tolerance (Puente-Maestu et al mortality 6%, Brunelli et al moratlity 4%). Furthermore, in the Puente-Maestu et al study the 2 year survival of those patients in the resection group was 66% versus 19% in those patients that did not undergo surgery.

CPET

- The BTS and SCTS state "The evidence for CPET in providing a useful definition of high risk is limited and there is no data to show how it can help predict unacceptable levels of post-operative dyspnoea"
- In the CALGB study where high risk was defined as a VO2max <15mls/kg/min, 68 high risk patients underwent surgical resection with an operative mortality of 4% and no difference in complication rate. The overall survival of high risk patients that underwent surgery was 36 months vs 15.8 months in high risk patients that did not undergo surgery
- The ERS/ESTS/ACCP generally consider a VO2max <10mls/kg/min prohibitive for surgery though this is based on a total of 27 patients from 4 studies with a mortality of 26%

Desaturation during function testing

- Evidence is contradictory on the ability of desaturation during exercise to predict complications. National and international guidelines do not recommend desaturation during exercise as a robust measure for the risk of complications however it is the policy of the MFT high risk thoracic surgery MDT to record and discuss any desaturation during exercise as part of a holistic risk assessment.

Appendix 4

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Criteria for High Risk MDT discussion:

Any patient meeting any of the following criteria should be discussed in the high risk MDT:

- ppo-FEV1 <40%
- ppo-DLCO <40%
- Shuttle walk <250m
- V02max <15mls/kg/min
- Desaturation during exercise - <90% or >4%
- ThRCRI >=2
- BMI <20
- Current smoker
- Pneumonecotmy
- Thoracoscore >5%
- Nottingham 90 day risk >10%
- Rockwood frailty score >=4

Note: any patient can be listed for high risk MDT as the discretion of the clinician as a number of high risk factors may not be captured in these criteria

Criteria for Cardiothoracic Critical Care Unit Admission:

Any patient meeting any of the following criteria should have a CTCCU bed booked for post-operative care:

- Pneumonectomy
- Chest wall resection
- VO2 max <12mls/kg/min
- Rockwood frailty >=4
- THRCRI >=3
- BMI <18
- High risk MDT decision for CTCCU bed

Note: intra-operative events may also dictate a need for CTCCU bed and are unpredicatble / unavoidable

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Patient information used to guide an informed decision making process

Information to be included on the consent form

Risk of 30 day mortality: .....%
(based on Thoracoscore)

Risk of 90 day mortality: .....%
(based on Nottingham 90 day mortality score)

Risk of peri-operative cardiac event: .....%
(based on ThRCRI)

Thoracic Revised Cardiac Risk Index:

Ischaemic Heart Disease
Cerebrovascular disease
Serum Creatinine >177umol/L
Pneumonectomy

Risk of major perioperative cardiac event:
0 factors = 0.4%
1 factors = 0.9%
2 factors = 7%
≥3 factors = 11%

Overall risk of mortality and complications based on lung function

Low risk = ppo-FEV1 & DLCO >40%	Moderate risk = ppo-FEV1 & DLCO 30-40%	High risk = ppo-FEV1 & DLCO <30%

Overall risk of mortality and complications based on exercise capacity

Shuttle walk

Low risk = >400m	Moderate risk = 250 - 400m	High risk = <250

CPET

Low risk = >15mls/kg/min	Moderate risk = 10-15mls/kg/min	High risk = <10mls/kg/min

Appendix 5

Greater Manchester Cancer

Guidance for the selection and pathway overview for patients with stage III-N2 NSCLC suitable for trimodality treatment

Introduction

In 2019 the National Institute for Health and Care Excellence (NICE) published its updated guidance for the diagnosis and management of lung cancer. This included a specific new recommendation for the management of patients with stage III-N2 NSCLC that are considered potentially resectable. Such patients can be considered for trimodality treatment (chemoradiotherapy followed by surgery). This is a highly intensive multi-modality treatment regime and one that is not currently used within routine clinic practice. Stage III NSCLC lung cancer is also a rapidly evolving field with new treatment paradigms (particularly in non-surgical treatment regimens) beginning to enter routine clinical practice. Therefore, patient selection, patient choice, shared decision making and access to appropriate expertise is critical in ensuring the very best patient outcomes.

This document, produced by a dedicated N2 taskforce, a sub-group of the Greater Manchester Cancer Lung Pathway Board, provides guidance on patient selection and referral, a standardised definition of 'potentially resectable' stage III-N2 NSCLC for all MDTs to use within their case discussions and an overview of the agreed pathway to facilitate rapid and efficient transition from chemoradiotherapy to surgery.

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Recommendations for patient selection for trimodality treatment in N2 NSCLC at Sector MDT discussion

MDT agreed Stage III N2 NSCLC and considered 'potentially resectable' in line with the GM standardised definition

AND:

- Deemed suitable for radiotherapy e.g. acceptable disease volume, absence of interstitial lung disease, absence of mediastinal vessel involvement
- Deemed suitable for chemotherapy e.g. adequate renal function, no hearing impairment
- Adequate physiological reserve for trimodality treatment*
- Absence of poor prognostic markers e.g. >10% weight loss
- Ability to travel and engage with multiple hospital visits at different trusts
- Appropriate social support during mulit-modality treatment

Recommended parameters of adequate physiological reserve for trimodality treatment:

- ✓ **PS 0-1**
- ✓ **Post-operative predicted lung function >40%**
- ✓ **Shuttle walk >400m or VO2 max >15mls/kg/min**
- ✓ **Normal left ventricular function on echocardiogram**
- ✓ **BMI >20**
- ✓ **Clinical frailty score 1-3**

Please note these are guidelines for patient selection for trimodality treatment. Given the highly individual patient and disease factors in every case of N2 NSCLC, the final decision and treatment recommendation rests in the expert hands of the sector MDT.

Patients identified as potentially suitable for trimodality treatment should be referred to both thoracic surgery and thoracic oncology teams as per the trimodality pathway.

Please ensure referrals for consideration of trimodality treatment include:

- ✓ **PDL1 status**
- ✓ **History of any autoimmune condition and its severity**
- ✓ **History of any corticosteroid use**
- ✓ **Smoking status: never, light, ex-smoker, current smoker**
  (please provide pack years & quit date if applicable)

Please ensure all patients have been provided with the necessary interventions to optimise for multi-modality treatment such as treatment for tobacco addiction, nutritional assessment and support and physical activity interventions.

NOTE: the PIONEER trial will open in 2020 and is a randomised controlled trial of surgical (including trimodality treatment) versus non-surgical multi-modality treatment in N2 NSCLC with a quality of life primary outcome. The North West and South Sector MDTs will actively recruit to this trial but we will happily facilitate rapid review of patients from across GM wishing to consider this trial – please contact **Matt Evison (m.evison@nhs.net)** or **Seamus Grundy (seamus.grundy@srft.nhs.uk)**.

Please support randomisation to this important trial.

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Appendix 5

Greater Manchester Cancer Guidelines
Definition of potentially resectable N2 NSCLC

- Pathologically confirmed N2 lymph node disease as part of a systematic nodal staging procedure (surgical or endoscopic) (single or multistation)
- Thorough radiological staging including at least positron emission tomography (PET)-CT and MR brain with contrast
- Primary tumour deemed resectable with high probability of clear pathological margins and complete resection, preferably avoiding a pneumonectomy
- Easily measurable and defined metastatic N2 lymph nodes free from major mediastinal structures including the great vessels and trachea with no individual lymph node measuring >3 cm.
- **Ultimately the assessment of resectability rests with the thoracic surgical team present in the MDT and then on face to face consultation with the patient**

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Greater Manchester Trimodality Treatment Pathway
Stage III – N2 Non-small Cell Lung Cancer

1 Sector MDT
Patient identified as possible candidate for trimodality treatment
Refer to Oncology and Thoracic Surgery to confirm suitability & discuss options

↓

2 Patient & clinicians agree to proceed with trimodality treatment
Chemoradiotherapy commences at The Christie

↓

3 Referral to RAPID hub at Wythenshawe Hospital
Responsible oncologist emails referral to
mft.rapidlungdiagnostic@nhs.net & m.evison@nhs.net with finishing date for CRT

↓

4 Date for post-chemoradiotherapy imaging confirmed
Patient is booked for contrast-enhanced CT brain, chest, abdomen & pelvis in one scan in the RAPID hub - date fed back to referring oncologist and Jackie Fenemore, Lead CNS at The Christie, jackie.fenemore@christie.nhs.uk (information is added to CWP at The Christie).
Patient is contacted with date - 7 days following finishing CRT.

↓

5 RAPID team contact patient 2 working days prior to appointment to check patient able to attend

↓

6 Post-chemoradiotherapy imaging & review*
Patient attends for RAPID scan - **hot reported and clinical review same morning**.
If no distant progression and no clear local progression to unresectable, patient is booked for
Surgical OP appointment within 3 working days
Patient & surgeon agree to proceed with surgery. Listed for surgery.
Prioritised as urgent: **surgery within 14 days.**

↓

7 Completion of trimodality treatment
Standard surgical follow-up and then returned to follow up of oncology team and local physician.

**Contrast enhanced CT imaging only - no indication for PET-CT, MR brain, nodal staging. Does not require post - CRT MDT discussion, proceed straight to imaging and surgical assessment.*

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