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Outpatient management of pulmonary emboli: when to ambulate

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Abstract

Pulmonary embolism is a potentially fatal consequence of venous thromboembolism and constitutes a significant proportion of the acute medical take. Standard management has previously required admission of all patients presenting with acute pulmonary embolism for initiation of anticoagulation and initial investigations. However, clinical trial data have demonstrated the feasibility and safety of managing a subset of patients with low-risk pulmonary embolism in the outpatient setting and this has since been reflected in national guidelines. This article provides a practical overview for general physicians with regards to identifying patients with low-risk pulmonary embolism, and when and how to manage these patients on an outpatient basis.

Key words: Ambulatory management; Anticoagulation; Clinical guidelines; Pulmonary embolism

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Introduction

Pulmonary embolism is a potentially fatal consequence of venous thromboembolism whereby emboli occlude the pulmonary arterial system, resulting in ventilation–perfusion mismatch and potential haemodynamic compromise and death. The annual incidence of pulmonary embolism is estimated at approximately 60–70 per 100 000 population (British Thoracic Society, 2003), accounting for a significant proportion of the acute medical take.

While the standard management of deep vein thrombosis is almost exclusively on an outpatient basis in most centres, the standard clinical practice for the management of pulmonary embolism involves admitting patients to hospital for observation and initiation of anticoagulation. However, clinical trial data have demonstrated that low-risk pulmonary embolism can also be managed safely and effectively on an outpatient basis (Aujesky et al, 2011). This, coupled with the availability of new oral anticoagulants that do not require initial treatment with low molecular weight heparin or monitoring of the international normalised ratio, has led to a shift towards managing patients with low-risk pulmonary embolism as outpatients. Indeed, an estimated 40% of patients with pulmonary embolism may be considered as low risk and suitable for outpatient management (Aujesky et al, 2005).

Clinical guidelines from the British Thoracic Society (2018) provide a robust framework to help identify low-risk adult patients who can be safely considered for outpatient management, avoiding hospital admissions. This article provides a practical overview for general physicians covering the risk stratification methods used to identify patients with low-risk pulmonary embolism and the guidelines surrounding the outpatient management of these patients.

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Can we manage patients with pulmonary emboli on an outpatient basis?

There is a growing body of evidence which supports the outpatient management of patients with low-risk pulmonary embolism. There have been two randomised controlled trials (Otero et al, 2010; Aujesky et al, 2011) and two subsequent meta-analyses (Piran et al, 2013; Zondag et al, 2013) supporting this, the results of which are summarised in Table 1.

Table 1. Evidence regarding the outpatient management of patients with pulmonary embolism

Reference	Study type	Patient cohort	Study design	Outcome
Aujesky et al (2011)	Randomised controlled trial: outpatient vs inpatient treatment	344 low-risk patients (as defined by PESI score)	Non-inferiority study	Outpatient treatment non-inferior to inpatient for mortality, venous thromboembolism recurrence at 14 and 90 days and bleeding complication at 14 days
Otero et al (2010)	Randomised controlled trial: early discharge (3–5 days) vs standard inpatient treatment	132 low-risk patients (using clinical prediction rule published by Uresandi et al (2007))	Non-inferiority study	No difference in venous thromboembolism recurrence or significant bleeding. Trial terminated early because of unexpectedly high early (within 10 days) mortality rate in early discharge arm, although overall mortality was 4.2% in the early discharge group and 8.3% in the standard hospitalisation group
Piran et al (2013)	Meta-analysis	1258 pooled patients (comprising outpatient and early discharges)		Low rate of adverse events including venous thromboembolism recurrence, major bleeding and mortality in patients managed as an outpatient
Zondag et al (2013)	Meta-analysis	2296 pooled patients (comprising outpatients, early discharges and inpatients)		Incidence of venous thromboembolism recurrence, major bleeding and mortality comparable between outpatients, early discharge and inpatients

PESI = Pulmonary Embolism Severity Index

How can we risk stratify patients with pulmonary emboli?

In order to assess whether outpatient management of pulmonary embolism should be considered, all patients should be risk stratified using a validated clinical risk score. A number of scoring systems have been developed allowing clinicians to risk stratify patients with a new diagnosis of pulmonary embolism. The two most commonly used scores are the well-validated Pulmonary Embolism Severity Index (PESI) score and the simplified PESI score (sPESI) (Aujesky et al, 2005; Jiménez et al, 2010) (Table 2).

Pulmonary embolism severity index

The PESI was developed by Aujesky et al (2005) based on data from 15 531 patients with confirmed pulmonary embolism. The score comprises 11 independent indicators of severity, each of which is readily available for most patients. These severity indicators were identified using logistic regression, with 30-day mortality as the primary outcome. Each indicator is allocated a score which is used to calculate the PESI class (I–V). Both derivation and validation samples were used to deduce and predict the associated mortality rates respectively (Table 3). Internal and external validation has shown consistent results, and the PESI score has since been used in a randomised control trial of inpatient vs outpatient care in PESI class I and II patients (Aujesky et al, 2011). Subsequently, Jiménez et al (2010) developed the sPESI score using the variables from the original PESI score that reached statistical significance. Validation testing showed that the sPESI did not differ from the PESI score in prognostic accuracy (Jiménez et al, 2010).

Using these scoring systems, patients who are PESI class I/II or have a sPESI score of 0 are deemed low-risk and could be considered for outpatient management. Patients who are PESI class III–V or have a sPESI score of 1 or more should commence treatment as an inpatient because of their higher risk of mortality. The predicted mortality determined by the PESI or sPESI score is summarised in Table 3.

Hestia criteria

If a patient is deemed low risk based on the PESI or sPESI score, the guidelines recommend they are then assessed using a set of exclusion criteria to fully determine if they are suitable for outpatient management (British Thoracic Society, 2018). The most widely used criteria

Table 2. Pulmonary Embolism Severity Index and Simplified Pulmonary Embolism Severity Index

	Pulmonary Embolism Severity Index		Simplified Pulmonary Embolism Severity Index	
	Parameter	**Score**	**Parameter**	**Score**
Demographic	Age	Age (years)	Age over 80 years	1
	Male sex	+10		
Comorbidities	Cancer	+30		
	Heart failure	+10	Active cancer	1
	Chronic lung disease	+10	Chronic cardiopulmonary disease	1
Clinical findings	Pulse ≥110 bpm	+20	Pulse ≥110 bpm	1
	Systolic blood pressure <100 mmHg	+30	Systolic blood pressure <100 mmHg	1
	Respiratory rate ≥30/min	+20		
	Temperature <36 °C	+20		
	Altered mental status	+60		
	Arterial blood oxygen saturation <90%	+20	Arterial blood oxygen saturation <90% (irrespective of fraction of inspired oxygen)	1

From Aujesky et al (2005); Jiménez et al (2010)

Table 3. Risk classification and associated 30-day mortality for PESI and sPESI scores

PESI				sPESI		
PESI score	**Risk class**	**Risk of 30-day mortality**	**Risk class**	**sPESI score**	**Risk class**	**Recommended treatment setting**
0–65	I	0.0–1.6%	Low	0	Low	Consider outpatient
66–85	II	1.7–3.5%				
86–105	III	3.2–7.1%	Intermediate	≥1	High	Inpatient
106–125	IV	4.0–11.4%	High			
≥126	V	10–24.5%	Very high			

PESI = Pulmonary Embolism Severity Index; sPESI = Simplified Pulmonary embolism Severity Index. From Aujesky et al (2005); Jiménez et al (2010)

are the Hestia criteria (Table 4) (Zondag et al, 2011). This set of exclusion criteria was developed as part of the Hestia study of outpatient management of pulmonary embolism and was derived from data from small observational studies (Zondag et al, 2011). If any one of the Hestia criteria is fulfilled, then the patient is deemed not to be a suitable candidate for outpatient treatment.

These exclusion criteria have been validated using prospective studies; den Exter et al (2016) identified that 51% of patients in their sample cohort were suitable for outpatient treatment. They used venous thromboembolism recurrence within 3 months as their primary outcome, and demonstrated a recurrence rate of 2% (comparable to data from a previous inpatient cohort).

Multiple meta-analyses support the use of clinical prediction rules to effectively identify patients at low risk of pulmonary embolism-related mortality who may be considered for outpatient management (Squizzato et al, 2012; Piran et al, 2013; Zondag et al, 2013).

Bleeding risk

The British Thoracic Society (2018) guidelines do not recommend the use of a specific tool to assess bleeding risk as there are limited studies into this. However, patients with active

Table 4. Hestia exclusion criteria for treating patients with pulmonary embolism as an outpatient
Is the patient haemodynamically unstable?*
Is thrombolysis or embolectomy necessary?
Is there active bleeding or high risk of bleeding?
Has the patient had more than 24 hours of oxygen supply to maintain oxygen saturation >90%?
Was pulmonary embolism diagnosed during anticoagulation treatment?
Is the patient in severe pain needing intravenous pain medication for >24 hours?
Is there a medical or social reason for treatment in hospital >24 hours?
Does the patient have a creatinine clearance <30 ml/min?
Does the patient have severe liver impairment?
Is the patient pregnant?
Does the patient have a documented history of heparin-induced thrombocytopenia?

**Defined as systolic blood pressure <100 mmHg with heart rate >100 beats per minute or requiring admission to an intensive care unit.*
From Zondag et al (2011)

bleeding or those deemed at 'high risk' of bleeding are actively excluded from outpatient management based on the Hestia criteria (Zondag et al, 2011). Regardless, all patients with a pulmonary embolism should be counselled on the increased risk of bleeding upon starting anticoagulant treatment and given advice about what to do should this occur.

Radiological evidence of right heart strain

Patients with evidence of right heart strain on either computed tomography pulmonary angiogram or echocardiogram may be deemed to be low risk on the basis of their clinical prediction scores (PESI, sPESI or Hestia criteria) which do not take account of the imaging findings. In these cases, there is emerging evidence to suggest that the use of biomarkers (such as B-type natriuretic peptide, troponin or lactate) can guide decision making with regards to suitability for outpatient management. Patients with radiological evidence of right heart strain, with negative cardiac biomarkers (B-type natriuretic peptide, troponin), remain at a low risk of a complicated clinical course and may be considered for outpatient management based on their PESI or sPESI score (Moores et al, 2010; Ozsu et al, 2013; Vanni et al, 2013; Becattini et al, 2014).

Outpatient management of pulmonary emboli in specific circumstances

Intravenous drug users

Intravenous drug users with suspected or confirmed pulmonary embolism should continue to be admitted. There is a lack of evidence regarding the safety of outpatient management in this population, and their lifestyle and social circumstances are likely to make robust outpatient follow up more challenging.

Active cancer

The sPESI scoring system automatically excludes outpatient management of patients with active cancer, while the PESI score will likely result in these patients being classified as high risk. The British Thoracic Society (2018) guidelines therefore recommend that the Hestia criteria may be used to identify patients with active cancer who may not require admission. However, given the increased 30-day mortality in this population (Carson et al, 1992), patients should be reviewed by a consultant before discharge. The same criteria should be applied to asymptomatic patients with cancer in whom a pulmonary embolism is diagnosed incidentally while undergoing computed tomography scanning for other reasons.

Pregnancy

The use of any clinical risk score in pregnant or postpartum women with suspected or confirmed pulmonary embolism is not recommended and the guideline review found no specific evidence regarding outpatient management in these circumstances (British Thoracic Society, 2018). Therefore clinical judgement, consultant review and early liaison with the obstetric and haematology teams is essential in determining whether outpatient management is an option on a case-by-case basis in these patients.

How can we safely discharge patients with pulmonary emboli?

Before discharge, patients who have been identified as low risk should ideally undergo imaging on the same day to confirm or refute a diagnosis of pulmonary embolism. If this is not possible, then British Thoracic Society (2018) guidelines suggest initial treatment with anticoagulation can be commenced and imaging arranged as part of an ambulatory care pathway within 24 hours of presentation.

The evidence base for the use of the risk stratification tools in these circumstances is smaller than in patients with confirmed pulmonary embolism. It is therefore essential that patients in whom a diagnosis of pulmonary embolism has not yet been confirmed are fully assessed, with other diagnoses being considered and investigations undertaken as appropriate, before consideration of outpatient management.

It is recommended that patients with either confirmed or suspected pulmonary embolism should ideally be reviewed by a consultant before discharge onto an outpatient pulmonary embolism pathway (British Thoracic Society, 2018); however, review can also be undertaken by a senior member of the medical team or specialist nursing staff with consultant advice available. Clearly, for patients who are discharged, particularly those who are still awaiting further investigations, it is imperative that local protocols are in place for these patients to be followed up the next day. For instance, the radiology department should ensure that there is the capacity to perform scans on patients with suspected pulmonary embolism the following day (ideally with dedicated slots). Both patients and their GPs should be provided with information to ensure they are discharged safely. A suggested checklist for use when discharging patients either with suspected or confirmed pulmonary embolism is shown in Table 5.

Figure 1 summarises the potential pathway for a clinically stable patient who presents to hospital with a suspected pulmonary embolism. In intermediate- or high-risk patients admitted to hospital for initial management there is some evidence that they can be considered for early discharge once their PESI or sPESI score improves into the low-risk category. Moores et al (2013) demonstrated that in patients who were initially admitted in PESI class III, either a PESI score of I or II or a sPESI of 0 at 48 hours reflected a low risk of mortality such that these patients could be considered for early discharge. This is reflected in the current British Thoracic Society (2018) guidelines on how and when to transition patients from inpatient to outpatient care. However, clinically unstable patients should all be admitted and treated as per local protocols.

Table 5. Suggested checklist for discharging patients with suspected or confirmed pulmonary embolism based on British Thoracic Society (2018) guideline recommendations

Information for patient	■ Single point of contact, eg a specialist nurse ■ Written information about their diagnosis, treatment and follow up ■ Potential adverse effects of treatment (including bleeding) or symptoms suggesting complications ■ Where to seek help and advice both in hours and out of hours
Information for GP	■ Informing them of the new diagnosis ■ Changes to the patient's regular medications ■ Follow-up appointments scheduled

Pharmacological treatment of patients with pulmonary emboli managed on an outpatient basis

There are a number of different pharmacological options for patients with a new diagnosis of pulmonary embolism, each of which has its own considerations (summarised in Table 6).

While the 2012 National Institute for Health and Care Excellence guidelines recommend starting warfarin with a target international normalised ratio of 2–3, bridged by low molecular weight heparin, the National Institute for Health and Care Excellence clinical knowledge summary published in 2019 suggests a number of alternative treatment options, including low molecular weight heparin, fondaparinux, unfractionated heparin, and oral anticoagulation including warfarin and the direct oral anticoagulants (apixaban, rivaroxaban, dabigatran and edoxaban) (National Institute for Health and Care Excellence, 2012, 2019).

The direct oral anticoagulants (previously called novel oral anticoagulants) have consistently performed well in randomised control trials comparing their efficacy and safety profile to low molecular weight heparin and warfarin (Robertson et al, 2015). The British Thoracic Society (2018) guidelines therefore now recommend using direct oral anticoagulants to treat confirmed pulmonary embolism in the outpatient setting. This can either be single agent direct oral anticoagulants (apixaban or rivaroxaban) or those requiring low molecular weight heparin lead in (dabigatran or edoxaban). The choice of direct oral anticoagulant is likely to be guided by local formularies. In clinical practice there may still be situations in which anticoagulation with warfarin may be preferred.

In those who are awaiting a confirmed diagnosis of pulmonary embolism the British Thoracic Society guidelines recommend either a single dose of low molecular weight heparin or a dose of single agent direct oral anticoagulant (apixaban or rivaroxaban). Patients

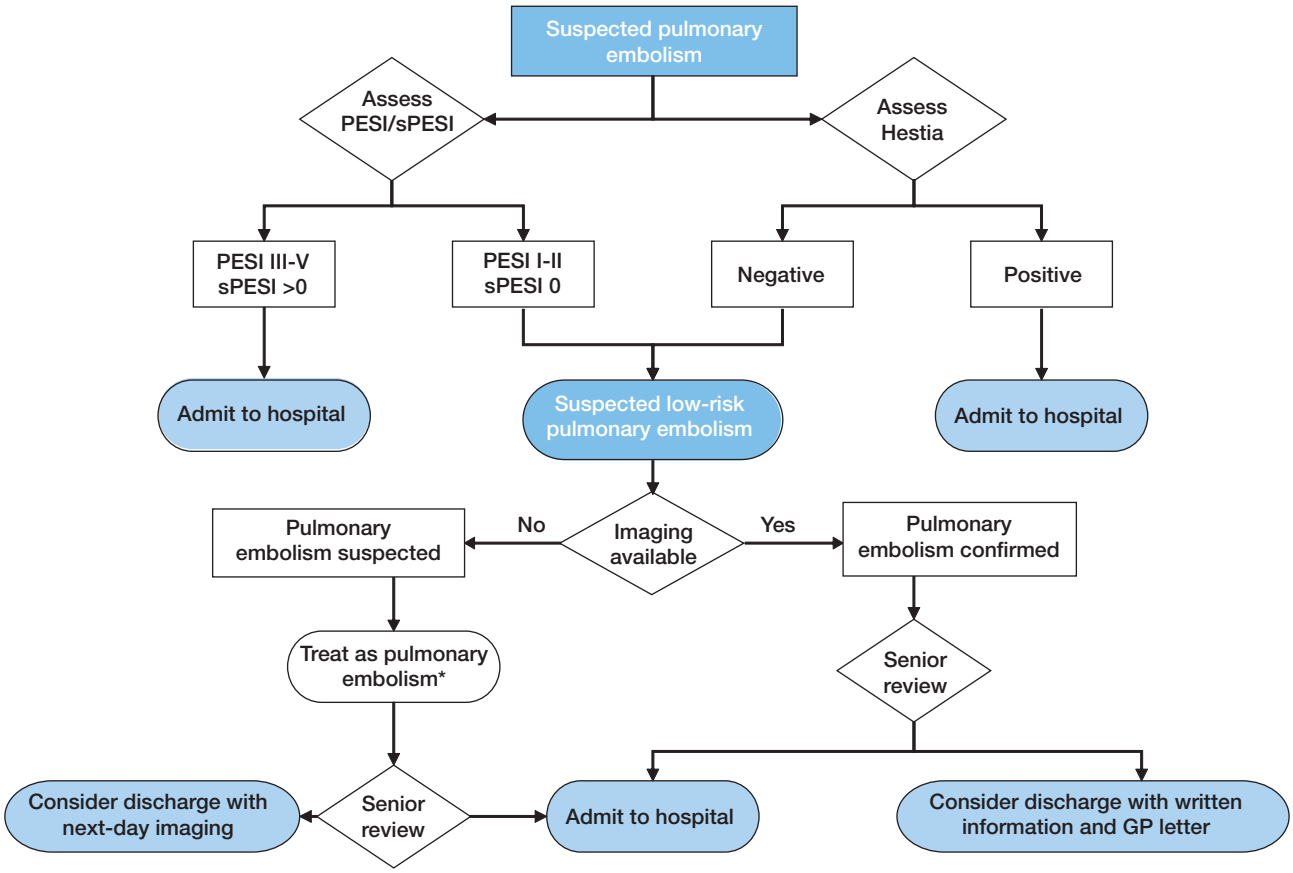

Figure 1. Potential pathway for clinically stable patients with suspected pulmonary embolism, adapted from British Thoracic Society (2018) guidelines. *Unless clinical contraindications present, in which case manage as per local protocols and discuss with senior as appropriate. PESI = Pulmonary Embolism Severity Index; sPESI = Simplified Pulmonary embolism Severity Index

Table 6. Pharmacological options for management of pulmonary embolism

		Dosing schedule	Renal function	Half-life (hours)*	Reversal
Low molecular weight heparin	Dalteparin	Usually once daily, check factor Xa assay if high risk	Reduce dose in renal impairment	4	N/A
	Enoxaparin		Avoid if creatinine clearance <15 ml/min	7	
Vitamin K antagonist	Warfarin	Once daily, dose titrated by international normalised ratio	N/A	40	Vitamin K, prothrombin complex
Direct-acting oral anticoagulant	Apixaban	10 mg twice daily for 7 days followed by 5 mg twice daily. If continued beyond 6 months then the dose is 2.5 mg twice daily	Caution if creatinine clearance 15–29 ml/min, avoid if creatinine clearance <15 ml/min	12	N/A
	Rivaroxaban	15 mg twice daily for 3 weeks, followed by 20 mg once daily	Caution creatinine clearance 15–29 ml/min, avoid if creatinine clearance <15 ml/min	5–9	
	Edoxaban	60 mg once daily following at least 5 days of parenteral anticoagulation	Reduce dose if creatinine clearance 15–50 ml/min, avoid if creatinine clearance <15 ml/min	10–14	
	Dabigatran	150 mg twice daily following at least 5 days of parenteral anticoagulation. Reduce dose if over 75 years old	Avoid if creatinine clearance <30 ml/min	12–14	Idarucizumab

*Adapted from National Institute for Health and Care Excellence (2020). *From https://www.medicines.org.uk/emc*

with active cancer or who are pregnant should be continued on low molecular weight heparin for the duration of treatment. Often patients with cancer are concurrently on other treatments, in particular chemotherapy, which can affect the pharmacokinetics of warfarin and direct oral anticoagulants. However, studies on the use of direct oral anticoagulants in active cancer are ongoing and this may change in future practice. In pregnancy, warfarin is teratogenic and direct oral anticoagulants are likely to cross the placental barrier; as such, neither should be used. Other specific circumstances that affect pharmacokinetics, such as extremes of weight and poor renal function, are likely to be guided by local formularies.

Patients should be advised about the importance of compliance with their treatment, and one of the recommendations in the British Thoracic Society guidelines is that dosing and administration of anticoagulant therapy should be kept as simple as possible to avoid confusion.

How should patients managed on an outpatient basis be followed up?

Robust pathways need to be in place to ensure the appropriate follow up of patients managed on an outpatient basis. The British Thoracic Society guidelines recommend that patients should be formally reviewed within 1 week of discharge (either telephone or face-to-face) to assess compliance and the presence of any early complications. Subsequently, outpatient clinic follow up should be arranged, ideally with a clinician with a special interest in venous thromboembolism. Patients should be assessed at that time for ongoing symptoms and potential complications, along with an assessment of the risk of venous thromboembolism recurrence and the optimum duration of anticoagulation (Konstantinides et al, 2019).

For those with venous thromboembolism events associated with transient risk factors (ie orthopaedic surgery, transient immobilisation) then the duration of anticoagulation is typically 3 months. This is extended to at least 6 months in patients with an unprovoked

venous thromboembolism and lifelong in recurrent unprovoked pulmonary embolism (if using apixaban or rivaroxaban beyond 6 months, a reduced dose can be considered; Konstantinides et al, 2019). In each case, outpatient review and assessment of ongoing venous thromboembolism risk factors and bleeding risk must be discussed with the patient and taken into consideration before decisions about duration of anticoagulation can be made (National Institute for Health and Care Excellence, 2012; Konstantinides et al, 2019).

When to screen for malignancy

In patients who have an unprovoked pulmonary embolism, the National Institute for Health and Care Excellence (2012) currently recommend malignancy screening, as this cohort of patients has a significantly increased rate of cancer diagnosis (Sandén et al, 2017). They recommend screening patients with a full history and examination (specifically looking for red flag signs and symptoms), followed by chest radiograph, urine dipstick and blood tests, including full blood count, serum calcium and liver function tests. They also recommend that in patients aged over 40 years consideration is given to computed tomography imaging of the abdomen and pelvis, and mammography in women with unprovoked pulmonary embolism who do not demonstrate any features of malignancy from the initial screen.

When to screen for thrombophilia

The British Thoracic Society (2018) guidelines do not discuss thrombophilia screening, but current National Institute for Health and Care Excellence (2012) guidelines recommend that clinicians consider screening for hereditary thrombophilia in patients with an unprovoked pulmonary embolism who have a first-degree relative with venous thromboembolism and if the plan is to discontinue anticoagulation. In addition, the National Institute for Health and Care Excellence (2012) recommends that consideration is given to checking antiphospholipid antibodies in patients with an unprovoked venous thromboembolism if the plan is to discontinue anticoagulation.

Conclusions

Pulmonary embolism remains a life-threatening condition. The British Thoracic Society (2018) guidelines support the use of risk stratification scoring systems and exclusion criteria, allowing clinicians to use an evidence-based approach to treat low-risk patients on an outpatient basis. If appropriate, outpatient treatment should be considered, provided there is a robust local pathway to ensure necessary follow up as well as patient support. There is a shift toward anticoagulation with the newer direct oral anticoagulants; however, considerations must be made for specific populations in whom other forms of anticoagulation remain more appropriate.

Overall, although patient management can be guided by risk-stratification scoring systems, clinical judgement and senior input are essential to achieve best clinical practice.

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Conflicts of interest

The authors declare no conflicts of interest

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Key points

- There is a growing evidence base to support management of low-risk pulmonary embolism in the outpatient setting.
- Risk stratification tools such as the Pulmonary Embolism Severity Index Score, Simplified Pulmonary Embolism Severity Index Score or Hestia criteria may be used to guide safe discharge.
- Appropriate follow up should be arranged for patients who have been discharged with suspected or confirmed pulmonary embolism.
- Further guidance can be found in the 2018 British Thoracic Society Guideline for the initial management of suspected acute pulmonary embolism and the 2019 European Society of Cardiology Guidelines for the diagnosis and management of acute pulmonary embolism developed in collaboration with the European Respiratory Society.

Curriculum checklist

This article addresses the following requirements from the general internal medicine training curriculum:

- Managing an acute unselected take
- Managing patients in an outpatient clinic, ambulatory or community setting, including management of long term conditions
- Managing a multi-disciplinary team including effective discharge planning.

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