

A11/S(HSS)/a

**2013/14 NHS STANDARD CONTRACT
FOR PULMONARY THROMBOECTOMY (ADULTS AND
ADOLESCENTS)**

PARTICULARS, SCHEDULE 2 – THE SERVICES, A - SERVICE SPECIFICATION

Service Specification No.	A11/S(HSS)/a
Service	Pulmonary Thromboectomy (Adults and adolescents)
Commissioner Lead	
Provider Lead	
Period	12 months
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

Description

Chronic thromboembolic pulmonary hypertension (CTEPH) is defined as pre-capillary pulmonary hypertension (mean pulmonary artery (PA) pressure > 25 mmHg, pulmonary capillary wedge pressure <15mmHg, pulmonary vascular resistance (PVR) >2 Wood Units) with persistent perfusion defects on imaging. In the World Health Organisation (WHO) classification of pulmonary hypertension, CTEPH is now recognised as an independent category and is one of the most important types to diagnose as it is potentially curable. In the absence of surgical treatment, CTEPH has historically had a poor prognosis, although recent studies internationally and from the UK have shown that the surgical and medical treatment of patients with pulmonary hypertension is improving prognosis.

The prevalence and incidence of CTEPH are difficult to calculate. Recent follow-up studies in patients presenting with acute pulmonary embolism (PE) give an estimates of cumulative incidence ranging from 0.8% to 3.8%. Given that acute PE is as common as 1 in 1000 population per year, the annual incidence of CTEPH following acute venous thromboemboli may be of the order of 8–40 cases per million population, but far fewer patients are currently diagnosed. In a study of 469 patients diagnosed prospectively with CTEPH in the UK adult pulmonary hypertension centres between 2001 and 2005, the calculated incidence in 2005 was 1.75 cases/year/million.

CTEPH results from physical obstruction of the pulmonary vascular bed by thromboemboli. It is likely that acute pulmonary embolism, whether symptomatic or asymptomatic, serves as the initiating event. Following a pulmonary embolism many patients recover as natural lysis of the occluding thrombus occurs. However, in a small percentage of patients the thrombus does not clear and CTEPH develops due to progressive pulmonary vascular occlusion and the development of a generalised hypertensive pulmonary arteriopathy. The thrombus turns to fibrotic scar that may completely occlude the lumen or form different grades of stenosis, webs and bands. In the non-occluded areas, a pulmonary arteriopathy indistinguishable from that of idiopathic pulmonary arterial hypertension can develop. This model of a two compartment cause for elevated pulmonary vascular resistance (PVR) explains why some CTEPH patients have severe pulmonary hypertension out of proportion to the degree of vascular obstruction visible in imaging investigations. Therefore, deciding on the risk/benefit ratio of endarterectomy surgery for some patients can be difficult and the distinction between *proximal* (operable) CTEPH and *distal* (inoperable) disease is based mainly on experience. Overall, the key determinant of operability is the correlation between the degree of visible disease in imaging studies and the haemodynamic dysfunction (absolute PA pressure, cardiac output and the function of both – PVR). In the UK, approximately 70% of patients referred with CTEPH are considered operable.

Evidence base

The disease was first recognised in the 1940s at post mortum, and first reported in the UK in 1951 (1). In the last 20 years much has been learnt about CTEPH and pulmonary endarterectomy surgery.

- CTEPH probably remains under recognised in most countries, even in the UK (2), but knowledge of the disease and effective treatment is increasing. Up until 2005 the demand for pulmonary endarterectomy surgery in the UK was approximately 40 cases per annum, but in 2010 it is expected to exceed 100 cases
- The pathophysiology of the disease is understood, although the reason why it develops in some patients and not others remains a mystery (3)
- The prognosis of patients without treatment is poor (4)
- Pulmonary endarterectomy is curative in many patients and with appropriate experience can be accomplished with low mortality and morbidity (5)
- The UK service has contributed significantly to the international evidence base, describing for the first time the outcome for a prospective cohort of national patients with CTEPH (6)
- The UK service has also been the only one to follow up patients comprehensively following endarterectomy surgery to provide novel data on medium term functional outcome and survival (6,7)
- The UK service has been the first to recognise that some patients, with more distal CTEPH may improve after endarterectomy surgery with excellent survival, but without completely normalised haemodynamics, and that some residual pulmonary hypertension may persist (6, 8). The recognition of this condition is important as drugs initially developed for treatment of idiopathic pulmonary hypertension are being trialled in CTEPH patients.

2. Scope

2.1 Aims and objectives of service

Aims

The aim of the pulmonary endarterectomy service is to treat all UK patients with operable CTEPH. Through the network of adult pulmonary hypertension units, all patients with a diagnosis of CTEPH are referred (data assessed at weekly multi-disciplinary team (MDT) meeting) for consideration of pulmonary endarterectomy (PTE) surgery. A secondary aim is to help spread awareness of CTEPH and the success of pulmonary endarterectomy surgery.

The population served is the whole UK adult population. All patients with CTEPH are considered potentially curable and patients from 17 to 84 years have been operated on, many with significant comorbidity including previous cardiac surgery.

The service has been commissioned at Papworth Hospital NHS Foundation Trust since 2000 and expanded considerably in response to increasing referrals over the last 10 years. Pulmonary endarterectomy surgery was initially developed at the University of California at San Diego (UCSD) and expanded during the 1990s.

CTEPH causes severe breathlessness and has a poor prognosis. In many patients pulmonary endarterectomy is curative, by surgical clearance of thrombo embolic disease from the pulmonary arteries resulting in immediate improvement of symptoms and prognosis by reduction in pulmonary hypertension.

Objectives

The strategic objective of the service is to assess all patients referred with CTEPH in the UK and offer pulmonary endarterectomy surgery to all those who might benefit. A further objective is comprehensive follow up of patients post surgery with structured reassessment at Papworth Hospital NHS Foundation Trust to monitor the effectiveness of the intervention and further the knowledge of the natural history of treated CTEPH. A secondary objective is to help the adult pulmonary hypertension centres increase recognition of CTEPH within the UK and to ensure the potential of curative surgery is understood.

The desired outcome is to accept a high proportion of CTEPH patients referred for pulmonary endarterectomy surgery, with low in-hospital mortality and significant improvement in post operative quality of life and survival.

In-hospital mortality has already been reduced to that of the best international comparisons (<5%), and outcome is tracked by the clinical effectiveness unit of the Royal College of Surgeons England, reported by cumulative sum control chart (CUSUM) analysis at six monthly NHS England meetings.

Functional and longer term survival data is difficult to compare internationally as the UK has lead the way with detailed follow up post surgery. Research by the provider has demonstrated that if patients survive to 3 months following surgery, their conditional five year survival is over 90%. Patients improve by more than one New York Heart Association (NYHA) functional class and > 100m on the six minute walk test.

2.2 Service description/care pathway

Referrals are directed to the service lead consultant surgeon, or occasionally to a Papworth pulmonary hypertension consultant and may be received from any of the following:

- national pulmonary hypertension centres
- district general hospital (DGH) usually cardiology or respiratory referrals
- general practitioner (GP)
- self referral

They may be received through telephone, letter, facimile or email. The majority arrive by letter with accompanying imaging investigations on compact disc. They are reviewed by the consultant on arrival and most are discussed at the next weekly MDT if sufficient information is enclosed.

Referring centres are provided with a list of information required prior to referral.

Patients are referred to pathway, usually but not exclusively, from an adult pulmonary hypertension centre when the likely diagnosis is CTEPH.

All referred patients are discussed at a weekly MDT and if the patient may benefit from surgery they will proceed on the pulmonary endarterectomy pathway. If more information is required this will be requested from the referrer. Some patients are discussed on a number of occasions if diagnostic investigations are incomplete at first referral.

Patients can be removed from the pathway at various stages depending upon their clinical condition and / or patient choice as to whether to proceed.

There is weekly communication at nurse specialist level with the other pulmonary hypertension centres during the stages up to the patient being admitted for their surgery to monitor the patient's condition.

Advice is available from the team of specialist nurses during usually working hours. Consultants are always available for additional advice at all times.

MDT meetings occur weekly. Outpatient clinics are held weekly and the number of slots can be flexed to meet demand.

Current service provision for the surgical procedure is on most weekdays. The trust

is able to be flexible in its provision and increase capacity when required.

Prior to discharge there will be an assessment made to identify specific care needs for the patient. Referrals will be made as appropriate. Both the patient's general practitioner (GP) and referring hospital will be informed of the discharge and arrangements made for anti-coagulation monitoring and post operative care.

Patients remain under the care of the Papworth Hospital NHS Foundation Trust pulmonary hypertension team (joint care with their referring team if London, Sheffield, Newcastle or Glasgow) for follow up investigations until they are a year post surgery:

- assessment of operability in patients with CTEPH via a weekly specific MDT including pulmonary endarterectomy surgeons, specialist radiologists and pulmonary hypertension physicians. To communicate the decision and reasoning behind it (for educational reasons) by detailed letter to referring physicians, copied widely to all doctors involved in that patients care
- to review potentially operable patients in clinic at Papworth Hospital NHS Foundation Trust, by nurse specialist and surgical consultant to discuss risks and benefits of endarterectomy surgery
- to perform the pre operative assessment studies for patients (phase I and II) within the trust's pulmonary hypertension area and where necessary repeat or perform the same for patients referred from outside our area with incomplete diagnostic information. Phase I investigations include:
 - CT pulmonary angiogram (CTPA)
 - ventilation/perfusion (V/Q)
 - MRI and/or pulmonary angiogram
 - chest x-ray
 - echocardiogram
 - respiratory function tests
 - six minute walk test and
 - right heart catheterisation

Phase II tests include coronary angiography and insertion of inferior vena cava filters (IVC filters) where appropriate

- when necessary to transfer patients acutely for urgent assessment or surgery as dictated by clinical condition
- to perform pulmonary endarterectomy surgery, including all perioperative care, at Papworth Hospital NHS Foundation Trust, with the provision of full support services including extra corporeal membrane oxygenation (ECMO) where necessary
- to discharge patients directly to home following surgery whenever possible
- to reassess all patients following surgery with detailed haemodynamic functional and radiological evaluation (as in phase I above) under the care of the pulmonary hypertension service at Papworth Hospital NHS Foundation Trust at six weeks, three months and six months. Further formal evaluation of all patients at Papworth Hospital NHS Foundation Trust at one year, with six minute walk test, echocardiogram and repeat imaging as appropriate
- assessment at the patients' local adult pulmonary hypertension centre then

occurs annually for the next five years

- to provide detailed specialist advice on the treatment of CTEPH to any patient or doctor in the UK and internationally. Information available via hospital website and specific patient information booklet
- to work with the adult pulmonary hypertension centres and the Pulmonary Hypertension Association (patient group) to help increase awareness of CTEPH and pulmonary endarterectomy surgery
- to work with NHS England to ensure sufficient considerations are given to communications

Discharge planning

Discharge planning is commenced at the pre admission outpatient clinic where any specific patient needs will be highlighted. This is then continued as part of the admission process.

The decision for discharge to home is made by the consultant surgeon, with input from the specialist nurse, physiotherapist and ward staff. Inpatients are reviewed weekly by the pulmonary hypertension medical consultants who may give specific advice relating to targeted drug therapy. Occasional patients are referred back to their local referring hospitals for inpatient care especially if prolonged rehabilitation is required.

Elements of care planned for discharge:

- therapeutic anticoagulation, warfarin and or enoxaparin
- acceptable mobility, ability to climb stairs and/or gym visit assessment by physiotherapist
- wound healing, input from tissue viability nurse consultant where applicable;
- apyrexial
- bowels moved and eating and drinking adequately
- oxygen weaned off with a pulse oxymetry of $\geq 90\%$ on air at rest or provision of home oxygen (usually in place pre admission)
- assessment of knowledge and understanding of surgical procedure and care requirements particularly regarding anti-coagulation
- distance of residence from Papworth; may influence discharge arrangements (particularly if flying required)
- social arrangements

Follow up care and communication

Patients are sent home with a discharge pack with contains:

- information re wound care
- information re painkillers and weaning
- information re other drugs being taken
- physical activity and sexual relations
- travelling
- returning to work

- follow up appointments and the schedule for the year ahead including location and frequency
- anti coagulation arrangements and letter for GP, international normalised ratio (INR) clinic and patient regarding therapeutic range of warfarin and enoxaparin usage (patients are also discharged home with a small supply of enoxaparin to use if INR sub therapeutic)

After discharge, responsibility for daily care is with the patient's GP, and specialist pulmonary hypertension care is with the adult pulmonary hypertension centre, jointly with Papworth Hospital NHS Foundation Trust for the first year.

Specific follow up at Papworth Hospital NHS Foundation Trust:

- The nurse specialist will contact the patient at home two weeks post discharge for a telephone consultation in which all clinical, physical, psychological and social progress is checked. The nurse will then advise the patient that any further support from the nursing team may be sought via use of the helpline number
- A 6 week phone call by the nurse or appointment with one of the pulmonary hypertension physicians (if required and feasible) will be carried out.

Either in person or through questioning the nurse / consultant will discuss the following:

- anticoagulant therapy using INR
- fluid management
- exercise
- wound
- review targeted therapy
- driving

Any questions or concerns raised during the nurse telephone consultation will be discussed with the consultant physicians or surgeon and the patient may be asked to attend their GP practice. Any international normalized ratio (INR) management problem that is highlighted during this phone call will be actioned by the nurse specialist contacting either the GP or INR clinic and providing clear guidance.

- All patients attend Papworth Hospital NHS Foundation Trust for an inpatient stay between three and six months after surgery during which they will undergo the following full assessment repeating the phase I pre operative schedule to objectively compare improvement:
 - right heart catheterisation
 - CTPA, Magnetic resonance imaging (MRI)
 - Echocardiography
 - respiratory function tests
 - six minute walk distance
 - blood screen
 - formal wound review (commence Mepiform for hypertrophic scarring)
 - review lifestyle issues
 - review anti coagulation

- fluid balance management
- patients may recommence targeted therapy (PTE nurses will alert referring centre of recommencement of treatment and to arrange an appointment with them)
- At six months all Papworth Hospital NHS Foundation Trust patients attend for review including:
 - respiratory function tests
 - six minute walk distance
 - blood screen
 - review lifestyle issues
 - review anti coagulation
 - fluid balance management
- At 1 year post surgery all patients return to Papworth Hospital NHS Foundation Trust for their final assessment.

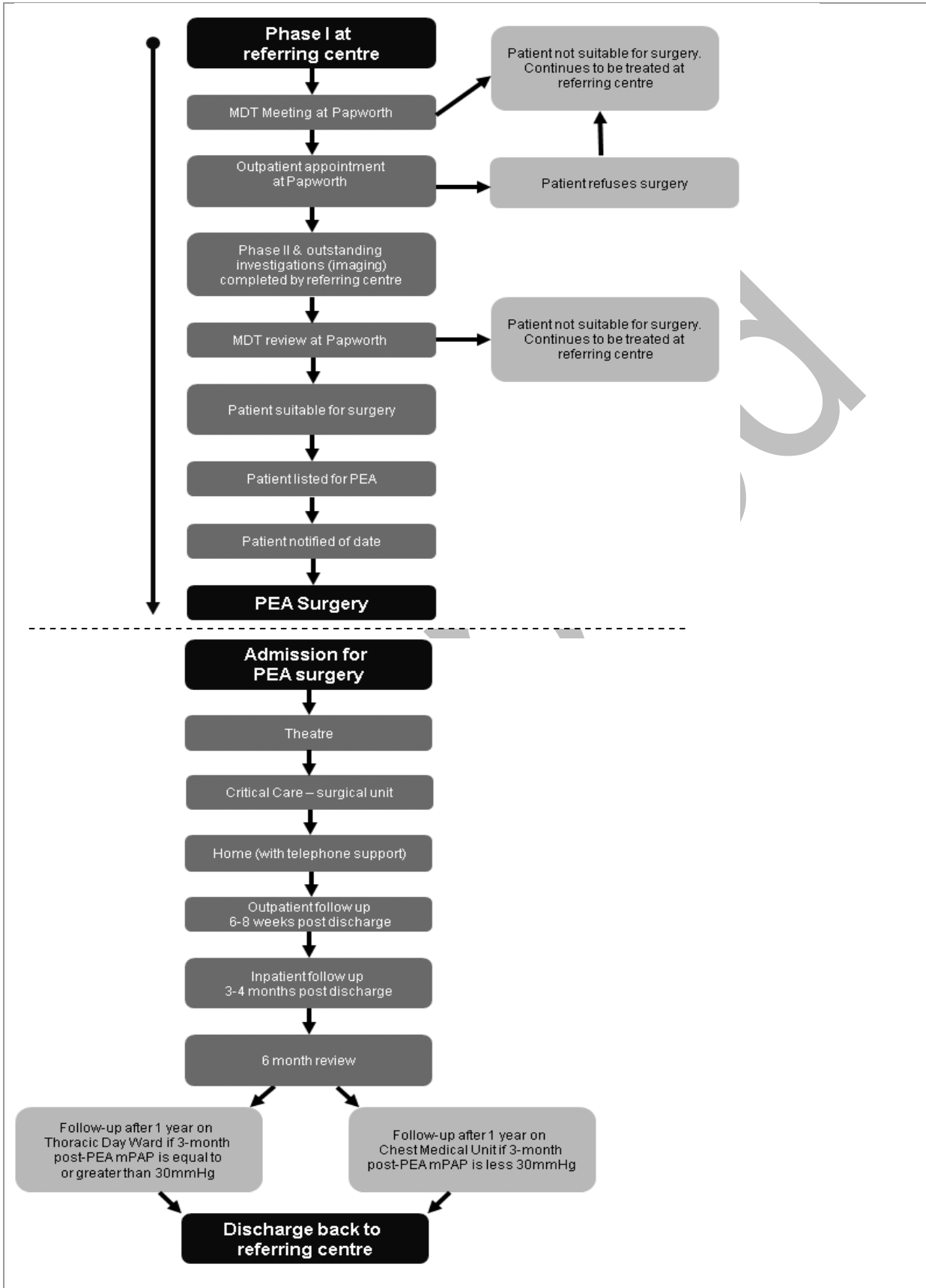
Patients with residual disease with a mean pulmonary artery (PA) pressure ≥ 30 mmHg will be admitted for a 2 night stay for:

- right heart catheterisation
- echocardiography
- pulmonary function tests (PFTs)
- six minute walk distance
- blood screen

Patients with a mean PA pressure < 30 mmHg will have day review involving

- echocardiography;
- PFTs
- six minute walk distance
- blood screen
- electrocardiogram (ECG)
- chest x-ray (CXR)

Following completion of the first year post operatively patients will be discharged from the surgical pathway and referred back to their local adult pulmonary hypertension centre for ongoing management and planned annual review for the next five years.



2.3 Population covered

NHS England commissions the service for the population of England. Commissioning on behalf of other devolved administrations is reviewed annually, and a current list is available from NHS England commissioners.

At the moment, NHS England contract includes provision for the service to treat eligible overseas patients under S2 [Under European Union (EU) regulations, patients can be referred for state funded treatment to another European Economic Area (EEA) member state or Switzerland, under the form S2 (for EU member states) or the form E112 (for Iceland, Norway, Liechtenstein and Switzerland)] referral arrangements. Providers are reimbursed for appropriately referred and recorded activity as part of NHS England contract.

Trusts performing procedures on EU-based patients outside of S2 arrangements will need to continue to make the financial arrangements directly with the governments involved, separately from their contract with NHS England.

With regard to S2, the mechanism for recovery of costs has been via the Department for Work and Pensions Overseas Healthcare Team. They are responsible for agreeing reconciliation and recovery of costs with European administrations. These arrangements were implemented in October 2009, though a similar process existed previously. The financial flows are therefore back into the treasury rather than back to trusts.

A small number of international patients are treated annually (from Eire, Europe and worldwide).

2.4 Any acceptance and exclusion criteria

Acceptance criteria

The service at Papworth Hospital NHS Foundation Trust is open to all eligible NHS patients irrespective of age, culture, disability or gender. Specific arrangements are in place to accommodate patients travelling longer distances in the UK with provision of a network of board and lodging houses in Papworth village for patients and families. Help is provided through the nurse specialist with advice on travelling especially when oxygen therapy is needed. An interpreter service is used in clinic when necessary especially to help with the consent process. Patients are accepted for surgery if the potential benefit is greater than the calculated risk irrespective of comorbidity, technical surgical difficulty or age. Papworth Hospital NHS Foundation Trust understands it has a duty to co-operate with the commissioner in undertaking equality impact assessments as a requirement of race, gender, sexual orientation, religion and disability equality legislation.

Referrals are usually directed to the service lead consultant surgeon and are reviewed on a daily basis. All patients referred electively are discussed at the next

weekly MDT meeting following receipt of referral. Following discussion at that meeting, a detailed assessment by the service lead is returned to the referring centre, GP and all doctors involved in the care, usually within two weeks. This summarises the information discussed, educates the referrer where appropriate and explains the decision, detailing any further investigations outstanding. If additional information is required to make a decision, this is highlighted in the assessment summary and in addition one of the nurse specialist team will contact the referrer directly. A minority of patients are referred on a more urgent consultant to consultant basis and opinion is usually available daily.

All patients are entered onto a dedicated spreadsheet so that their progress can be monitored. Information is forwarded to NHS England monthly. The adult pulmonary hypertension referring centres are contacted on a weekly basis by either phone or e-mail by one of the specialist nursing team to update patient information/progress. Any patients requiring additional imaging or tests at Papworth Hospital NHS Foundation Trust will have these booked at the time of the MDT.

Once all the required information is complete then the patient will be discussed again at the MDT for a final decision, if this was not possible at initial referral. This phase is often dependent on the referring centre.

Patients are then seen in clinic by the consultant surgeon and nurse specialist at Papworth Hospital NHS Foundation Trust to discuss the particular risk and benefits of pulmonary endarterectomy. A comprehensive patient booklet is provided at this stage. Clinic review is usually in chronological order from completion of referring process unless Papworth is notified that the patient's condition has deteriorated. A further letter detailing the outpatient clinic consultation and outcome is sent to the patient, original referring centre and GP at this time. The nurse specialist contacts the patient by telephone to reiterate the consultation and answer any questions within two weeks.

As soon as the patient has been reviewed in clinic and has accepted surgery, he or she is added to the waiting list for surgery. Time from acceptance of surgery to admission for operation is usually less than three months. Patients join an 18 week pathway once they had been accepted as having operable disease.

Exclusion criteria

No absolute, each patient is considered on his or her individual risk/benefit ratio from pulmonary endarterectomy.

2.5 Interdependencies with other services

There is a patient specialist group, the Pulmonary Hypertension Association.

The pulmonary endarterectomy service works closely with the adult pulmonary hypertension service, both locally at Papworth Hospital NHS Foundation Trust and nationally. Referral of all patients with a likely diagnosis of CTEPH is encouraged with cooperation on patient care with the other centres. Direct referrals are also

accepted from secondary care (cardiology, respiratory medicine) and specialist investigations performed at Papworth Hospital NHS Foundation Trust.

The service is dependent on the adult pulmonary hypertension centres for diagnosing and referring patients with CTEPH. It is also dependent on the same centres for the majority of phase I and II investigations. Within Papworth Hospital NHS Foundation Trust the service is dependent on cardiology to perform coronary angiography where necessary and on radiology for insertion of inferior vena cava (IVC) filters pre-surgery.

The speed of processing patients through the diagnostic studies (phase I and II) pre-surgery is often dependent on the waiting times for multiple investigations performed in other departments e.g. radiology, respiratory physiology, and echocardiography. A sudden change in the number of patients referred for surgery has implications for diagnostic capacity pre-surgery and for the follow-up schedule post surgery. All patients continue on lifelong anticoagulation post-surgery and the on-going responsibility for this is under the care of their local anticoagulation clinics and GPs.

3. Applicable Service Standards

3.1 Applicable national standards e.g. NICE, Royal College

Papworth Hospital NHS Foundation Trust is the sole provider so there are no comparative national standards. Clinical standards have already been set and agreed by NHS England medical adviser. Inpatients are discussed at the weekly MDT meeting including any complications or adverse events. The hospital has an electronic system for incident reporting by any member of staff. Activity and mortality is recorded by the audit department and reported at the monthly surgical mortality meeting. Job plans have time for continuing professional development, and the hospital provides 20 days for professional/study leave for consultants per annum. A detailed clinical guide to the perioperative care of pulmonary endarterectomy patients is provided for staff and available on the intensive care intranet including all management protocols.

Regular internal teaching days are provided to teach new staff about pulmonary endarterectomy.

See also NHS England service standards for PTE

4. Key Service Outcomes

Quality Performance Indicator	Threshold	Method of measurement	Consequence of breach	Report Due
In hospital mortality (deaths/number of PTEs)	Significant variation from the outcomes achieved in the previous three years	Measured by CUSUM analysis based on previous performance	Review & action plan	NHS England Annual report (September of contract year)
CUSUM and SPRT plots statistical methods to identify trends collected six-monthly	Significant variation from the outcomes achieved in the previous three years		Review & action plan	NHS England Annual report (September of contract year)

5. Location of Provider Premises

Designated provider

Papworth Hospital NHS Foundation Trust