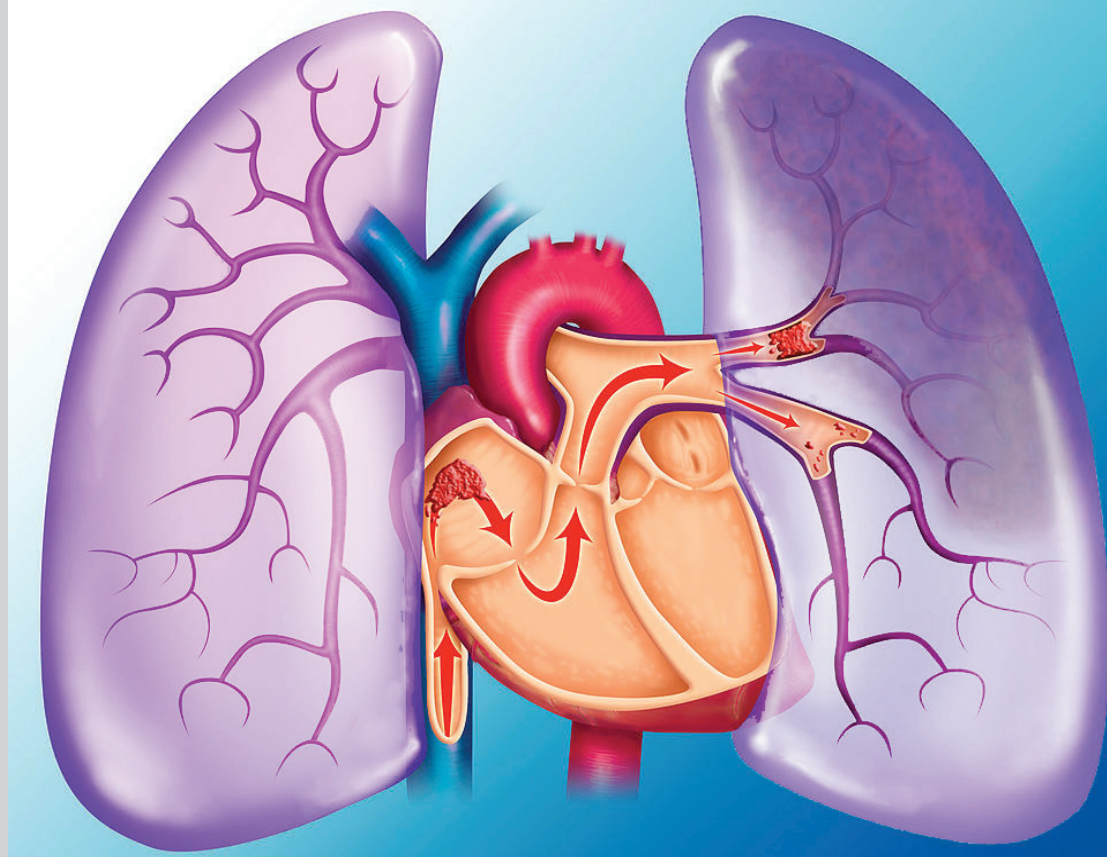


# Know the Score

A review of the quality of care provided to patients aged over 16 years with a new diagnosis of pulmonary embolism

## SUMMARY



# Know the Score

A review of the quality of care provided to patients aged over 16 years with a new diagnosis of pulmonary embolism.

A report published by the National Confidential Enquiry into Patient Outcome and Death (2019)

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The authors and Trustees of NCEPOD would like to thank the NCEPOD staff for their work in collecting and analysing the data for this study: Aysha Butt, Donna Ellis, Heather Freeth, Dolores Jarman, Kathryn Kelly, Kirsty MacLean Steel, Nicholas Mahoney, Eva Nwosu, Karen Protopapa, Hannah Shotton and Anisa Warsame.

This report should be cited as: The National Confidential Enquiry into Patient Outcome and Death. Know the Score. 2019. London

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# Introduction

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Despite advances in the ability to prevent, diagnose and treat acute pulmonary embolism (PE) it remains an important cause of morbidity and mortality. Its association with air travel, hospitalisation, active cancer, pregnancy and some chronic conditions is well recognised and involves all age groups, including the young. Estimates suggest that there are more than 25,000 hospital deaths in the UK each year from venous thromboembolism (VTE),<sup>2</sup> and previous studies have shown that for every diagnosed case of a non-fatal PE there are 2.5 cases of fatal PE that were not diagnosed.<sup>3</sup>

Key steps to effective care for patients includes prevention, prompt diagnosis and treatment:

- Prevention of healthcare-related deep vein thrombosis (DVT) includes the use of anticoagulants or mechanical methods. The Commissioning for Quality and Innovation (CQUIN) for VTE introduced in England in 2010 requiring all hospitalised patients to have a VTE risk assessment at admission, has resulted in significant improvement in the assessment and prevention of VTE.<sup>4</sup>
- CT Pulmonary Angiography (CTPA) is commonly used to diagnose PE.<sup>5</sup> However, to be effective this service should be available, promptly in all hospitals, especially out-of-hours. Also, because of the risk posed by x-rays and iodinated contrast media, alternative strategies are required in high-risk patients such as pregnant patients suspected to have an acute PE.
- The standard treatment is anticoagulation. The combined recommendations from NICE guideline 144 and Quality Standard 29 recommends that heparin therapy should be started immediately if the time taken to confirm the diagnosis is likely to be more than one hour.<sup>5,8</sup> This can expose patients to unnecessary treatment and the associated risks of anticoagulation. Furthermore, inadequate monitoring of some anticoagulant medications can lead to under-treatment of PE or adverse effects, like excessive bleeding. Unrecognised drug interactions, particularly with antibiotics, can also contribute to harm.

To aid safe and effective treatment it is possible to estimate the risk of adverse outcomes of PE, following diagnosis, using prediction tools like the Pulmonary Embolism Severity Index (PESI) (See Appendix 1). CTPA can also provide objective evidence of right heart strain, an indicator of PE severity, but the consistency with which this is acted upon is unknown.

Following the success of DVT management in outpatient settings, selected patients with an acute PE are now being considered for ambulatory care. However, the risk assessment and governance of outpatient management for PE has not yet been standardised. In fact there were no UK national standards for the outpatient management of PE until the British Thoracic Society (BTS) published their guideline for the initial outpatient management of PE in 2018.<sup>6</sup> More recently the Cochrane Library published a systematic review on the outpatient versus inpatient treatment for acute PE. It concluded that only low quality evidence is available from two published randomised controlled trials on outpatient versus inpatient treatment in low risk patients with acute PE. The studies did not provide evidence of any clear difference between the two pathways in overall mortality, bleeding or recurrence of PE.<sup>7</sup>

There is a large body of existing UK guidance on the care for patients with venous thromboembolism which has been used as reference material in this study:

- NICE Clinical Guideline 144 (Venous Thromboembolic Diseases: diagnosis, management and thrombophilia testing) (2012 updated in 2015)<sup>5</sup>
- NICE Quality Standard QS29 for the diagnosis and management of venous thromboembolism (2013)<sup>8</sup>
- British Thoracic Society (BTS) guideline for the initial outpatient management of pulmonary embolism - Quality Standards for the outpatient management of pulmonary embolism (PE) are being drafted<sup>6</sup>
- The Scottish Intercollegiate Guideline Network (SIGN) Guideline 122 (Prevention and Management of Venous Thromboembolism) (2010 updated in 2014).<sup>9</sup>

## INTRODUCTION

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In addition, a range of international guidelines and scientific statements are also available including:

- European Society of Cardiology Guidelines on the Diagnosis and Management of Acute Pulmonary Embolism (2014)<sup>10</sup>
- American Heart Association Scientific Statement on the Management of Massive and Sub-massive Pulmonary Embolism, Iliofemoral Deep Vein Thrombosis and Chronic Thromboembolic Pulmonary Hypertension (2011)<sup>11</sup>
- The Best Practice Advice from the Clinical Guidelines Committee of the American College of Physicians (2015): Evaluation of Patients with Suspected Acute Pulmonary Embolism<sup>12</sup>
- The American College of Chest Physicians Guideline and Expert Panel Report (2016) which included guidance on the management of isolated sub-segmental PEs<sup>13</sup>

At the opposite end of the severity spectrum from those patients cared for as outpatients or on an ambulatory care pathway are patients with a massive PE, identified by the presence of haemodynamic compromise. These patients are at a high risk of death and should be considered for thrombolysis. A more controversial area is the optimal care for patients with a sub-massive PE. These patients are haemodynamically normal, but have evidence of right heart strain on CTPA or echocardiography and raised biomarkers like troponin or brain-type natriuretic peptide (BNP).

The study described in this report aimed to identify and explore remediable factors in the process of care for patients with a new diagnosis of PE, who either presented to hospital with symptoms of PE and who were cared for as outpatients or were admitted to hospital, or who developed PE whilst in hospital being treated for another condition.

# Executive summary

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## Aim

The aim of this study was to highlight areas where care could be improved in patients with a new diagnosis of acute pulmonary embolism (PE).

## Method

A retrospective case note and questionnaire review was undertaken in 526 patients aged 16 and over who had a PE either presenting to hospital or who developed a PE whilst as an inpatient for another condition.

## Key messages

One delay or more in the process of care was identified in 161/420 (38.3%) patients, with recognition, investigations and treatment being the most common.

The primary treatment for PE is anticoagulation. It is imperative that this is started as soon as possible. Where there might be a delay to the diagnosis of acute PE anticoagulation should be commenced. In this study the case reviewers reported an avoidable delay in commencing treatment in 90/481 (18.7%) patients.

Once PE has been diagnosed an assessment of PE severity needs to be undertaken in order to treat patients effectively. In 144/179 (80.4%) hospitals their PE policy/guideline included the assessment of PE severity.

This severity assessment was based on a validated scoring system such as PESI or Hestia in 128/142 (90.1%) hospitals. Case reviewers found no evidence of a PE severity assessment in the majority of patients (436/483; 90.3%).

Severe (massive) PE requires additional or alternative treatment. A guideline/protocol for the diagnosis and care of patients with PE was provided at 151/180 (83.9%) hospitals.

Ambulatory care has recently become a recognised pathway for PE management in those patients with low-risk of adverse outcomes. An ambulatory care pathway was used for all or part of the patient journey in 77/474 (16.2%) patients in this study. Wide variation in the selection of patients for ambulatory care was observed, with some high-risk patients being selected on this pathway and low-risk patients not being considered for it, resulting in unnecessary hospital admissions.

Patients should receive all the information they need to make an informed choice, particularly with respect to taking anticoagulation. Treating clinicians were unable to determine if the patient was given verbal or written information regarding PE in 336/600 (56.0%) instances and specific information/ education regarding PE was not routinely provided to patients at 55/167 (32.9%) hospitals.

An outpatient follow-up was not routinely arranged following a PE diagnosis in 32/179 (17.9%) hospitals. Where routine outpatient follow-up was a standard arrangement, it included a decision on the duration of anticoagulation in 138/147 (93.9%) hospitals and an assessment of whether the PE was provoked or unprovoked in 135/143 (94.4%). Case reviewers were of the opinion that follow-up was inadequate for 50/308 (16.2%) patients where there was adequate information for them to make a determination.

# Recommendations

These recommendations have been formed by a consensus exercise including all those listed in the acknowledgements and highlight a number of areas that are suitable for local quality improvement initiatives.

Recommendations 1 to 6 have been highlighted as being the primary focus for action.

<b>PRINCIPAL RECOMMENDATIONS</b>		Key findings and guidelines that support the recommendation. The #number is the key finding number in the report	
1	Give an interim dose of anticoagulant to patients suspected of having an acute pulmonary embolism (unless contraindicated) when confirmation of the diagnosis is expected to be delayed by more than one hour. The anticoagulant selected, and its dose, should be personalised to the patient. This timing is in line with NICE QS29 2013. <i>(All Clinicians, Quality Improvement Lead)</i>	<p><b>CHAPTER 8 – PAGE 58</b> #52. Case reviewers were of the opinion that there was an avoidable delay in commencing treatment in 90/481 (18.7%) patients</p> <p><b>CHAPTER 8 – PAGE 58</b> #53. More than half of the avoidable delays recorded were because an anticoagulant was not prescribed 44/90 (48.9%) and/or not administered 5/90 (5.5%)</p>	NICE QS29 - Venous thromboembolism in adults: diagnosis and management
2	Document the severity of acute pulmonary embolism immediately after the confirmation of diagnosis. Severity should be assessed using a validated standardised tool, such as 'PESI' or 'sPESI'. This score should then be considered when deciding on the level of inpatient or ambulatory care. <i>(All Clinicians)</i>	<p><b>CHAPTER 7 – PAGE 53</b> #45. Case reviewers found no evidence of a formal assessment of PE severity in 436/483 (90.3%) cases reviewed</p> <p><b>CHAPTER 7 – PAGE 53</b> #46. Data from clinician questionnaires revealed that PE severity was not recorded in 456/559 (81.6%) patients</p>	Howard LSGE, Barden S, Condliffe R, et al British Thoracic Society Guideline for the initial outpatient management of pulmonary embolism (PE) Thorax 2018;73:ii1-ii29

## RECOMMENDATIONS

PRINCIPAL RECOMMENDATIONS	Key findings and guidelines that support the recommendation. The #number is the key finding number in the report	
<p>3 Standardise CT pulmonary angiogram reporting. The proforma should include the presence or absence of right ventricular strain. The completion of these proformas should be audited locally to monitor compliance and drive quality improvement. <i>(At a national level, the Royal College of Radiologists with input from other clinical specialist societies such as the British Thoracic Society).</i> <i>(Clinical Lead for Radiology and Quality Improvement Lead)</i></p>	<p><b>CHAPTER 2 – PAGE 22</b> #7. Proformas or other structured reporting systems for CTPA were only used in 22/156 (14.1%) hospitals</p> <p><b>CHAPTER 5 – PAGE 47</b> #37. In 177/349 (50.7%) CTPA reports no comment was made on the thrombus burden</p> <p><b>CHAPTER 5 – PAGE 47</b> #38. Right heart strain was identified in 93/333 (27.9%) patients and 115/333 (34.5%) of reports commented on its absence. In 125/333 (37.5%) no comment was made on the right ventricle</p> <p><b>CHAPTER 5 – PAGE 49</b> #40. Case reviewers considered half of CTPA reports to be less than good (179/346; 51.7%), including 33/346 (9.5%) which were graded as poor; most commonly due to the lack of comment on the right heart (30/33; 90.9%)</p> <p><b>CHAPTER 5 – PAGE 49</b> #41. Where a CTPA report was only rated as adequate and a reason was given (99/146; 67.8%) the most common concerns were a failure to comment on the right ventricle in 55/99 (55.6%)</p>	
<p>4 Look for indicators of massive (high-risk) or sub-massive (intermediate-risk) pulmonary embolism, in addition to calculating the severity of acute pulmonary embolism in the form of:</p> <ol style="list-style-type: none"> <li>i. Haemodynamic instability (clinical)</li> <li>ii. Right heart strain (imaging)</li> <li>iii. Elevated troponin or brain natriuretic peptide (biochemical).</li> </ol> <p>Escalate promptly based on local guidance and document in the case notes. <i>(All Clinicians)</i></p>	<p><b>CHAPTER 2 – PAGE 21</b> #4. A guideline/protocol for the diagnosis and care of patients with massive PE was not provided in 29/180 (16.1%) hospitals. The corresponding figure for sub-massive PE diagnosis and management was 65/176 (36.9%)</p> <p><b>CHAPTER 4 – PAGE 43</b> #31. Initial investigations which might have altered management were not performed in 143/486 (29.4%) patients in the opinion of the case reviewers and in 119/689 (17.3%) patients in the view of the clinicians at the hospital</p> <p><b>CHAPTER 4 – PAGE 43</b> #32. In the opinion of the case reviewers, investigations which are usually used to diagnose sub-massive PE (point of care echocardiography) or assess the risk of sub-massive PE patients dying (troponin, BNP/ NT-pro-BNP) were omitted in 11/486 (2.3%), 41/486 (8.4%) and 15/486 (3.1%)</p>	



RECOMMENDATIONS

PRINCIPAL RECOMMENDATIONS		Key findings and guidelines that support the recommendation. The #number is the key finding number in the report
5	<p>Assess patients suspected of having an acute pulmonary embolism for their suitability for ambulatory care and document the rationale for selecting or excluding it in the clinical notes. <i>(All Clinicians)</i></p>	<p><b>CHAPTER 6 – PAGE 51</b> #42. 77/474 (16.2%) patients who presented to hospital with clinical suspicion of PE, were cared for on an ambulatory care pathway for all or part of their patient journey</p> <p><b>CHAPTER 6 – PAGE 51</b> #43. Case reviewers were of the opinion that a further 43/366 (11.7%) patients could have benefitted from an ambulatory pathway</p> <p><b>CHAPTER 7 – PAGE 53</b> #45. Case reviewers found no evidence of a formal assessment of PE severity in 436/483 (90.3%) cases reviewed</p> <p><b>CHAPTER 7 – PAGE 53</b> #46. Data from clinician questionnaires revealed that PE severity was not recorded in 456/559 (81.6%) patients</p> <p><b>CHAPTER 7 – PAGE 54</b> #47. Retrospective calculation of PE severity by the case reviewers identified 194 patients in the PESI low-risk groups (Class I and II), 133 patients in the intermediate risk group (Class III) and 162 patients in the higher risk groups (Class IV and V)</p> <p><b>CHAPTER 7 – PAGE 55</b> #48. 43/188 (22.9%) low-risk patients were treated on an ambulatory pathway, suggesting potential missed opportunities for the remaining 145/188 (77.1%) low-risk patients</p> <p><b>CHAPTER 7 – PAGE 55</b> #49. 24/214 (11.2%) with intermediate risk and 6/74 (8.1%) with high-risk scores were ambulated, suggesting excessive risk taking</p>

Commissioning for Quality and Innovation (CQUIN) Guidance for 2019-2020

## RECOMMENDATIONS

PRINCIPAL RECOMMENDATIONS		Key findings and guidelines that support the recommendation. The #number is the key finding number in the report	
6	<p>Provide every patient with an acute pulmonary embolism with a follow-up plan, patient information leaflet and, at discharge, a discharge letter which should include:</p> <ol style="list-style-type: none"> <li>The likely cause of the pulmonary embolism</li> <li>Whether it was provoked or unprovoked</li> <li>Details of follow-up appointment(s)</li> <li>Any further investigations required</li> <li>Details of anticoagulant prescribed and its duration, in line with NICE CG144 <i>(All Clinicians, Service Users, General Practitioners)</i></li> </ol>	<p><b>CHAPTER 2 – PAGE 28</b> #17. Specific information/education regarding PE was not routinely provide to patients at 55/167 (32.9%) hospitals</p> <p><b>CHAPTER 2 – PAGE 29</b> #18. Outpatient follow-up was not routinely arranged following a PE diagnosis in 32/179 (17.9%) hospitals. Where routine outpatient follow-up was arranged it included a decision on the duration of anticoagulation in 138/147 (93.9%) hospitals and an assessment of whether the PE was provoked or unprovoked in 135/147 (91.8%)</p> <p><b>CHAPTER 9 – PAGE 65</b> #62. Treating clinicians were unable to determine if patients were given verbal and written information regarding PE in 336/600 (56.0%) cases</p> <p><b>CHAPTER 9 – PAGE 66</b> #63. Case reviewers were of the opinion that follow-up was inadequate for 50/308 (16.2%) patients where there was adequate information to make a determination</p>	<p>Howard LSGE, Barden S, Condliffe R, et al British Thoracic Society Guideline for the initial outpatient management of pulmonary embolism (PE) Thorax 2018;73:ii1-ii29</p> <p>NICE CG92 Venous thromboembolism: reducing the risk for patients in hospital NICE NG89 Venous thromboembolism in over 16s: reducing the risk of hospital-acquired deep vein thrombosis or pulmonary embolism</p> <p>NICE CG144 Venous thromboembolic diseases: diagnosis, management and thrombophilia testing</p>

## RECOMMENDATIONS

ADDITIONAL RECOMMENDATIONS		Key findings and guidelines that support the recommendation. The #number is the key finding number in the report	
7	Calculate the clinical probability of pulmonary embolism in all patients presenting to hospital with a suspected new diagnosis of pulmonary embolism using a validated score, such as the 'Wells' Score'. Record the score in the clinical notes. This is in line with NICE CG144. <i>(Clinicians, particularly Emergency and Acute Medicine Physicians)</i>	<b>CHAPTER 4 – PAGE 39</b> #30. A PE clinical probability score was documented in the notes for only 80/407 (19.7%) cases where the patient presented with symptoms of PE	NICE CG144 Venous thromboembolic diseases: diagnosis, management and thrombophilia testing  Thromboembolic Disease in Pregnancy and the Puerperium: Acute Management. Green-top Guideline No. 37b J. 2015
8	Ensure there are hospital protocols/ guidance for assessing the severity of pulmonary embolism soon after diagnostic confirmation. Include timely access to point of care ultrasonography (POCUS)/ echocardiography and measuring biomarkers like troponin and BNP <i>(Hospital Executive Board)</i>	<b>CHAPTER 2 – PAGE 20</b> #3. A policy/guideline for the assessment of the severity of PE was provided at 144/179 (80.4%) hospitals. In 128/142 (90.1%) hospitals severity assessment was based on a validated scoring system such as PESI	
9	Ensure there is a robust system in place to alert the clinician who requested a CTPA or V/Q scan or V/Q SPECT scan of any amendments or updates to the report. This in line with the Royal College of Radiologist's communication standards for radiology reports 2016. <i>(Clinical Lead for Radiology)</i>	<b>CHAPTER 2 – PAGE 23</b> #8. A radiology report alteration alert system had been implemented in 132/169 (78.1%) hospitals	Royal College of Radiologist's communication standards for radiology reports 2016
10	Develop and document a monitoring and treatment escalation plan for, and with, all patients diagnosed with acute pulmonary embolism. Any reason for not doing so should also be documented in the case notes. <i>(All Clinicians, Clinical Directors)</i>	<b>CHAPTER 8 – PAGE 60</b> #55. There was no evidence of a treatment escalation plan in 211/386 (54.7%) patients	

## RECOMMENDATIONS

ADDITIONAL RECOMMENDATIONS	Key findings and guidelines that support the recommendation. The #number is the key finding number in the report	
<p>11 Document whether the inferior vena cava (IVC) filter inserted into a patient with pulmonary embolism is intended to be permanent or temporary. Temporary filters should have a retrieval date booked at the time of insertion and have a fail-safe tracking system to ensure the filter is removed, unless this becomes clinically inappropriate. This is in line with MHRA 2013 guidance. <i>(Interventional Radiologists)</i></p>	<p><b>CHAPTER 2 – PAGE 27</b> #13. For hospitals with an IR department only 63/118 (53.3%) could identify how many temporary IVC filters were placed in 2017 and 66/118 (55.9%) for permanent filters</p>	<p>Medicines and Healthcare products Regulatory Agency Device Alert. Retrievable inferior vena cava (IVC) filters - serious complications associated with attempted IVC filter retrieval. 2013</p>
<p>12 Ensure an ambulatory care pathway is available 7 days a week, at all hospitals where patients with an acute pulmonary embolism present. <i>(Hospital Executive Boards, Clinical Directors in the Emergency Department and Acute Medicine, Quality Improvement Lead)</i></p>	<p><b>CHAPTER 2 – PAGE 23</b> #1. An ambulatory care centre was present in 157/189 (83.1%) hospitals and a further 19 without a designated centre had an ambulatory care pathway that operated separately from a specific centre, raising the total number of hospitals with ambulatory care to 176/189 (93.1%)</p> <p><b>CHAPTER 2 – PAGE 23</b> #14. Ambulatory care centres were open 7 days/week at 81/157 (51.6%) hospitals whilst 55/157 (35.0%) were only open on weekdays</p> <p><b>CHAPTER 2 – PAGE 24</b> #16. A lack of capacity in ambulatory care that sometimes resulted in patients being admitted was reported from 24/142 (16.9%) hospitals with a PE ambulatory care pathway</p> <p><b>CHAPTER 4 – PAGE 37</b> #26. most common reason was the patient not going to the GP or the emergency department (61/91; 67.0%) although patients presented throughout the week</p> <p><b>CHAPTER 6 – PAGE 51</b> #42. 77/474 (16.2%) patients who presented to hospital with clinical suspicion of PE, were cared for on an ambulatory care pathway for all or part of their patient journey</p> <p><b>CHAPTER 6 – PAGE 51</b> #43. Case reviewers were of the opinion that a further 43/366 (11.7%) patients could have benefitted from an ambulatory pathway</p> <p><b>CHAPTER 7 – PAGE 54</b> #47. Retrospective calculation of PE severity by the case reviewers identified 194 patients in the PESI low-risk groups (Class I and II), 133 patients in the intermediate risk group (Class III) and 162 patients in the higher risk groups (Class IV and V)</p>	

## RECOMMENDATIONS

ADDITIONAL RECOMMENDATIONS	Key findings and guidelines that support the recommendation. The #number is the key finding number in the report		
13	<p>Formalise pulmonary embolism treatment networks for access to catheter-directed thrombolysis, surgical embolectomy or mechanical thrombectomy for the treatment of patients with pulmonary embolism who either fail to improve or have absolute contraindications to systemic thrombolysis.</p> <p><i>(Hospital Executive Boards, Commissioners, Clinicians)</i></p>	<p><b>CHAPTER 2 – PAGE 26</b> #10. Catheter-directed thrombolysis was unavailable on-site or off-site in 60/168 (35.7%) hospitals. In 80/156 (51.3%) hospitals and 60/166 (36.1%) hospitals, mechanical thrombectomy and surgical embolectomy were not treatment options</p> <p><b>CHAPTER 2 – PAGE 26</b> #11. Surgical embolectomy for PE was available on-site in 24/174 (13.8%) hospitals with a further 90/174 (51.7%) having off-site access to this treatment</p> <p><b>CHAPTER 2 – PAGE 26</b> #12. In those hospitals with off-site access to surgical embolectomy this was formalised in a service agreement or a formal network in 16 hospitals (16/75; 21.3%). The most common situation was for this to be an ad-hoc arrangement (42/81; 51.9%)</p>	<p>NICE IPG 523 - Ultrasound-enhanced, catheter-directed thrombolysis for deep vein thrombosis interventional procedures guidance (IPG523)</p>

## Method and data returns

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### Study Advisory Group (SAG)

A multidisciplinary group of clinicians in: cardiology, acute medicine, critical care, emergency medicine, cardiothoracic surgery, radiology, trauma and orthopaedics, respiratory medicine, anaesthetics, general practice, specialist nursing, pharmacy and lay/patient representatives. This group steered the study from design to completion.

### Study aim

To identify and explore avoidable and remediable factors in the process of care for patients diagnosed with pulmonary embolism (PE), both as an inpatient and those on an ambulatory care pathway.

### Objectives

The SAG identified a number of objectives that would address the primary aim of the study, these included:

- Risk assessment and prevention of venous thromboembolism
- Availability, timeliness and quality of diagnostic assessment
- Risk stratification and treatment
- Appropriate patient selection and application of ambulatory care
- Management of high-risk patients and escalation decisions
- Organisational aspects of care delivery for ambulatory and inpatient pathways

### Study population and case ascertainment

#### Inclusion criteria

- All patients aged 16 years and older who presented to hospital with symptoms of a PE or who developed PE as an inpatient (using ICD10 codes I26.0 and I26.9) between 1st July 2017 and 31st August 2017 inclusive
- Ambulatory care/same day emergency patients and patients admitted to hospital were included in the study

Selection of patients into the study was biased towards those more likely to have a severe PE. This was done by dividing patients into 3 categories and where the number of cases allowed, two patients from each category were included per hospital:

- 1) Primary coding diagnosis of PE with a length of stay  $\leq 3$  days
- 2) Any coding of PE with a length of stay  $> 3$  days
- 3) Primary coding diagnosis of PE, admitted to critical care and/or who died with any length of stay

### Hospital participation

National Health Service hospitals in England, Scotland, Wales and Northern Ireland were expected to participate as well as public hospitals in the Isle of Man, Guernsey and Jersey. Within each hospital, a named contact, referred to as the NCEPOD Local Reporter, acted as a link between NCEPOD and the hospital staff, facilitating case identification, dissemination of questionnaires and data collation.

### Data collection

#### Spreadsheet

A pre-set spreadsheet was provided to every Local Reporter to identify all patients meeting the study criteria during the defined time period. From this initial cohort the sampling for inclusion into the study took place.

#### Questionnaires

Two questionnaires were used to collect data for this study: a clinician questionnaire for each patient and an organisational questionnaire for each participating hospital.

#### Clinician questionnaire

This questionnaire was sent to the named consultant caring for the patient at the time of their inpatient/ambulatory care discharge. Information was requested on the patient's presenting features/comorbid conditions, previous hospital attendances, initial management, investigations, escalation in care and follow-up.

### **Organisational questionnaire**

The data requested in this questionnaire included information on ambulatory care provision for patients with PE, guidelines and standard operating procedures relevant to the care of patients with PE and availability of specific investigations and interventions.

### **Case notes**

Copies of case note extracts were requested for peer review:

- General practitioner referral letter
- Ambulance service Patient Report Form/notes
- All inpatient annotations/medical notes/nursing notes
- Ambulatory care notes
- Emergency department clerking proforma/records
- Venous thromboembolism proformas
- Critical care notes/charts
- Microbiology reports
- Haematology/biochemistry results
- Blood gas reports
- Operation/procedure notes
- Radiology investigation reports
- Observation charts
- Fluid balance charts
- Drug charts including anticoagulation charts
- Consent forms
- Do not attempt cardiopulmonary resuscitation forms
- Treatment escalation forms
- Discharge letter/summary
- Medical/nursing notes for any follow-up appointments or readmissions for the 6 months post-discharge

### **Peer review of the case notes and questionnaire data**

A multidisciplinary group of case reviewers comprising consultants, trainees and clinical nurse specialists from: cardiology, anaesthesia, intensive care medicine, acute medicine, emergency medicine, respiratory medicine, neurosurgery and radiology was recruited to peer review the case notes and associated clinician questionnaires.

Questionnaires and case notes had all patient identifiers removed by the non-clinical staff at NCEPOD before being presented to the group. Each set of case notes was reviewed by at least one reviewer within a small multidisciplinary

meeting using a semi-structured electronic questionnaire. At regular intervals throughout the meeting the Chair allowed a period of discussion for each reviewer to summarise their cases and ask for opinions from other specialties or raise aspects of the case for discussion.

The grading system below was used by the case reviewers to grade the overall care each patient received:

- **Good practice:** A standard that you would accept from yourself, your trainees and your institution
- **Room for improvement:** Aspects of **clinical** care that could have been better
- **Room for improvement:** Aspects of **organisational** care that could have been better
- **Room for improvement:** Aspects of both **clinical and organisational** care that could have been better
- **Less than satisfactory:** Several aspects of clinical and/or organisational care that were well below that you would accept from yourself, your trainees and your institution
- **Insufficient data:** Insufficient information submitted to NCEPOD to assess the quality of care

### **Information governance**

All data received and handled by NCEPOD comply with all relevant national requirements, including the General Data Protection Regulation 2016 (Z5442652), Section 251 of the NHS Act 2006 (PIAG 4-08(b)/2003, App No 007), PBPP (1718-0328) and the Code of Practice on Confidential Information.

Each patient was given a unique NCEPOD number. The data from all paper questionnaires received were electronically scanned into a pre-set database. All electronic questionnaires were submitted through a dedicated online application. Prior to any analysis taking place, the data were cleaned to ensure that there were no duplicate records and that erroneous data had not been entered. Any fields that contained data that could not be validated were removed.

### **Data analysis**

Following cleaning of the quantitative data, descriptive data summaries were produced.

Qualitative data collected from the case reviewers' opinions and free text answers in the clinician questionnaires were coded, where applicable, according to content to allow quantitative analysis. The data were reviewed by NCEPOD Clinical Co-ordinators, a Clinical Researcher and Researcher to identify the nature and frequency of recurring themes.

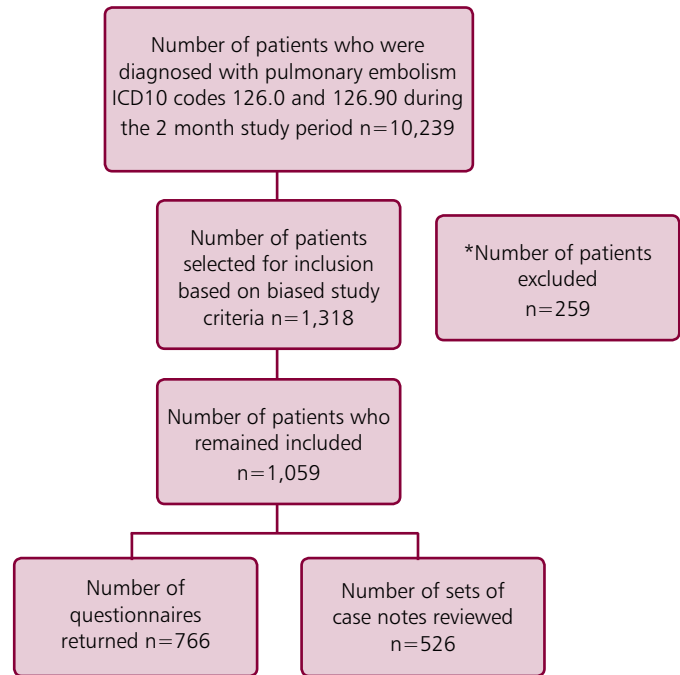
Case studies have been used throughout this report to illustrate particular themes.

The findings of the report were reviewed by the Study Advisory Group, Case Reviewers, NCEPOD Steering Group including Clinical Co-ordinators, Trustees and Lay Representatives prior to publication.

**Data returns**

**Clinical data**

In total 10,239 patients were identified as meeting the study inclusion criteria (Figure 1.1). Up to six patients per hospital was selected in accordance with the sampling criteria defined above. This resulted in 1,318 patients being included in the initial sample. 259 patients were excluded as they did not appear to have had a diagnosis of PE (mainly on review of the case notes). Of the remaining sample of 1,059 patients, 766 completed clinician questionnaires were returned and 526 sets of notes were included in the peer reviewed by the case reviewers.



**Figure 1.1 Data returns**

Table 1.1 shows the types of patient, in terms of outcome, length of stay and diagnosed position of PE whose cases were reviewed by the case reviewers, compared to the overall dataset (all patients). This demonstrates the bias of the peer review sample towards patients who had a worse outcome/longer length of stay.

**Organisational data**

Organisational questionnaires were returned from 189/218 (86.7%) hospitals.

**Table 1.1 Patients included into the study sample**

Primary diagnosis of pulmonary embolism	Admitted – length of stay ≤ 3days		Admitted – length of stay > 3days		Total
	Alive	Died/ admitted to critical care	Alive	Died/ admitted to critical care	
All patients	3,157 (60.2%)	114 (2.2%)	1,743 (33.2)	229 (4.4%)	5,243
Selected for peer review	184 (43.4)	23 (5.4%)	170 (40.1%)	47 (11.1%)	424
Other primary diagnosis (inpatient PE)	Alive	Died/ admitted to critical care	Alive	Died/ admitted to critical care	Total
All patients	1,789 (42.3%)	130 (3.1%)	1,801 (42.6%)	507 (12.0%)	4,227
Selected for peer review	0	0	71 (69.6%)	31 (30.4%)	102



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Published October 2019  
by the National Confidential Enquiry  
into Patient Outcome and Death

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978-1-9995925-3-0

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