INTEGRATED CARE PATHWAY FOR PULMONARY EMBOLISM

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1. INTRODUCTION

Pulmonary thromboembolism (PE) is the result of obstruction of the pulmonary arterial circulation by an embolus originating, in most cases, from the deep venous system of the lower extremities. For this reason, deep vein thrombosis (DVT) and PE are considered part of the same pathophysiological process: venous thromboembolic disease (VTE).

The risk factors (Annex 1) of PE are related to its etiopathogenic mechanisms: stasis, endothelial injury, and hypercoagulability.

The epidemiology of PE is difficult to assess given its nonspecific presentation and frequent diagnostic errors. Annual incidence rate for PE is estimated at one case per 1,000 population, although its actual incidence is likely to be higher. According to data from the Ministry of Health, in 2010, 22,250 cases of PE were diagnosed in Spain, with a mortality rate during admission of 8.9% (1).

Diagnosis

The diagnosis of acute symptomatic PE should be considered in all patients who report new onset dyspnea, worsening of their usual dyspnea, chest pain, syncope or hypotension without an alternative explanation (Annex 2), particularly when basic complementary tests (chest X-ray , electrocardiogram and arterial blood gas) rule out other differential diagnoses.

No single test is sensitive and specific enough to confirm or rule out the presence of acute symptomatic PE. For this reason, the diagnosis of the disease must combine clinical suspicion, D-dimer testing and imaging tests, the most commonly used being multidetector computed tomography chest angiography (imaging test of choice), lung scintigraphy of ventilation-perfusion and venous ultrasound of LES with or without Doppler.

At present, multidetector CTPA is the method of choice for imaging the pulmonary vasculature in patients with suspected PE. It allows adequate visualization of the pulmonary arteries down to the subsegmental level. Several studies have provided evidence in favour of CTPA as a stand-alone imaging test for excluding PE. Taken together, the avail- able data suggest that a negative CTPA result is an adequate criterion for the exclusion of PE in patients with low or intermediate clinical probability of PE. On the other hand, it remains controversial whether patients with a negative CTPA and a high clinical probability should be further investigated.

Compression ultrasonography (CUS) of the lower extremities is the method of choice for the detection of deep vein thrombosis in patients with PE. The main diagnostic criterion is the lack of compressibility of the venous lumen. It is especially sensitive and specific in patients with DVT symptoms and in the femoro-popliteal territory. Approximately 50% of patients with acute symptomatic PE have concomitant DVT at the time of diagnosis, of which only half are symptomatic.

The diagnostic process does not justify delays in the initiation of anticoagulant treatment, which must be early in patients with intermediate or high clinical suspicion.

The clinical prediction rules (CPR) are reliable and non-invasive tools that, based on the history and clinical findings, determine the pre-test probability and, in patients with suspected PE, assess the need to carry out different tests diagnostic.

Various CPR models have been validated, the most revised and validated being the Wells clinical prediction rule and the revised Geneva (Annex 3). These rules, as part of a diagnostic algorithm and in combination with the determination of a D-dimer (DD) testing in blood, can exclude PE in low-risk groups without the need for further examinations.

Treatment

In patients with high or intermediate clinical probability of PE, anticoagulation should be initiated while awaiting the results of diagnostic tests. This is usually done with subcutaneous, weight adjusted low-molecular weight heparin (LMWH) or fondaparinux or i.v. unfractionated heparin (UFH). Based on pharmacokinetic data an equally rapid anticoagulant effect can also be achieved with a non-vitamin K antagonist oral anticoagulant (NOAC). LMWH are as effective and safe as unfractionated heparin, they reach therapeutic doses faster, are used in fixed doses, and confer less risk of serious bleeding.

Percutaneous catheter-directed treatment is indicated in high-risk PE with absolute or relative contraindication to systemic thrombolysis, or in patients who have undergone systemic thrombolysis, but are unable to regain hemodynamic or ventilatory status. Its objective is to remove or fragment the obstructive thrombus of the main pulmonary artery and thus decrease the pulmonary vascular resistance (the afterload of the right ventricle) and recover the ventilatory function and cardiac output. The most used techniques are:

- Thrombus fragmentation: manually with catheters or balloons that dilate the area where the thrombus is.
- Rheolytic thrombectomy: saline is injected under pressure at the level of the thrombus, which causes the removal of fragments of thrombi.
- Suction embolectomy: inserting a catheter to which negative pressure is applied.
- Rotational thrombectomy: through a catheter that has a spiral in its central part and that when rotating generates a negative pressure, aspirating the thrombotic material.
- Direct catheter thrombolysis: consists of administering doses of 2 to 10mg of t-PA directly into the main pulmonary artery.

For the elaboration of this care process, a review of the available knowledge has been made through bibliographic searches and the recommended action guidelines are mainly based on three documents: the 2016 CHEST Guide (2), 2019 ESC Guidelines for the diagnosis and management of acute pulmonaryembolismthe (3) and the Integrated Healthcare process of the Junta de Andalucía of 2007 (4). We hope to contribute to improving the health outcomes of patients with pulmonary embolism.

2. OBJECTIVES

The aims of this process are:

- Define and standardize the management of PE by describing the activities aimed at its evaluation, diagnosis, therapeutic approach and follow-up.
- Reduce unjustified variability in clinical practice in PE management, both in its diagnostic and therapeutic aspects.
- Promote comprehensive care for the person and their families, with a multidisciplinary vision.
- Facilitate coordination between the different professionals involved in caring for people with PE, as well as between the different levels of care, thus contributing to an integrative management of the disease.

3. SCOPE OF APPLICATION / TARGET POPULATION

Scope

- The care process addresses the care that patients with PE should receive from professionals, both in Primary Care and in Hospital Care in the sanitary area of , in those aspects related to evaluation, diagnosis, therapeutic approach and follow-up.

Target population:

- Patients admitted to the Hospital Complex with suspected PE, coming from the reference healthcare area or from other healthcare areas.
- Patients who during their admission to Hospital Complex suffer an episode of PE.

Main users to whom the assistance process is directed

- This care process is aimed at all those Services and Units involved in the PE management, such as Primary Care, Admission, Quality, Cardiology, Pharmacy, Internal Medicine, Pulmonology, Social Work, Critical Care Units and Emergencies.

4. DEFINITIONS

- **Pulmonary embolism:** disorder in which, after a sudden thrombotic pulmonary artery obstruction, there is a varied symptomatology (depending on the size of the embolus and the previous cardio-respiratory situation) that may include: sudden unexplained dyspnea, tachypnea, chest pain with pleuritic characteristics, anxiety , cough, hemoptysis and syncope. 90% of pulmonary thromboembolisms originate in the venous system of the lower extremities, so deep vein thrombosis (DVT) and PE are considered part of the same pathophysiological process: venous thromboembolic disease (VTE) .

5. RESPONSIBILITIES

They are defined in the text.

6. DEFINITION OF THE CARE PROCESS

Functional definition:

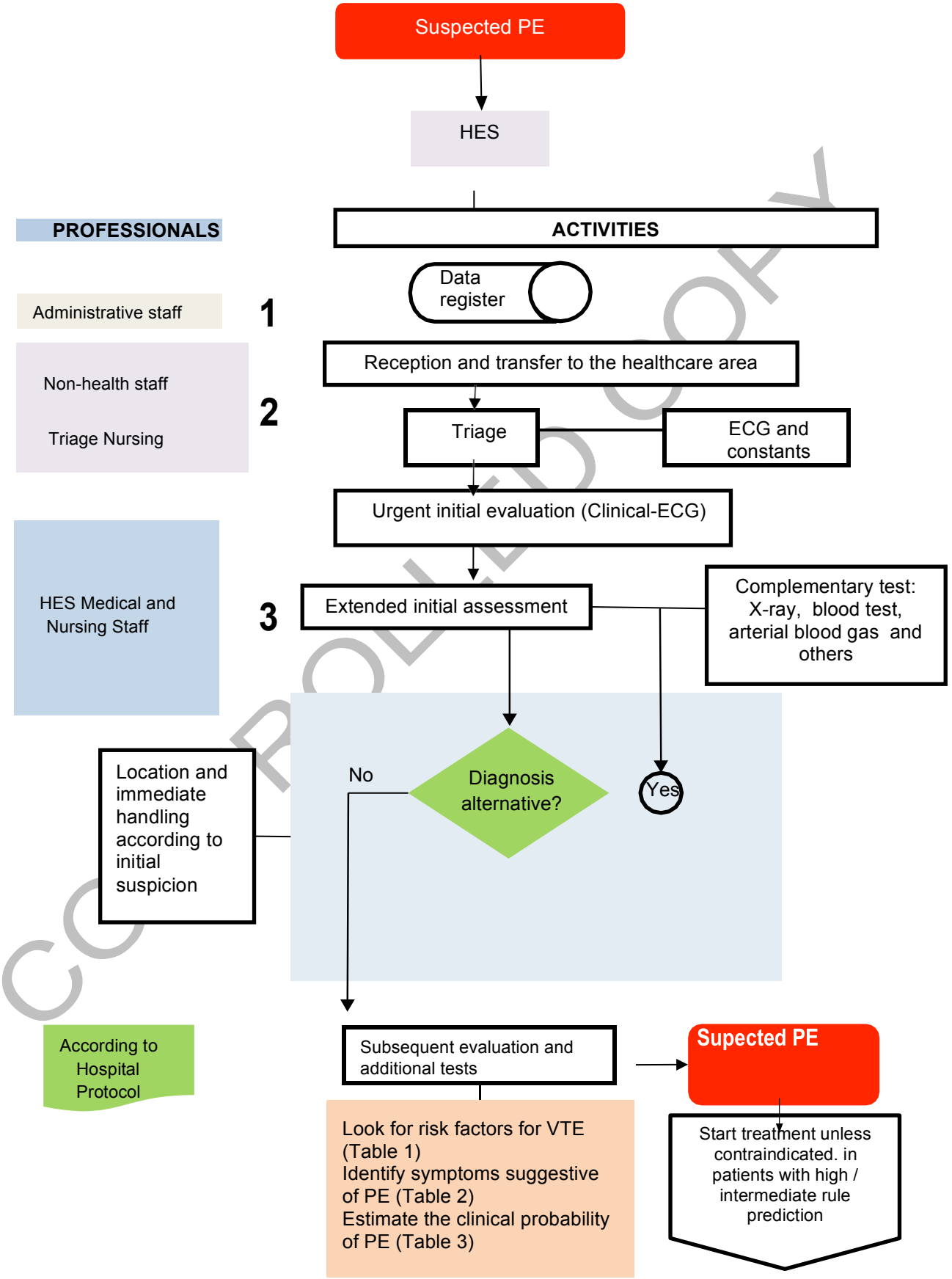
- Process by which the patient, after requesting assistance (generally due to dyspnea and / or chest pain) at any center in the our health area, proceeds to establish a clinical suspicion of PE, to administer anticoagulant treatment (except if there are contraindications) and to subsequent confirmation with the pertinent complementary examinations. Once the definitive diagnosis has been reached, the most appropriate treatment will be followed, generally including anticoagulation and, occasionally, fibrinolysis, embolectomy or vena cava filters. Finally, continuity of care is ensured by monitoring the patient in outpatient Specialized Care and / or Primary Care consultations.

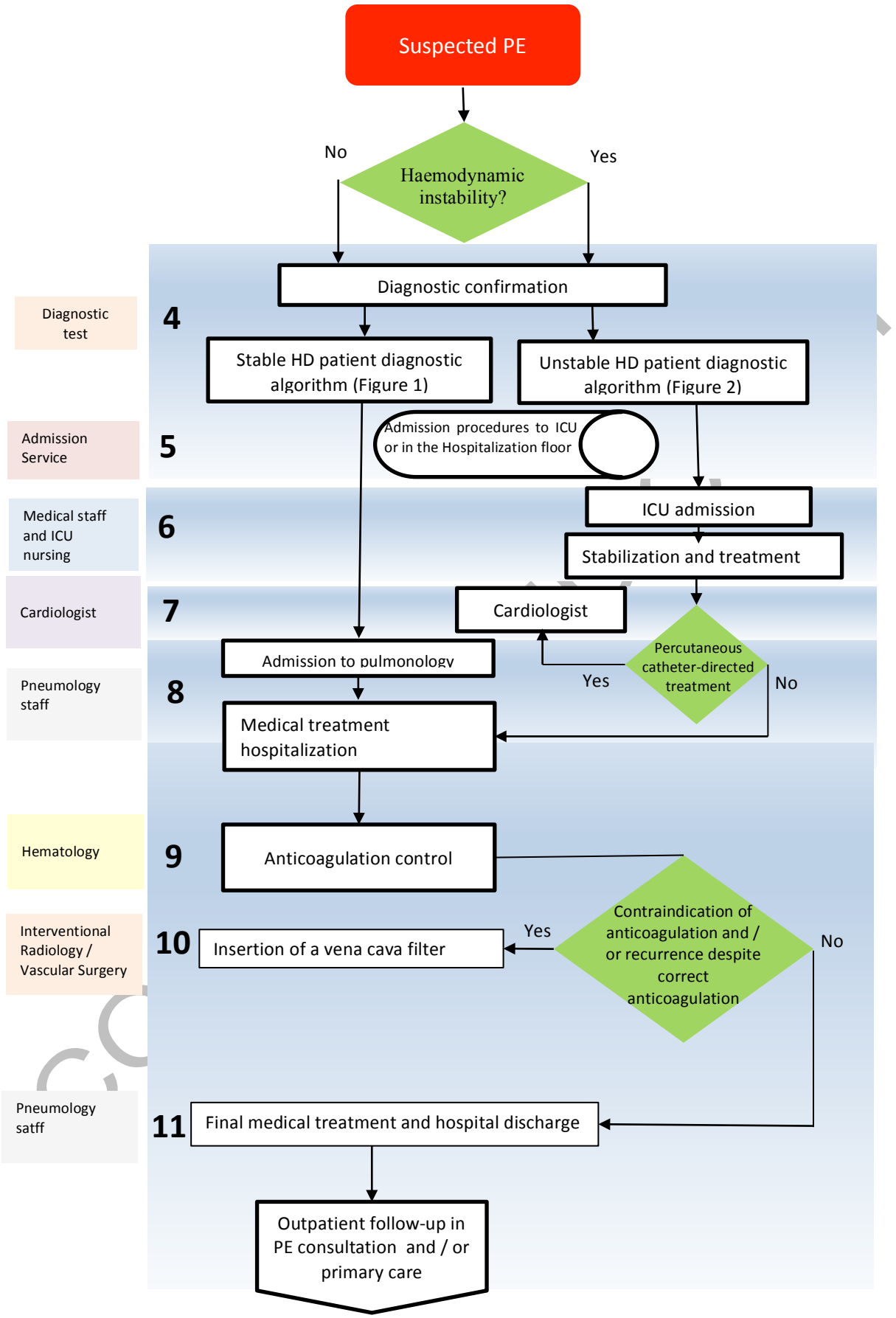
Entrance to the process:

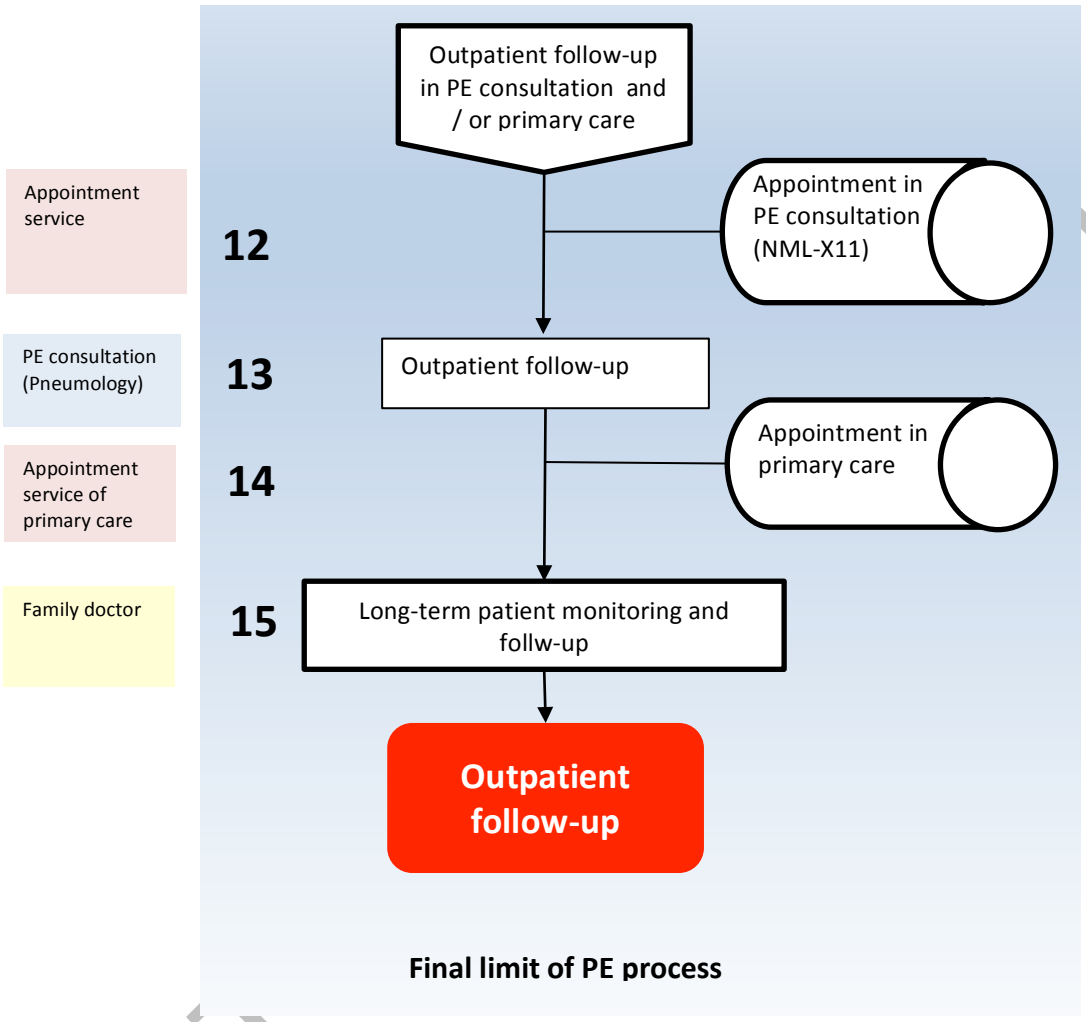
- When there is a clinical suggestive of PE, entry to the health system can be through an Emergency service (emergency phone call, primary care emergencies, Hospital Emergency Service) or a Health Center (Family Doctor). Another situation is that the patient is already admitted to a hospital ward for another reason.

PROCESS ARCHITECTURE

Entry through a Hospital Emergency Service (HES)




Suspected PE
No
Haemodynamic instability?
Yes
Diagnostic test
4
Diagnostic confirmation
Stable HD patient diagnostic algorithm (Figure 1)
Unstable HD patient diagnostic algorithm (Figure 2)
Admission Service
5
Admission procedures to ICU or in the Hospitalization floor
Medical staff and ICU nursing
6
ICU admission
Stabilization and treatment
Cardiologist
7
Cardiologist
Pneumology staff
8
Admission to pulmonology
Percutaneous catheter-directed treatment
Yes
No
Medical treatment hospitalization
Hematology
9
Anticoagulation control
Interventional Radiology / Vascular Surgery
10
Insertion of a vena cava filter
Yes
Contraindication of anticoagulation and / or recurrence despite correct anticoagulation
No
Pneumology satff
11
Final medical treatment and hospital discharge
Outpatient follow-up in PE consultation and / or primary care


Appointment service
PE consultation (Pneumology)
Appointment service of primary care
Family doctor
Outpatient follow-up in PE consultation and / or primary care
12
Appointment in PE consultation (NML-X11)
13
Outpatient follow-up
14
Appointment in primary care
15
Long-term patient monitoring and follw-up
Outpatient follow-up
Final limit of PE process

COMPONENTS

<table>
<tr><td rowspan="3">1. Identification of patients with suspected PE in the Emergency Department</td><td colspan="2">Activities</td></tr>
<tr><td>Administrative
Identification and formalization of the patient's admission</td><td>After the patient's arrival at the Emergency Service, his identity will be verified.
• If identifying data is available:
➢ If the patient has a medical history in the hospital, their personal data is checked.
➢ If the patient does not have a Hª Clinic, one is created, being necessary the accreditation of his identity.
• If no identification is available:
➢ A Hª Clinic of unknown will be created. When data is available, it will be sought if the patient has a Hª Clinic. In case of having it, the Nursing Unit will be provided and a note will be sent to the Archive for its unification. If there is no Hª Clinic, the unknown will be modified with the patient's already confirmed data. In both cases, the new identification tags and bracelets will be provided.
In the event that the patient is not accompanied by family members and they cannot be found, contact the Social Work Service.
The Emergency Admission Service is responsible for formalizing the admission of patients to the Emergency Service and for providing identification labels and bracelets along with the emergency care documents. The nursing staff of the corresponding area must claim the bracelet in case of
that is not provided.</td></tr>
<tr><td>Health personnel
Verification of the patient's identity</td><td>The identification bracelet will be used on all patients, regardless of their severity or location.
The Triage nursing staff must verify the identity of the patient and the agreement with the data printed on the identification tag or bracelet, as follows:
• It will ask the patient his name and surname, without being suggested by the nursing professional.
• In the cases in which it is not possible or the patient is a minor and attends with a relative / companion, it will be the accompanying person who confirms the identity of the patient without being suggested by the nursing staff.
• In cases where the patient is not in a position to confirm their identity and goes unaccompanied, the identity verification will be carried out by means of any document (DNI or others) that allows their unequivocal identification.
• The nursing staff of each Unit will be responsible for identifying the patient with their corresponding bracelet and claiming it if it is not provided.
Special care should be taken in identifying the following cases:
o Patients with social or fragile problems (low level of consciousness, with dementia ...) without a reference companion.
o Observation patients, monitors, critics and cubicles.
o Patients admitted directly to the ICU or to the Operating Room: if it is not possible to make their identification in advance, the nursing staff of these units must request a bracelet identification to the Admission Service and place it on the patient.</td></tr>
</table>

<table>
<tr><td rowspan="3">2. Triage of the patient with suspected PE</td><td colspan="2">Activities</td></tr>
<tr><td>Non-health staff
Transfer of the patient to the triage room</td><td>• If the patient is accompanied by XXX Health Emergency Technicians, they will be in charge of passing the patient and their Hª Clínica data to the Triage.
• If the patient comes alone or accompanied, it will be the gatekeeper who will accompany the patient to the Triage.</td></tr>
<tr><td>Nurse
Triage of the patient with suspected PE</td><td>Assignment of priority following the Alert diagnostic algorithm of the Manchester Triage System

<table><tr><th>Level</th><th>Colour</th><th>Time of waiting</th></tr><tr><td>1</td><td>Red</td><td>Assistance immediate</td></tr><tr><td>2</td><td>Orange</td><td>10-15 minutes</td></tr><tr><td>3</td><td>Yellow</td><td>60 minutes</td></tr><tr><td>4</td><td>Green</td><td>two hours</td></tr><tr><td>5</td><td>Blue</td><td>4 hours</td></tr></table>
• ECG performance and immediate medical evaluation (in the first 10 minutes) of all patients with non-traumatic chest pain, following the "Guide to criteria for post-trip initial location"
• The location in the Emergency Department of the patient with suspected PE will depend on the hemodynamic and / or respiratory situation (Risk stratification)
○ If the patient has hemodynamic instability / respiratory will be located in the Critical area.
○ If the patient does not present hemodynamic instability, but there is data of cardiac dysfunction / stress (by imaging tests / analytical markers), he will be located in the Monitors room.
○ If the patient is stable from the hemodynamic / respiratory point of view, with no evidence of cardiac dysfunction, they will be located in the Boxes or Observation area.</td></tr>
</table>

3. General care protocol for patients with suspected PE	Activities (1)	
	HES Physician Evaluation	With an initial suspicion of PE, the following will be sought: • Risk factors for venous thromboembolic disease (VTE) (Annex 1), especially history of immobilization, surgery in the previous 3 months, cancer, thrombophlebitis, and lower extremity fracture / trauma. • Clinical data most frequently associated with PE (Annex 2): the diagnosis of acute symptomatic PE should be considered in all patients who report new-onset dyspnea, worsening of their usual dyspnea, chest pain, syncope or hypotension without an alternative explanation, particularly when Basic complementary tests (chest X-ray, electrocardiogram, and arterial blood gas) rule out other differential diagnoses. • Complementary studies: electrocardiogram, chest X-ray, blood analysis (determination of D-Dimer only in patients with low or intermediate clinical pre-test probability) and arterial blood gas. • Collect in the clinical history the pre-test clinical probability of PE using CPR. • Patients admitted to centers that do not have the necessary means to establish the diagnosis or carry out the appropriate treatment in serious situations, they will be referred to the referral hospital.
	HES Nurse Care	The following procedures should be performed: • Vital signs at the Hª Clinic on arrival at the emergency room: blood pressure, heart rate, temperature, respiratory rate and oxygen saturation. • Peripheral venous cannulation with a three-way stopcock. • Blood analysis with determination of hemogram, biochemistry and coagulation (assess D-Dimer). • Twelve-lead electrocardiogram. • Arterial blood gas if pulse oximetry oxygen saturation <95% • Monitoring of all patients with intermediate-high/ high risk PE.
	HES Physician Suspected PE	In view of a suspicion from probability clinic intermediate-high from PE, hemodynamically stable, it is recommended: • Absolute rest. • Start with anticoagulant treatment (LMWH, except for contraindications), without waiting for definitive confirmation of PE by imaging techniques. • If hypoxemia: supplemental oxygen therapy and even temporary mechanical ventilation. • If pain: provide analgesia, avoiding morphics in patients with incipient cardiovascular collapse, due to their hypotensive effect. A non-steroidal anti-inflammatory drug (NSAID) is generally effective and safe despite concomitant anticoagulation.

Four . Diagnostic protocol for PE in the ED	Activities (1,3,5,11)	
	HED Physician **Diagnosis**	No single test is sufficiently sensitive and specific to confirm or rule out the presence of acute symptomatic PE. Diagnosis of the disease should combine clinical suspicion, D-dimer results, and imaging tests: ventilation / perfusion (V / Q) lung scan, contrast spiral thoracic CT angiography, echocardiogram, and lower limb venous compresion ultasonograpy. **Hemodynamically stable patients (Figure 1):** • With low or intermediate probability of PE, a negative (<500 ng / mL) high-sensitivity D-dimer (latex by immunoturbidimetry) excludes the diagnosis of PE. These patients are not anticoagulated and the incidence of VTE in the 3 subsequent months is 0.14%. • With a high clinical probability of PE, the D-dimer should not be determined since its value is irrelevant. ○ A multidetector computed tomography chest angiogram (CT Angiography of the pulmonary arteries) will be ordered, currently the imaging test of choice for the diagnosis of PE. ○ In pregnant women, a venous ultrasound of the lower limbs is first recommended. If it were negative, a perfusion scan would be done before a multidetector CT angiography due to the less radiation (provided that the chest X-ray was normal). ○ Request a V / Q scan in patients with an allergy to iodinated contrast agents, renal failure, or pregnant women with suspected PE in whom the LES Doppler ultrasound has been negative, and provided that the chest radiograph is normal. The lung scan is considered diagnostic according to the criteria of the PIOPED study (Annex 4). A "non-diagnostic" result requires the performance of other diagnostic imaging techniques. ○ Lower extremity venous Doppler ultrasound is recommended in patients with disagreement between clinical probability and the result of chest imaging tests, in patients with inconclusive chest tests, and in pregnant patients. **Hemodynamically unstable patients (Figure 2):** • Bedside echocardiography can provide valuable diagnostic information if multidetector CT angiography is not available, or if the patient's instability prevents transfer to the radiology room. In critically ill patients, the absence of echocardiographic signs of right chamber dysfunction or overload rules out PE as a cause of hemodynamic compromise.

Figure 1
Diagnostic algorithm for patients with suspected pulmonary embolism without haemodynamic instability

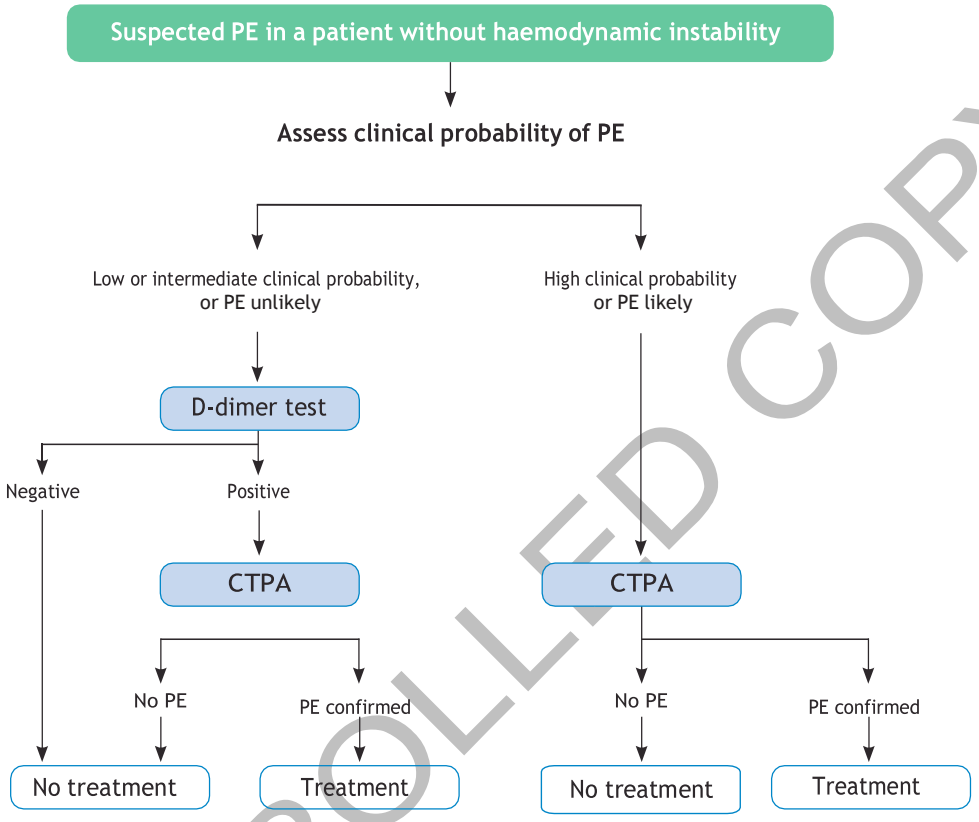
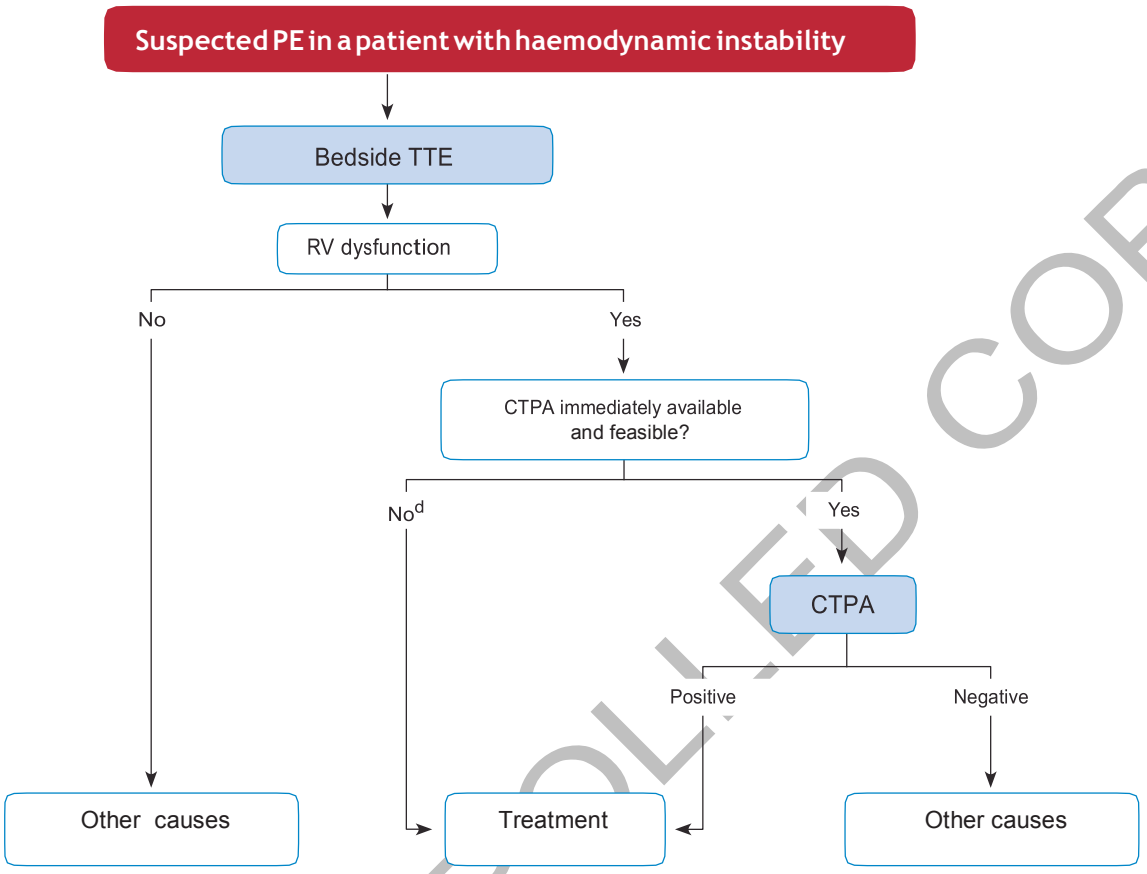


Figure 2
Diagnostic algorithm for patients with suspected high-risk pulmonary embolism presenting with haemodynamic instability



Four . Diagnostic protocol for PE in the ED	Activities (1,3,5,11)	
	HED Physician Diagnosis	**Urgent echocardiography should be requested in all patients with intermediate and high risk PE**. • Parameters that indicate involvement of the right ventricle and quantification of pulmonary pressure will be analyzed (Annex 5): – PSAP – TAPSE – RV dimensions: baseline and mean DTD. RV / LV ratio – RVOT flow (pulsed doppler): Pulmonary transvalvular acceleration time – Pulmonary failure (continuous doppler) • **Location**: will be classified based on the AngioTC: a) CENTRAL PET: involvement of central or lobar pulmonary arteries b) PERIPHERAL PET: Without involvement of the main or lobar arteries • In patients with a confirmed diagnosis of PE, troponin levels will be requested (if not previously requested) and Pro-BNP if available. **Mortality scales** • The prognostic scale of mortality at 30 days Pulmonary Embolism Severity Index (PESI) and its simplified form (PESIs), are validated and accepted scales for prognostic stratification of patients with PE. It is accepted that when the risk is low (PESI), or zero (PESIs), an outpatient treatment can be considered, or at least be discharged early (Annex 6). • The PESI or PESIs must be registered in the Clinical History **Entry** • Patients with confirmed PE with data of cardiac dysfunction, with or without hemodynamic instability and / or severe respiratory failure, will be admitted to the ICU. Those with a stable clinical situation can be admitted directly to conventional hospital beds of Pulmonology (or in the hospital ward, at Hospital do Barbanza).

5. S. Admission	Activities	
	Administrative	• It will carry out the administrative procedures for admission to the ICU or hospitalization ward. • Avoid unnecessary delays.

<table>
<tr><td rowspan="3">6. Health personnel of the Intensive Care Unit</td><td colspan="2">Activities (1-3.6)</td></tr>
<tr><td>Health professionals
Vital support</td><td>• Stabilization and urgent initial treatment of PE in critical condition.
• A patient is considered in critical condition if:
➢ Hemodynamic instability: Signs of shock: hypotension with systolic blood pressure (sBP) less than 90 mm of Hg maintained for 15 minutes or a drop of 40 mm of Hg maintained for 15 minutes, or require vasoactive amines to maintain SaO_2 of at least 90 mm of Hg.
➢ Severe respiratory failure despite oxygen therapy.
➢ RV dysfunction with echocardiographic / CT parameters and markers Biochemicals of myocardial injury / right ventricular failure. According to stratification, they would correspond to high-risk PE and intermediate- risk.</td></tr>
<tr><td>ICU doctor
Evaluation and treatment</td><td>• Surveillance and control of the patient's condition, with monitoring of ECG, vital signs and oximetry. The necessary hemodynamic monitoring will be carried out, taking into account the individual risk / benefit of invasiveness with anticoagulation and eventual fibrinolysis.
• Determine Pro-BNP and troponin levels and perform an urgent echocardiogram to assess the existence of RV overload / dysfunction (if not performed), as well as to rule out that the patient's instability is due to other pathologies.
• Stratify the bleeding risk, using the HAS-BLED scale, considering a significant risk score equal to or greater than 3 points. (See Annex 7).
• Treatmentaccording to updated Clinical Practice Guidelines or updated protocols of the Hospital Complex itself, with 5 objectives:
○ Provide anticoagulant or reperfusion treatment (fibrinolytic or pharmacoinvasive).
○ Monitor the high risk and high intermediate risk patient.
○ Soothe the pain.
○ Provide supplemental oxygen therapy or mechanical ventilation as required, including the possibility of ECMO if indicated.
○ Improve the hemodynamic situation of the patient. To do this, we highlight some fundamental recommendations that are expressed below.
• In general, low molecular weight heparin anticoagulation will be used. Unfractionated heparin will be used preferably in the following patients:
○ Renal insufficiency (clearance <30 ml / min).
○ Hemodynamic instability or bleeding risk (possible use of thrombolytics, pharmacoinvasive or surgical procedure)
○ Possible need for suspension or reversal of anticoagulation.
○ Obesity or subcutaneous malabsorption</td></tr>
</table>

6. Health personnel of the Intensive Care Unit	Activities (1-3.6)	
	ICU doctor Evaluation and treatment	• In high-risk cases of PE, with hemodynamic instability (hypotension maintained for 15 min below 90 mm Hg of SAT, or <40 mm Hg of maintained SAT, signs of shock or need for amines to maintain> 90 mm Hg), fibrinolytic treatment will be performed. • In patients with PE, of intermediate-high risk, with tissue perfusion and ATnormal, but with echocardiographic evidence of RV dysfunction and elevated markers of myocardial damage (Troponin) or heart failure (ProBNP). Once the anticoagulation with heparin has been started, they should be admitted to the ICU for monitoring in case hemodynamic deterioration develops, with immediate availability of thrombolytic drugs, or opt for drug-invasive treatment with indications equal to those listed above for high-risk PE. See algorithm. • In patients whose PE is not high risk or high intermediate risk and who are admitted to the Intensive Care Unit, fibrinolytics should not be administered but heparin. • In cases where the use of fibrinolytics is considered indicated, any of the thrombolytic regimens approved for PTE can be used, which are outlined in Annex 8 (in our Complex, priority is given to the use of rTPA. • If fibrinolytic treatment fails, there is a risk of imminent death or high risk of bleeding (3 or more points on the HAS-BLED scale), pharmacoinvasive treatment will be proposed to the Hemodynamics team. In a situation of hemodynamic instability or hemorrhagic risk, pending initiation of pharmacoinvasive treatment, fibrinolytic treatment must always be available for immediate use (administered as a bolus, analogous to the situation with CRP). • In case of failure of the pharmacoinvasive strategy, the Surgical embolectomy even with ECMO support. • In the case of massive embolism, if there are contraindications for anticoagulant / fibrinolytic treatment, episodes of major bleeding in the acute phase or a new embolic episode despite adequate anticoagulation, it is necessary to consider using a filter in the inferior vena cava, to prevent a new PE that could be fatal. • Treatment of pain: adequate analgesia should be provided using opioids that cause less hemodynamic instability, using low loading doses and continuous infusion. Bear in mind that pleuritic pain can sometimes resolve better with anti-inflammatory drugs. • Hypoxemia should be treated with supplemental oxygen therapy and mechanical ventilation may even be considered.

6. Health personnel of the Intensive Care Unit	Activities (1-3.6)	
	ICU doctor Evaluation and treatment	In cases of poor hemodynamic situation (right heart failure and Cardiogenic shock): • the drug of first choice is norepinephrine to maintain myocardial perfusion of the right ventricle, and dobutamine can be used, associated to improve right ventricular contractility. • Careful use of volume expansion can improve the situationhemodynamics, monitoring cardiac function using semi-invasive methods and echocardiography to adequately maintain preload (Cautious volume loading, saline, or Ringer's lactate, ≤ 500 mL over 15 30 min) In the event of cardiac arrest suggestive of Pulmonary Embolism (clinical andelectrical activity without initial pulse) or stop witnessed in a patient diagnosed with pulmonary embolism, it is recommended to perform thrombolysis within cardiopulmonary resuscitation by means of a bolus of 50 mg of rTPA that can be repeated, it is also recommended to maintain CPR at least 30 minutes after rTPA administration.

<table>
<tr><td rowspan="3">7. Cardiology. Hemodynamics Service.</td><td colspan="2">Activities (2-3, 8-10, 16-17)</td></tr>
<tr><td>Hemodynamic duty doctor</td><td>INCLUSION CRITERIA for pharmacoinvasive therapy directed by catheterization:
➢ Patients with high-risk PE with a central location and a PSAP> 45mmHg (if it cannot be measured by echocardiogram, catheterization can be performed to quantify the PSAP and act in accordance with its value) and:
○ High risk of bleeding (HAS-BLED ≥ 3)
○ Systemic fibrinolytic treatment failure, or high probability of immediate death
• Once the patient has been stratified, if intervention is decided, the Cardiology ward will be contacted, who will notify the Hemodynamic ward.
• The patient will be informed of the procedure and the Informed Consent will be delivered (Annex 9)</td></tr>
<tr><td>Hemodynamic duty doctor</td><td>HEMODYNAMIC ROOM
• Radial approach with 4 or 5F to monitor systemic BP.
• Administration of 2500U of sodium heparin through the venous introducer.
• Cannulation of the femoral vein with 6F to introduce pig-tail catheter to the pulmonary arteries, measuring PSAP (if it is above 45mmHg, start with pharmacoinvasive therapy).
• Contrast injection in both lungs to visualize thrombus.
• Infusion of local fibrinolytic, alteplase (rtPA) 20 mg.
• Wait 15 minutes and fragment the thrombus with the pig-tail catheter itself.
• Exchange 6F introducer for one 10F using a 260cm 0.035 guide.
• Insert Pronto 10F aspiration catheter and aspirate in both lungs
• The objective is: in massive or high-risk PE, patient stabilization and significant decrease in PSAP and in non-massive or intermediate-high risk PE, decrease in PSAP.
• Remove venous introducer at 4 hours by manual compression.</td></tr>
</table>

8. Health personnel of the Pneumology hospitalization ward	**Activities (1-3, 12-14)**	
	Nurse	• During the stay in the hospitalization floor, it will be monitored and recorded the patient's condition, vital signs and oximetry.
	Plant doctor Treatment	• IV unfractionated heparin (UFH) should be used in: High-risk PE, when it may be necessary to quickly reverse the anticoagulant effect or in patients with high bleeding risk. In the absence of these conditions, sc low molecular weight heparin is preferred from the outset (see dosage in Annex 8). • Treatment with heparin can be administered from the first day together with oral anticoagulants (dicoumarin), withdrawing heparin after 4-5 days. The dicoumarin dose should be adjusted to achieve an INR between 2 and 3. • Anticoagulant treatment should be maintained for 3 months in patients with PE due to transient risk factors (provoked). If the PE does not have a known risk factor (unprovoked), it is recommended to maintain an extended treatment, depending on the balance between the benefit of avoiding recurrences and the bleeding risk in each case. • If pleuritic chest pain, prescribe non-steroidal anti-inflammatory drugs within a period of no more than 24 to 48 hours. Its administration does not increase the risk of bleeding in the acute phase of PE. • Administer supplemental oxygen therapy to maintain adequate oxygenation of the patient. • In patients with VTE and cancer, it is recommended to maintain anticoagulation with LMWH. • The current ACCP Guidelines on Antithrombotic Therapy suggest that long-term treatment with dabigatran, rivaroxaban, apixaban or edoxaban (direct-acting anticoagulants) be used in patients with DVT or PE without cancer, rather than with vitamin antagonists. K (AVK). (Level of evidence 2B). The main limitation is the lack of funding in Spain for direct-acting anticoagulants (DOAC) for the treatment of VTE.
	Plant doctor Studies complementary	• Lower limb venous Doppler will be requested to screen for deep vein thrombosis (DVT) if it has not been done previously. • Perform a detailed device history, especially in those cases without identifiable risk factors for VTE. Subsequent complementary studies will be requested based on relevant findings in the medical history or suspicion of hidden neoplasia: tumor markers, abdominal-pelvic ultrasound / CT (thoracic, if not previously performed), mammography, prostate study or PET among others . • The systematic search for occult neoplasia is not recommended in patients with an episode of unprovoked PE if there is no clinical or Basic complementary examinations that guide their presence.

9. Hematology health personnel	Activities (2)	
	Hematology Physician	• Carry out the necessary coagulation controls and the corresponding readjustments of the anticoagulant treatment with heparin and / or dicoumarins, so that an adequate level of anticoagulation is maintained. • In the case of UFH, a APTT should be maintained between 1.5 and 2.5 times the upper limit of normality of the control value and in the case of dicoumarins, an INR of around 2.5 (between 2 and 3) should be achieved. • To identify thrombocytopenia secondary to heparin, platelet counts will be performed 24 hours after starting said treatment and after 7-10 days of it. • Rule out states of primary hypercoagulability, in subjects under 50 years with recurrent PE or a strong family history of thromboembolism. Although a hypercoagulable state is suspected early, its study will generally be completed later, once the treatment in the acute phase has been completed, during the outpatient follow-up of the patient. • In the event of recurrences of PE, assess whether they have occurred despite a adequate anticoagulation.

10. Vascular Surgery / Interventional	Activities (2)	
	Doctor of Vascular Surgery or Radiology Interventionist	**Filter placement in the inferior vena cava (IVC)** IVC filters should be considered in: • Patients with acute PE and absolute contraindications to anticoagulation. • In cases of PE recurrence despite therapeutic anticoagulation.

11. Health personnel of the Pulmonology ward	Activities	
	Hospitalize doctor	• Issuance of a clinical report of assistance, where it is clearly specified: the clinical status of the patient, the explorations carried out and those pending with their corresponding dates and with an explicit indication of the place and date of review, to guarantee continuity of care. The treatment must also be specified, including preventive norms and recommendations. • In cases of PE with evidence of proximal DVT, it is recommended to add gradual compression elastic stockings to treatment that should be used routinely to prevent post-thrombotic syndrome. • Inform the patient and family about the process, its favorable factors and the preventive measures to avoid them. Report the side effects of anticoagulant treatment and its interactions with other drugs. • Indicate in the report the date of control and monitoring of anticoagulant treatment by the Hematology service. • Specify in the discharge report the date of review in the Pulmonary Thromboembolism monographic consultation of the Pulmonology Service (Diary NMLX-11).

Note: Activities 12-15 correspond to the outpatient follow-up of the patient and begin after the patient is discharged from hospital. Its purpose is to guarantee continuity of care.

12. S. Admission	Hospital appointment	
	Administrative	• Arrange appointments for follow-up in external consultations. • Computerized registry of affiliation / administrative data of correctly identified and updated patients.

13. Monographic consultation of Pulmonary Thromboembolism Pneumology	Activities (1-3, 13-15)	
	Doctor / Consultation	• Monographic Consultation of PE, belonging to the Pneumology Service (Diary NML-X11), with activity on Wednesdays from 12 to 15 hours • Outpatient follow-up of patients who have been diagnosed with PE, after hospital discharge, the follow-up of these patients must be adequately programmed to verify their response to treatment, their clinical evolution, possible recurrences of DVT / PE and / or complications. • The frequency of the reviews should be individualized based on the presence of risk factors for PTE, the need to expand studies, the magnitude of the previous PTE and its degree of resolution, as well as the presence of comorbidities. • In general, the first check-up of the patient should be scheduled between 6 and 12 weeks after hospital discharge, with check-ups at 3 months, 6 months, and later individualized. This programming will be individualized according to each case. • Patients with PE and DVT will undergo a control venous ultrasound at the 6th month. • After the acute phase of PE, a thrombophilia study will be requested, especially in patients under 50 years of age, without identifiable risk factors for VTE, patients with recurrent VTE, unusual location or family history of VTE. • In patients with unprovoked PE, an extension study to screen for occult neoplasia will be assessed on an individual basis. • In cases of PTE on underlying respiratory pathology, who have been discharged with home oxygen therapy, arterial blood gases will be performed to assess the need for maintenance or withdrawal. • Control D-Dimer will be requested on an individual basis, especially in male patients in whom anticoagulation withdrawal is considered. This determination will be made prior to withdrawal of anticoagulation and one month after stopping treatment. • In cases of PE in which data of right heart dysfunction and / or pulmonary hypertension have been observed in the acute phase, a follow-up echocardiogram will be requested. As well as in all those cases in which chronic thromboembolic pulmonary hypertension (CTEPH) is suspected. • The duration of anticoagulation will be performed individually, taking into account the presence or absence of persistent or transient risk factors for VTE, with a minimum treatment of 3 months. • Extended treatment (without end date) will be assessed in those patients with unprovoked VTE, assessing the risk of bleeding versus the risk of recurrence of VTE during follow-up. • The cases of patients with PE and extended treatment should be followed up in consultation. • ASA is known to be much less effective in preventing VTE recurrence than anticoagulants, so it is not considered an alternative to anticoagulant treatment in patients who have an indication for extended treatment. However, in individualized cases of patients in whom it has been decided to suspend anticoagulation, ASA after anticoagulant treatment reduces the risk of recurrence of VTE after a first unprovoked VTE, without significantly increasing the risk of bleeding, therefore in patients With unprovoked PE in whom anticoagulation is suspended and have no contraindication to ASA, ASA is suggested to prevent VTE recurrence.

14. S. Admission	Prior appointment of Primary Care	
	Administrative	• Good management of appointment deadlines. • Manage an appointment for a Primary Care Physician • Possibility of telephone / online summons

15. Primary Care Physician	Activities	
	Family doctor	• Clinical surveillance of the patient and long-term follow-up • Flexible and agile accessibility, depending on the needs of the patient. • Adequate monitoring of compliance and response to treatment. Specifically, close monitoring of coagulation controls. • Health education. Information on preventive measures for DVT and PE. • Information and promotion of healthy habits and control of risk factors for DVT and PE. • Report the side effects of anticoagulant treatment and its interactions with other drugs. • Periodic surveillance of symptoms-signs of new episodes of DVT and PE. • Correct identification and referral without delay of aggravating situations that require a new Specialized Care consultation.

<table>
<tr><td rowspan="2">Informed consent (Annex 9)</td><td colspan="2">Activities (18)</td></tr>
<tr><td>Health professionals
General considerations</td><td>Law 41/2002, of November 14, basic regulating the autonomy of the patient and rights and obligations regarding information and clinical documentation states that all actions in the field of health of a patient need their free and voluntary consent, being, as a rule, verbal.
However, it will be provided in writing in the following cases:
• surgical intervention
• invasive diagnostic and therapeutic procedures
• in general, in procedures that involve risks or inconveniences of notorious and foreseeable negative repercussions on the health of the patient.
The limits of informed consent are considered:
• When non-intervention poses a risk to public health.
• When he is not able to make decisions, in which case the right will correspond to his family members.
• When the urgency does not allow delays due to the possibility of causing irreversible injuries or there is a danger of death.
Consent by representation will be granted in the following cases:
• When the patient is not able to make decisions, at the discretion of the doctor responsible for the care, or his physical or mental condition does not allow him to take charge of his situation. If the patient does not have a legal representative, consent will be given by the people related to him for family or de facto reasons.
• When the patient is legally incapacitated.
• When the minor patient is not intellectually or emotionally capable of understanding the scope of the intervention. In this case, consent will be given by the minor's legal representative after hearing his opinion if he is twelve years old. In the case of minors who are not incapable or incapacitated, but emancipated or have reached the age of sixteen, consent cannot be given by proxy. However, in the event of a serious risk action, according to the discretion of the physician, the parents will be informed and their opinion will be taken into account when making the corresponding decision.
The provision of consent by representation will be appropriate to the circumstances and proportionate to the needs to be attended, always in favor of the patient and with respect for their personal dignity. The patient will participate as much as possible in decision-making throughout the healthcare process. If the patient is a person with a disability, they will be offered the relevant support measures, including information in appropriate formats, following the rules set by the principle of design for all in a way that is accessible and understandable to people with disabilities, in order to favor that you can give your consent.</td></tr>
</table>

1. Entry through Family Doctor (FD) Consultation and Primary Continuing Care Point (PCCP)

The clinical presentation of PE is highly variable, sometimes with little clinical expression and nonspecific symptoms such as unexplained sudden-onset dyspnea, tachypnea, pleuritic chest pain, anxiety, cough, hemoptysis, and syncope, so its clinical suspicion and diagnosis is a genuine challenge for FD. Its clinical suspicion is crucial for proper decision-making, which will clearly influence the patient's prognosis, taking into account that without treatment, PE is associated with a mortality of 30%, which is reduced to 2-8%, after a accurate diagnostic identification followed by appropriate anticoagulant treatment.

Due to the characteristics of Primary Care, without immediate access to complementary laboratory studies (D-dimer) or specific imaging tests, the diagnostic suspicion will be based solely on a detailed anamnesis, the evaluation of risk factors (Table 1), a clinical suggestive (Annex 2) and clinical probability scales (Wells and Geneva) (Annex 3).

COMPONENTS:

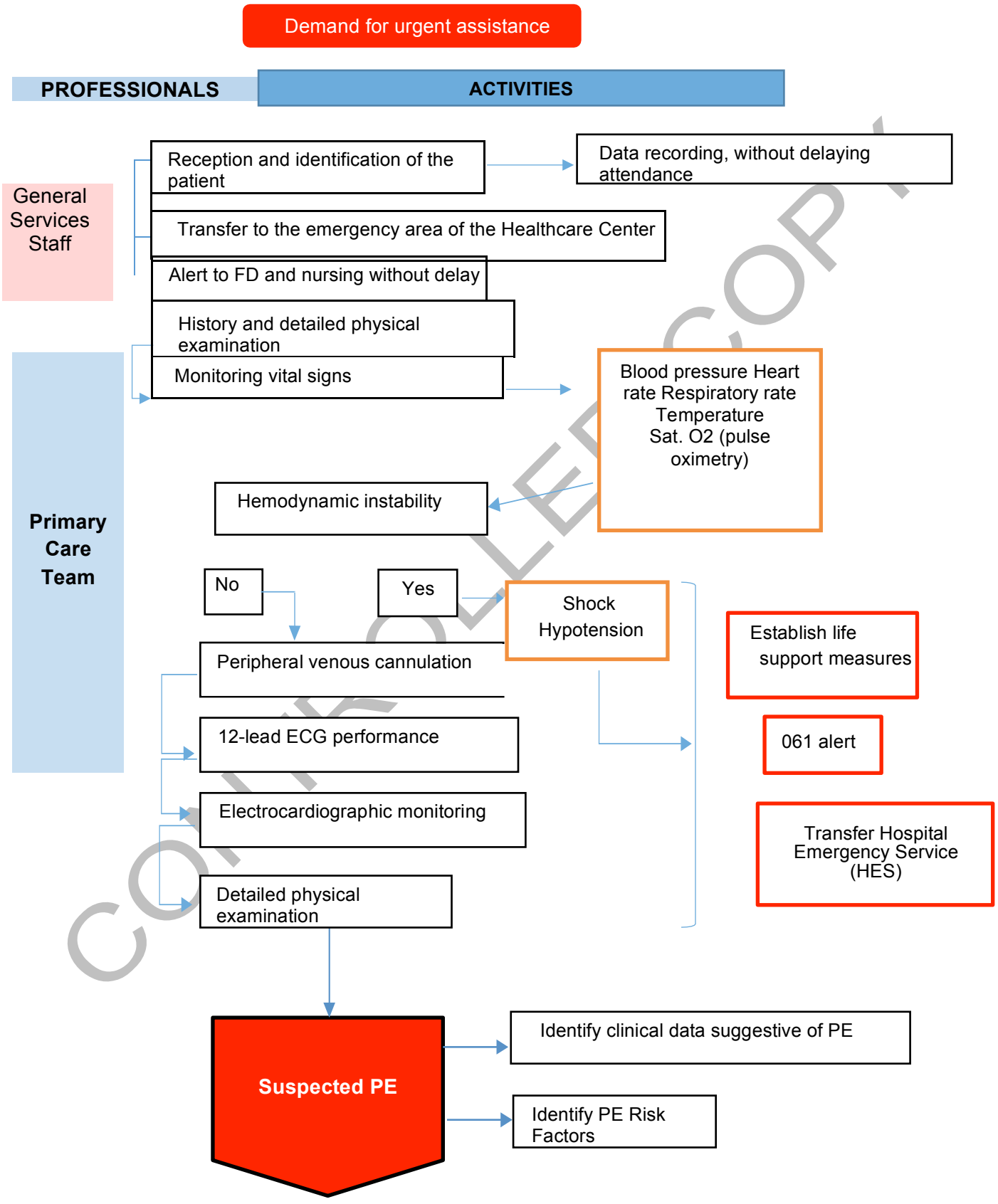
What	Urgent consultation at the Health Center.
Who	**Administrative**
Activity	Reception and identification of the patient.
	Registration of the demand for medical assistance.
	Basic reason for consultation.
	Alert responsible MAP without delay.
	Responsible nurse alert without delay.
	Location of the patient in the emergency room of the health center.
	Collaboration availability if necessary.

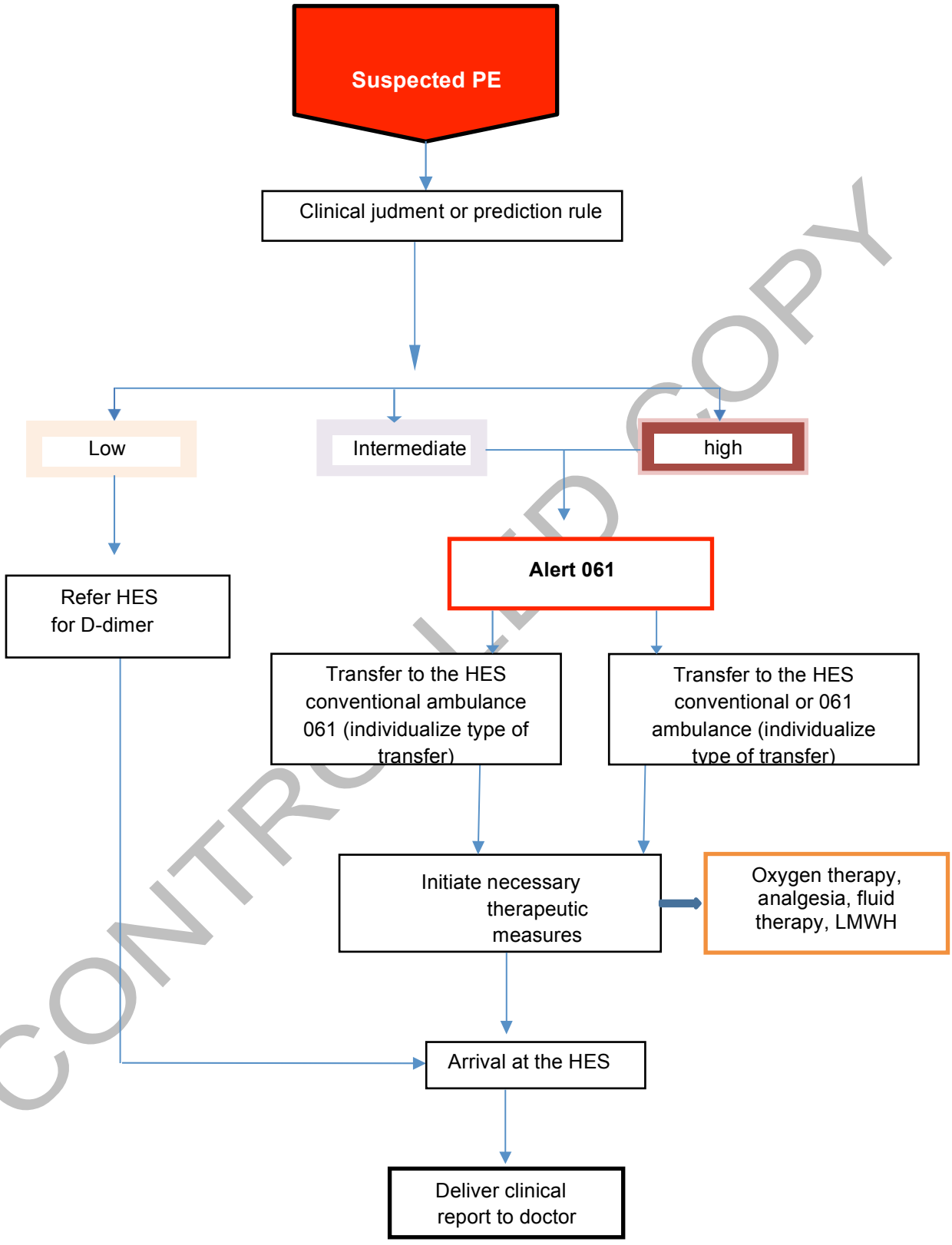
What	Urgent consultation at the Health Center.
Who	**Nurse**
Activity	Constant monitoring
	Cardiac monitoring
	ECG performance
	Peripheral venous cannulation.
	Administration of drugs if required for it.

What	Urgent consultation at the Health Center
Who	**MAP**
Activity	Anamnesis of the episode.
	Detailed physical examination.
	Perform a differential diagnosis with other clinical entities.
	Establish the clinical suspicion of PE from RF and compatible clinical data
	Hemodynamic stability / instability assessment of the patient.
	Initiate the necessary therapeutic measures.
	Establish the probability of PE based on the Wells / Geneva scales.
	Indicate the transfer based on your clinical suspicion.
	Indicate the modality of transfer based on the probability of PE.
	Activate 061 if you need a medical transfer.
	Issue a clinical report to ensure continuity of care.
	Inform the patient and family.

PROCESS ARCHITECTURE

2. 2. Entry through Family Doctor Consultation and Primary Continuing Care Point (PCCP)





COMPONENTS

2. Entry through Family Doctor (FD) Consultation and Primary Continuing Care Point (PCCP)

1. Identification and receipt of patient	Activities	
	General Services Staff	• Receive and identify the patient, recording their affiliation data, if the situation allows it and without delaying medical assistance. • Transferring the patient to the area of the Health Center destined to the care of emergencies and emergencies, will identify the basic reason why the patient demands medical assistance and will immediately alert the doctor and nurse responsible for the patient. • The general services staff will be attentive and available to help health professionals in whatever they may need (undressing the patient, helping to mobilize him ...) • He will be in charge of establishing communication with the 061 health emergency center in case it is required to do so by health professionals. • The transfer will be carried out if necessary in a wheelchair or stretcher, prioritizing the care of those who present signs of instability or impairment of the general condition

2. General care protocol for patients with suspected PE in PC	Activities	
	AP Nurse	• Record of vital signs: blood pressure, heart rate, temperature, respiratory rate and oxygen saturation) • Peripheral venous access cannulation with a three-step key if required • 12-lead ECG. • Patient monitoring if required.
	Family doctor	• In critically ill patients with hemodynamic instability or shock, look for causes and treat identifiable ones (arrhythmias, sepsis, …). Establish the necessary life support measures in each case and immediately alert the 061 to make the transfer to the Hospital Emergency Service in a medicalized device for stabilization and definitive treatment. • Perform a detailed history and systematic physical examination to establish a suspected diagnosis of PE. • Look specifically for risk or predisposing factors (Table 1). • Search for the clinical data most frequently associated with PE (Table 2). • Vital signs, risk factors, and clinical data suggestive of PE should be recorded in the care report. • Estimate the clinical probability of PE, associating the presence of risk factors and typical clinical data of PE, using the Wells and Geneva clinical probability scales (Table 3 and 4), stratifying the patients in probability, low , intermediate and high. • In those patients without hemodynamic instability considered "high probability" and a variable proportion of those with "intermediate probability" (depending on the individual assessment of each case), they will be considered as "well-founded or reasoned clinical suspicion of PE". In them there will be strict surveillance and control of the physical state and constants, continuous ECG monitoring and oximetry, with transfer to the HES through 061 in a medicalized ambulance as quickly as possible. Whenever possible, the destination hospital will be notified. • During the transfer, continuous ECG and oximetry monitoring, constant recording, permanent clinical evaluation and appropriate treatment will be carried out for the clinical suspicion. Therapeutic measures with IV or SC heparin will be instituted, except for contraindications (IV UFH, in case of suspicion of massive PE, unstable patient and given the need for immediate reversibility), supplementary oxygen therapy in case of hypoxemia, improvement of the hemodynamic situation in unstable patients and correct pain control. • Patients with a clinical probability of intermediate PE will be transferred urgently to the HES using a conventional xxx ambulance. The need to carry out the medical transfer will be individualized. • Patients with a low clinical probability of PE should be referred to the HES for a D-dimer to rule out the clinical suspicion established in Primary Care. • In any case, the doctor will be in charge of informing the patient and family about the process and about the decision made. A clinical report will be issued specifying: history, current clinical history of the patient, physical examination, constants, and treatment administered and the complementary tests performed (ECG, chest X-ray, etc.) will be attached. • The transfer of the patient will be carried out by providing said clinical report to the receiving doctor, who will collect the relevant information and include the clinical course and treatment provided.

Follow-up in PC after hospitalization for PTE	Activities	
	Primary care team	• After the patient is discharged from the hospital, the primary care team will contact the patient through the "Conecta 72" program. • The medical treatment upon discharge of the patient must be correctly reconciled with the patient's usual medication and correctly updated the prescription sheet with the prescriptions correctly issued in IANUS and with the estimated duration of the treatment, so that the patient can go to the pharmacy office to withdraw the prescribed medication after discharge. It will basically consist of dicoumarinics, which will be kept for a minimum of 3 to 6 months, with the corresponding controls to achieve an INR between 2 and 3. • Accessibility to the primary care team must be flexible and agile, depending on the needs of the patient. They will be in charge of adequately monitoring compliance and response to treatment. Specifically, close monitoring of coagulation controls. They will establish health education measures with information on preventive measures for DVT and PE, as well as information and promotion of healthy habits and control of risk factors for DVT and PE. • The patient will be informed of the collateral effects of anticoagulant treatment and its interactions with other drugs. • The appearance of symptoms or signs of new episodes of DVT and PE will be periodically monitored, before which a new Specialized Care consultation will be sent without delay.

7. EVALUATION INDICATORS (19)

1. Image confirmation of the diagnosis of PE.

Definition: percentage of patients with a confirmed diagnosis of PE by some imaging test. The rationale for this indicator is that although the suspicion of PE is sufficient to initiate urgent treatment with heparin, it must always be confirmed by imaging before establishing a definitive diagnosis that will mean keeping a patient anticoagulated for months.

- Standard: 90%
- Source: Electronic clinic hour (audits)
- Result 2016: 99.1%

2. Risk stratification of the patient with a diagnosis of pulmonary thromboembolism.

Definition: percentage of patients in whom risk stratification has been recorded in the medical history using the prognostic scale of mortality at 30 days Pulmonary Embolism Severity Index (PESI) or its simplified form (PESIs).

- Standard: 90%
- Source: Electronic clinic hour (audits)
- Result 2016: 100%

3. Treatmentof recanalization in high-risk PE without contraindications.

Definition: The basis for this indicator is based on the fact that fibrinolytic treatment is indicated in high-risk cases of PE (in our Complex, priority is given to the use of rTPA), usually systemic. If this fails, there is a risk of imminent death or a high risk of bleeding (3 or more points on the HAS-BLED scale), pharmacoinvasive fibrinolytic treatment will be proposed (available as of 2017).

- Formula:

$$\frac{\text{Nº patients with high-risk PE receiving reperfusion treatment}}{\text{Total of patients with high-risk PE without contraindications}} \times 100$$

- Standard:> 75%
- Source: Electronic clinic hour (audits)
- Result 2016: 100%

4. Mortality

4.1. In-hospital mortality (from any cause).

Definition: percentage of patients diagnosed with PE who die during their hospital stay from any cause.

- Formula:

$$\frac{\text{Nº of patients admitted for PE who died during admission due to any cause}}{\text{Total patients admitted for PE}} \times 100$$

- Standard: <10%
- Source: CMBD-H
- Result 2016: 1.9%

4.2. Overall mortality at 30 days

Definition: percentage of patients diagnosed with PE who die during the first month after admission, from any cause.

- Standard: <5%
- Source: Registry of the Pulmonology Service
- Result 2016: 1.9%

4.3. Specific mortality at 30 days

Definition: percentage of patients diagnosed with PTSD who die during the first month after admission, due to a cause directly related to the PTSD.

- Standard: <10%
- Source: Registry of the Pulmonology Service
- Result 2016: 0.9%

5. Percentage of non-fatal major bleeds at 30 days

Definition: percentage of patients diagnosed with PTE who, during the first month after admission, present a bleeding episode from any location that requires hospital admission.

- Standard: <4%
- Source: Registry of the Pulmonology Service
- Result 2016: 3.8%

6. Readmissions for any reason during the first 30 days after initial discharge.

Definition: percentage of patients who are readmitted for any cause in the 30-day period after initial hospital discharge due to ET

- Standard: <8%
- Source: Registry of the Pulmonology Service
- Result 2016: 7.5%

7. Readmissions for PTE during the first 30 days after initial discharge.

Definition: percentage of patients who are readmitted with the same diagnosis of PE in the 30-day period after initial hospital discharge.

- Standard: <4%
- Source: Registry of the Pulmonology Service
- Result 2016: 0.9%

8. Follow-up of patients in a monographic PET consultation

Definition: percentage of patients with a diagnosis of PE who are followed up in a monographic consultation.

- Standard:> 75%
- Source: Clinical Application. Pneumology Service Registry.
- Result 2016: 89.6%

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10.ANNEXES

Annex 1. Risk factors for thromboembolic disease

Strong risk factors (OR > 10)
Fracture of lower limb
Hospitalization for heart failure or atrial fibrillation/flutter (within previous 3 months)
Hip or knee replacement
Major trauma
Myocardial infarction (within previous 3 months)
Previous VTE
Spinal cord injury
Moderate risk factors (OR 2-9)
Arthroscopic knee surgery
Autoimmune diseases
Blood transfusion
Central venous lines
Intravenous catheters and leads
Chemotherapy
Congestive heart failure or respiratory failure
Erythropoiesis-stimulating agents
Hormone replacement therapy (depends on formulation)
In vitro fertilization
Oral contraceptive therapy
Post-partum period Infection (specifically pneumonia, urinary tract infection, and HIV)
Inflammatory bowel disease
Cancer (highest risk in metastatic disease)
Paralytic stroke
Superficial vein thrombosis
Thrombophilia
Weak risk factors (OR < 2)
Bed rest >3 days
Diabetes mellitus
Arterial hypertension
Immobility due to sitting (e.g. prolonged car or air travel)
Increasing age
Laparoscopic surgery (e.g. cholecystectomy) Obesity
Pregnancy
Varicose veins

Annex 2. Suggestive PE Clinic

CLINICAL SUSPECT
New onset dyspnea
Worsening of habitual dyspnea
Pleuritic pain
Syncope or presyncope Haemoptysis
Lower limb pain
Anxiety and palpitations

Annex 3. Clinical prediction rules for pulmonary embolism

WELLS Clinical Prediction Rule	Points
No more likely alternative diagnosis	3
Signs of DVT	3
Previous PE or DVT	1.5
HR> 100	1.5
Surgery or immobilization in the previous 4 weeks	1.5
Cancer treated during the previous 6 months or in palliative treatment	1
Hemoptysis	1
Low probability: 0-1 **Intermediate: 2-6 points** **High: ≥ 7 points**	

GENEVA Clinical Prection Rule for PE	Points
Age> 65 years	1
Previous PE or DVT	3
Surgery or fracture within the past 1 month	2
Active cancer	2
Unilateral lower-limb	3
Haemoptysis	2
75-94 b.p.m	3
≥ 95 b.p.m	5
Tenderness in LES and unilateral edema	4
Low probability: 0-3 **Intermediate: 4-10** **High: ≥ 11 Points**	

Annex 4. PIOPED diagnostic criteria in V / Q scintigraphy

PROBABILITY	Clinical feature
HIGH	• 2 or more large segmental perfusion defects (> 75% of a segment) with no abnormalities on ventilation scan or chest radiograph, or substantially greater than ventilation defects or abnormalities coincident radiological. • One large segment and 2 or more moderate segmental perfusion defects (> 25% and ≤75% of a segment), with no coincident alterations on ventilation scan or chest radiograph. • 4 or more moderate segmental perfusion defects with no abnormalities on ventilation scan or chest radiograph.
INTERMEDIATE	• That which is not diagnostic, or that which does not meet the criteria to be defined as high or low probability, but which is not considered normal either.
SHORT	• More than 3 small segmental perfusion defects (<25%), or one perfusion defect of any size on chest radiograph with obvious abnormality.

Annex 5. Echocardiographic markers of RV dysfunction

ECHOCARDIOGRAPHIC MARKERS OF RV DYSFUNCTION
Tricuspid planne systolic excursion (TAPSE) PSAP
RV Dimensions: Baseline and Mid DTD
RVOT flow (pulsed doppler): Pulmonary transvalvular acceleration time
Pulmonary insufficiency (continuous doppler)

Annex 6. Clinical prognostic assessment scales: Pulmonary Embolism Severity Index (PESI) and simplified PESI (PESIs)

Pulmonary Embolism Severity Index (PESI)	
Parameter	Points
Age	Years
Male sex	+10
Cancer	+30
Chronic heart failure	+10
Chronic pulmonary disease	+10
Pulse rate ≥ 110	+20
Systolic blood pressure <100 mmHg	+20
Respiratory Rate >30 breaths per min	+30
Temperature < 36ºC	+20
Altered mental status	+20
Arterial Sat O2 <90%	+60
	+20
Class I ≤ 65 points **Class II 66 – 85** **Class III 86 – 105** **Class IV 106- 125** **Class V >125**	

Simplified PESI	
Age> 80 years	1
Cancer	1
Chronic cardiopulmonary disease	1
Heart rate ≥ 110 / min	1
Systolic Blood pressure <100 mmHg	1
$SatO_2$ <90%	1
Low risk: 0 points **High Risk: ≥ 1 point (s)**	

Annex 7. Treatment guidelines for the acute phase of PE
(current options included in the Clinical Guidelines)

Beginning	Dose	Interval
Bemiparin	115 IU / kg	Every 24 h
Dalteparin	100 IU / kg 200 IU / kg	Every 12 h Every 24 h
Enoxaparin	1.0 mg / kg 1.5 mg / kg	Every 12 h Every 24 h
Nadroparin	85.5 IU / kg 171 IU / kg	Every 12 h Every 24 h
Tinzaparin	175 IU / kg	Every 24 h
Fondaparinux	5.0 mg (<50 kg) 7.5 mg (50-100 kg) 10 mg (> 100 kg)	Every 24 h
Heparin no fractional	18 IU / kg / h	Perfusion
THROMBOLITHICS		
r-TPA	100 mg 0.6 mg / kg in 15 min (maximum dose, 50 mg)	In 2 h
Urokinase	4,400 IU / kg as a 10-minute loading dose, followed by 4,400 IU / kg / h Accelerated regimen: 3 million IU	In 12-24 h In 2 h
DIRECT ACTION ANTICOAGULANTS *		
Apixaban	10 mg (day 1-7) 5 mg (from day 8) 2.5 mg (from 3 months)	Every 12 hours Every 12 hours Every 12 hours
Dabigatran	150mg Days 1-5 in combination with LMWH	Every 12 hours
Rivaroxaban	15 mg (days 1-21) 20 mg (from day 22)	Every 12 h Every 24 h
Edoxaban	60 mg Days 1-5 in combination with LMWH	Every 24 h

rtPA: recombinant tissue plasminogen activator.
*** The table shows direct-acting anticoagulants indicated for the treatment of venous thromboembolic disease at the time of EPI approval. It should be noted that none of them have been funded to date with this indication**.

Annex 8. Haemorrhagic risk. HAS-BLED scale

PARAMETERS	POINTS	BLEEDING RISK
Uncontrolled hypertension	1	
Abnormal liver/renal function	1	0- 2: low
Previous stroke	1	≥ 3: high
Bleeding history or predisposition	1	
Labile INR (time in therapeutic range <60%)	1	
Age >65 years	1	
Concomitant drugs or alcohol		

Annex 9. Informed consent model

INFORMED CONSENT

- Article 8 of Law 41/2002, of November 14, regulating basic patient autonomy and rights and obligations regarding information and clinical documentation.
- Article 4 of Law 3/2001, of May 28, regulating the informed consent and clinical history of patients, modified by Law 3/2005 of March 7.

INVASIVE DRUG TREATMENT OF PULMONARY THROMBOEMBOLISM

Patient's data:

Mr./Doña _____ higher from age,

with DNI _____, address at: _____

_____

_____

and phone _____

I declare that:

- I was informed by Dr./a _____ belonging to the Service of _____ **of the University Hospital Complex of Santiago**, on the characteristics of the drug-invasive treatment procedure for pulmonary thromboembolism, as well as the possibility of modifying the planned technique if an unexpected situation arises.
- I understand the information received about the objective of the procedure, the existing risks and foreseeable complications derived, and the expected benefits, having formulated and satisfactorily clarified the doubts presented.

INVASIVE DRUG TREATMENT OF PULMONARY THROMBOEMBOLISM

CONSENT STATEMENT

Consequently, I freely and consciously decide to grant consent for the performance of the drug-invasive treatment procedure for pulmonary thromboembolism, knowing that I can revoke it at any time prior to its performance, without the need to state the cause for the revocation.

Santiago de Compostela, to_____from_____of 20

PATIENT'S SIGNATURE SIGNATURE OF OPTIONAL /LEGAL REPRESENTATIVE

The patient / legal representative receives a copy of this document

REVOCATION OF CONSENT

Mr./Doña _____higher from age,
with DNI_____and address at:_____
_____
_____

I revoke with date _____the consent granted to carry out the drug-invasive treatment procedure for pulmonary thromboembolism.

PATIENT'S SIGNATURE
/LEGAL REPRESENTATIVE

PATIENT INFORMATION

INVASIVE DRUG TREATMENT OF PULMONARY THROMBOEMBOLISM

What does it consist of

It is a treatment that serves to reopen any of your central pulmonary arteries occluded by a thrombus or embolus and prevent right heart failure from occurring with hemodynamic (hypotension, dizziness, loss of consciousness), respiratory (dyspnea, feeling of suffocation) and respiratory work), a pulmonary infarction, or avoid the progression of cardio-respiratory instability, if this has already occurred, which endangers their integrity and quality of life. The procedure is performed with an angiography equipment (digital) by expert personnel from the Interventional Cardiology Department. Local anesthesia is usually used in the area of vascular puncture, and occasionally sedation. A venous blood vessel is punctured, usually in the groin and then flexible tubes are inserted into it. called catheters, which will reach the main pulmonary vessels that come out of the right side of your heart. Through the catheter that is advanced to the lesion to be treated, pharmacological agents are introduced to dissolve the thrombi (fibrinolytic - alteplase, rtPA) or devices until the clot lodged in the artery to be treated is destroyed or removed. As a general rule, after the procedure, you will be admitted to the Intensive Care Unit (ICU) to continue with the treatment and with the necessary measures to try to stabilize and overcome this serious clinical situation. To control the development of the procedure, an iodinated contrast (which is introduced through the catheters) and X-rays, which are ionizing radiation, are used. After the procedure, these tubes will be removed and compressed by hand and that will reach the main pulmonary vessels emerging from the right side of your heart. Through the catheter that is advanced to the lesion to be treated, pharmacological agents are introduced to dissolve the thrombi (fibrinolytic - alteplase, rtPA) or devices until the clot lodged in the artery to be treated is destroyed or removed. As a general rule, after the procedure, you will be admitted to the Intensive Care Unit (ICU) to continue with the treatment and with the necessary measures to try to stabilize and overcome this serious clinical situation. To control the development of the procedure, an iodinated contrast (which is introduced through the catheters) and X-rays, which are ionizing radiation, are used. After the procedure, these tubes will be removed and compressed by hand and that will reach the main pulmonary vessels emerging from the right side of your heart. Through the catheter that is advanced to the lesion to be treated, pharmacological agents are introduced to dissolve the thrombi (fibrinolytic - alteplase, rtPA) or devices until the clot lodged in the artery to be treated is destroyed or removed. As a general rule, after the procedure, you will be admitted to the Intensive Care Unit (ICU) to continue with the treatment and with the necessary measures to try to stabilize and overcome this serious clinical situation. To control the development of the procedure, an iodinated contrast (which is introduced through the catheters) and X-rays, which are ionizing radiation, are used. After the procedure, these tubes will be removed and compressed by hand and Through the catheter that is advanced to the lesion to be treated, pharmacological agents are introduced to dissolve the thrombi (fibrinolytic - alteplase, rtPA) or devices until the clot lodged in the artery to be treated is destroyed or removed. As a general rule, after the procedure, you will be admitted to the Intensive Care Unit (ICU) to continue with the treatment and with the necessary measures to try to stabilize and overcome this serious clinical situation. To control the development of the procedure, an iodinated contrast (which is introduced through the catheters) and X-rays, which are ionizing radiation, are used. After the procedure, these tubes will be removed and compressed by hand and Through the catheter that is advanced to the lesion to be treated, pharmacological agents are introduced to dissolve the thrombi (fibrinolytic - alteplase, rtPA) or devices until the clot lodged in the artery to be treated is destroyed or removed. As a general rule, after the procedure, you will be admitted to the Intensive Care Unit (ICU) to continue with the treatment and with the necessary measures to try to stabilize and overcome this serious clinical situation. To control the development of the procedure, an iodinated contrast (which is introduced through the catheters) and X-rays, which are ionizing radiation, are used. After the procedure, these tubes will be removed and compressed by hand and rtPA) or devices to destroy or extract the clot lodged in the artery to be treated. As a general rule, after the procedure, you will be admitted to the Intensive Care Unit (ICU) to

continue with the treatment and with the necessary measures to try to stabilize and overcome this serious clinical situation. To control the development of the procedure, an iodinated contrast (which is introduced through the catheters) and X-rays, which are ionizing radiation, are used. After the procedure, these tubes will be removed and compressed by hand and rtPA) or devices to destroy or extract the clot lodged in the artery to be treated. As a general rule, after the procedure, you will be admitted to the Intensive Care Unit (ICU) to continue with the treatment and with the necessary measures to try to stabilize and overcome this serious clinical situation. To control the development of the procedure, an iodinated contrast (which is introduced through the catheters) and X-rays, which are ionizing radiation, are used. After the procedure, these tubes will be removed and compressed by hand and To control the development of the procedure, an iodinated contrast (which is introduced through the catheters) and X-rays, which are ionizing radiation, are used. After the procedure, these tubes will be removed and compressed by hand and To control the development of the procedure, an iodinated contrast (which is introduced through the catheters) and X-rays, which are ionizing radiation, are used. After the procedure, these tubes will be removed and compressed by hand and
/ or compression mechanisms at the puncture site so that blood does not accumulate (hematoma).

Risks that the procedure may present

Most stable patients undergoing this treatment do not experience any serious complications, although the patient may feel slight discomfort at the site of introduction of local anesthesia or venipuncture. It is not detrimental to the patient. In more unstable and serious patients, at risk of death prior to the procedure, serious complications may occur, not only derived from the technique but also from the serious clinical situation itself produced by Massive Pulmonary Thromboembolism. Death may occur.

More frequent and less serious risks

- Those common to any angiography or catheterization, such as the formation of a clot (thrombus) in the vessel under study, in the tube (catheter) or in the place of vascular access that could exceptionally leave no venous return to the lower extremity that is punctures. As a consequence, edema, swelling, accumulation of blood or hematoma may appear at the puncture site, although this occurs only in 5% of cases.
- The derivatives of the use of iodinated contrast that could, exceptionally, trigger an allergic reaction. This is usually mild and immediate (urticaria, itching, redness, ...) or very unlikely serious (laryngeal edema, drop in blood pressure, ...), and death may occur in one in every one hundred thousand studies.

Less frequent and more serious risks

- Rupture of the pulmonary artery to be treated and bleeding as a result of it, which can cause severe pulmonary hemorrhage that could require urgent surgical intervention or invasive measures for its treatment.

- Although medications are used to reduce coagulability, during embolization a new thrombus could form in one of the pulmonary arteries near the injury, or as a result of the medications used to reopen the vessel, pulmonary hemorrhage or some adverse effect could be facilitated not previously described since alteplase is not yet authorized for use as pharmacoinvasive therapy, however, its molecular and pharmacokinetic characteristics make it suitable for this indication.
- X-rays are used which are ionizing radiation. Its use is very safe and its advantages far outweigh its drawbacks. However, there are some risks, even if they are minimal, derived from radiation. In adults, the probability of tumor development as a consequence of radiation is remote.
- Complications could be fatal and even lead to death, more rarely in stable patients than in the most unstable and severe.

Custom risks:

- If you are allergic to metals or iodine (contrast media), you should warn this before performing this test.
- In cases of heart or kidney disease, these pathologies could be aggravated by the use of iodinated contrast.

Contraindications

There are no absolute contraindications except if you have a known Ehlers Danlos disease.

Possible alternatives

- Currently, the most accessible alternative that exists is the introduction of a drug capable of dissolving thrombi in the pulmonary arteries (fibrinolysis) through a peripheral or central venous catheter. They are treatments similar to those used in thrombectomy but with doses 3 times higher than that used in this technique, which would significantly multiply the risk of bleeding and without the possibility of obtaining an image that confirms its efficacy.
- Another alternative that exists is cardiac surgery with extracorporeal circulation ("open heart") reserved for severely ill patients with large thrombi at the origin of the pulmonary arteries and who are allergic to fibrinolytic drugs. Before signing this document, if you want more information or have any questions, do not hesitate to ask the medical team, being treated with pleasure.

Particular situations and individualized risks according to the clinical situation

In your specific case (* specify if necessary :)

_____
_____
_____
_____

Other considerations

_____
_____
_____
_____