Thrombolytic options in view of global alteplase shortage

Rapid Trust-wide Guidelines

This guidance does not override the individual responsibility of health professionals to make appropriate decision according to the circumstances of the individual patient in consultation with the patient and /or carer. Health care professionals must be prepared to justify any deviation from this guidance.

Introduction

The National Patient Safety Alerting Committee have issued a National Patient Safety Alert titled "Shortage of alteplase and tenecteplase injections" – NatPSA/2022/006/DHSC on 3rd August 2022- see appendix 1.

There will be supply constraints facing alteplase (Actilyse®) 10mg, 20mg and 50mg injections for the remainder of 2022. Tenecteplase (Metalyse®) 10,000unit injections will go out of stock in the coming months. At present the situation is expected to improve in early 2023.

Alteplase is licensed for thrombolytic treatment of acute ischaemic stroke, acute myocardial infarction (MI) and acute massive pulmonary embolism (PE) with haemodynamic instability. Tenecteplase is licensed for the management of acute MI.

Boehringer Ingelheim is the sole supplier of both these products in the UK. There are manufacturing constraints causing global issues with the supply of these products.

With the above in mind, through rapid dissemination of information and completing the actions outlined in the NPSA alert, this guideline has been developed by University Hospitals Plymouth and locally adapted to help with dosing and administration of thrombolytics.

This guideline is for use by the following staff groups:

All qualified healthcare professionals involved in prescribing or administering thrombolytic therapy in adult patients in the emergency departments or inpatient wards at Worcestershire Acute NHS Trust

Lead Clinician(s)

Lindsay Stewart	Clinical Team Lead Pharmacist, Speciality Medicine
Keith Hinton	Clinical Team Lead Pharmacist, Critical Care, Surgery and Theatres
Approved by Trust Thrombosis Committee on:	14th September 2022
Approved by Medicines Safety Committee on:	14th September 2022
Review Date: This is the most current document and should be used until a revised version is in place	14th September 2025

Key amendments to this guideline

Date	Amendment	Approved by:
September 2022	New document	TTC, MSC

Indications and First-line thrombolytic agents as agreed across specialities in response to NPSA Alert

Indication	First Line Thrombolytic Agent	Areas Stocked in hospital
Acute Ischaemic Stroke	Alteplase	Emergency Departments, ASU, Pharmacy
Myocardial Infarction	Streptokinase or Tenecteplase	Emergency Departments, Pharmacy, CCU's, Cardiac Catheter Lab.
Cardiac arrest and presumed PE*	Tenecteplase (or alteplase if no tenecteplase – consultant decision only) Streptokinase if alteplase stock level is critically low (communication will be issued)	Emergency Departments, Pharmacy, Critical Care Units
Pulmonary Embolism with haemodynamic instability*	Streptokinase	Emergency Departments, Pharmacy, Critical Care Units
DVT requiring thrombolysis	Streptokinase	Emergency Departments, Pharmacy, Critical Care Units, MAU's, Laurel 1 vascular
Catheter directed thrombolysis of DVT	Urokinase	Interventional radiology, Laurel 1 Vascular, Pharmacy
Acute occlusive Peripheral Arterial Disease with limb threatening ischaemia	Urokinase or Streptokinase	Interventional radiology, Laurel 1 Vascular, Pharmacy
Thrombosed intravascular catheters and cannulae	Urokinase	Interventional radiology, Laurel 1 Vascular, Pharmacy, Rowan Oncology, Laurel 3
Pleural Infection	Urokinase (to be used in conjunction with dornase alfa)	Ward 5, ARU.

* Patient should be a candidate for level 3 care and meet the criteria for shock prior to administration decided by a senior decision maker. The ESC guidance has useful definitions of haemodynamic compromise / instability which include:

- Obstructive shock (systolic BP <90 mmHg or vasopressors required to achieve a BP ≥90 mmHg despite an adequate filling status, in combination with end-organ hypoperfusion), or
- Persistent hypotension (systolic BP <90 mmHg or a systolic BP drop ≥40 mmHg for >15 min, not caused by new-onset arrhythmia, hypovolaemia, or sepsis).

Where patients are ineligible for the first line therapies, a multi-disciplinary discussion must be undertaken including either the Director of Pharmacy, Deputy Director of Pharmacy or a senior pharmacist to discuss and agree use of any alternative thrombolytic agent. The outcome of these discussions and decision made should be recorded on Datix for monitoring of deviation from this guideline.

1. Alteplase

Alteplase is to be conserved for acute ischaemic stroke thrombolysis.

Decision to treat with alteplase requires consultant approval.

Stock in the Emergency department will be treated as a controlled drug, requiring enhanced record keeping for stock management.

Where requests for alteplase come during working hours outside of the emergency department, these should be supplied via the ward pharmacy team after being screened by the ward clinical pharmacist.

Acute Ischaemic Stroke

Please follow dosing guidance as agreed by the on call stroke consultant. This may be based on a reduced dose (0.6mg/kg) as used in the ENCHANTED trial protocol (Low-Dose versus Standard-Dose Intravenous Alteplase in Acute Ischemic Stroke | NEJM). Please use the dose banding table for either the 0.6mg/kg or the 0.9mg/kg as advised, see tables below:
Until our alteplase stock has been restored, these dosing tables supersede those within the current stroke thrombolysis guideline (PF WR5000 Thrombolysis Proforma Version 1 Jan 2016[2].pdf)

For any concerns regarding the alteplase dosing for stroke thrombolysis, please contact the stroke team via the on call stroke consultant or stroke CNS (Bleep 597).

Dose banding for 0.6mg/kg alteplase dosing (low dose- unlicensed)				
Weight Band	Total dose in mls using 1mg/ml solution*	10% Bolus dose given over 1-2 minutes (in mls of 1mg/ml)	Infusion dose = Infusion rate in mls/hr	Vials to use
40-50kg	27	3	24	1 x 50mg
51-60kg	33	3	30	1 x 50mg
61-70kg	39	4	35	1 x 50mg
71-80mg	45	4	41	1 x 50mg
81-90kg	50	5	45	1 x 50mg
91-100kg	57	6	51	1 x 50mg + 1 x 20mg**
>100kg	60	6	54	1 x 50mg + 1 x 20mg **

Dose banding for 0.9mg/kg alteplase dosing (standard dose- licensed)				
Weight Band	Total dose in mls using 1mg/ml solution*	10% Bolus dose given over 1-2 minutes (in mls of 1mg/ml)	Infusion dose = Infusion rate in mls/hr	Vials to use
40-50kg	40	4	36	1 x 50mg
51-60kg	49	5	44	1 x 50mg
61-70kg	58	6	52	1 x 50mg + 1 x 20mg**
71-80kg	67	6	61	1 x 50mg + 1 x 20mg**
81-90kg	76	7	69	2 x 50mg
91-100kg	85	8	77	2 x 50mg
>100kg	90	9	91	2 x 50mg

*Mid-point of weight band used for dose banding
** Use 1 x 50mg and 1 x 20mg if available, if no 20mg available use 2 x 50mg

Cardiac arrest and presumed PE

Alteplase 50mg IV bolus over 2 minutes then – if still in cardiac arrest 50mg IV after 30 minutes

2. Tenecteplase
Indication: Acute myocardial infarction/ PE with cardiac arrest

Dose: by intravenous injection: 30–50 mg (max. per dose 50 mg), dose to be given over 10 seconds and initiated within 6 hours of symptom onset, dose varies according to body weight – see table below.

Patients' bodyweight	Tenecteplase (Units)	Tenecteplase (mg)	Corresponding volume of solution (ml)
< 60	6,000	30	6
≥ 60 to < 70	7,000	35	7
≥ 70 to < 80	8,000	40	8
≥ 80 to < 90	9,000	45	9
≥ 90	10,000	50	10

Table from Tenecteplase SPC

Further information is available on Medusa Homepage (wales.nhs.uk)®

3. Streptokinase

1. Alternative choice agent for thrombolysis in myocardial infarction and pulmonary embolism/DVT where thrombolysis required.
2. An accelerated regimen of 1,500,000 units (1.5MIU) may be infused over two hours, as outlined in the European Society of Cardiology Guidelines for the diagnosis and management of acute pulmonary embolism developed in collaboration with the European Respiratory Society (ERS): The Task Force for the diagnosis and management of acute pulmonary embolism of the European Society of Cardiology.
3. Treatment with aspirin (150 mg daily) for at least 4 weeks is recommended for prophylaxis after streptokinase therapy for acute myocardial infarction. The first dose should be given as soon as possible after the myocardial infarction.
4. Streptokinase is derived from bacterial proteins and thus can result in allergic reactions. Allergic reactions have been noted in up to 4.4% of patients and may present with fever, shivering, or rash. In rare cases, anaphylaxis may occur, which appears to be IgE mediated. Patients who develop anaphylactic signs and symptoms should promptly discontinue treatment and receive adrenaline.
5. The therapeutic effect of streptokinase may be reduced in patients with recent streptococcal infections such as streptococcal pharyngitis. Repeat treatment with streptokinase administered for more than 5 days in less than 12 months after initial treatment may not be effective. For these patients use alternative thrombolysis.
6. DVT rarely need thrombolysis, systemic anticoagulation is preferred – see trust guideline WAHT-HAE-002 V8.1.pdf
7. See monograph on Medusa Homepage (wales.nhs.uk) on how to administer
8. Dosing as taken from Streptokinase SPC/BNF below

Indication: Deep vein thrombosis

- An initial dose of 250 000 IU streptokinase should be infused into a peripheral vein over 30 minutes. A maintenance infusion of 100 000 IU/hour for 72 hours should follow.

Indication: Pulmonary embolism

- Infuse 1,500,000 IU streptokinase into a peripheral vein preferably over 2 hours.

Indication: Myocardial Infarction (Only after discussion with the PPCI consultant on call if PPCI is not possible or delayed)

- Infuse 1,500,000 IU streptokinase into a peripheral vein preferably over an hour.

Occlusive peripheral arterial disease

- Administer streptokinase with a local intra-arterial catheter-directed infusion using one of the following regimes:
- Gradual infusion: 1000 to 2500 IU streptokinase at an interval of 3 to 5 minutes for a maximum of 10 hours and a total maximum dose of 250 000 IU
- Prolonged continuous low-dose infusion (using an infusion pump): 5000 to 10,000 IU streptokinase per hour for up to 5 days maximum.

Contraindications to treatment with Streptokinase, because of the increased risk of haemorrhage under thrombolytic therapy, include	
Existing or recent internal haemorrhage	Acute pancreatitis
Recent cerebrovascular accident, intracranial or intraspinal surgery	Known neoplasm with risk of haemorrhage
Intracranial neoplasm	Recent implantation of a vessel prosthesis
Recent head trauma	Simultaneous or recent treatment with oral anticoagulants (INR >1.3)
Arteriovenous malformation or aneurysm	Severe liver or kidney damage
Uncontrollable hypertension with systolic values over 200 mm Hg and/or diastolic values over 100 mm Hg or hypertensive retinal changes Grades III/IV	Endocarditis or pericarditis. Isolated cases of pericarditis, misdiagnosed as acute myocardial infarction and treated with streptokinase, have resulted in pericardial effusions including tamponade
All forms of reduced blood coagulability, particularly spontaneous fibrinolysis and extensive clotting disorders	Known haemorrhagic diathesis
Recent major operations (6th to 10th post-operative day, depending on the extent of the procedure)	Invasive operations, e.g. recent organ biopsy, long-term (traumatic) closed chest cardiac massage

The following conditions would normally be considered contraindications to streptokinase therapy, but in certain situations the benefits could outweigh the potential risks:	
Recent severe gastrointestinal bleeding, e.g. active peptic ulcer	Risk of severe local haemorrhage, e.g. in case of translumbar aortography
Recent trauma and cardiopulmonary resuscitation	Puncture of non-compressible vessels, intramuscular injections, large arteries
Invasive operations, e.g. recent intubation	Recent abortion or delivery
Pregnancy	Known septic thrombotic disease
Diseases of the urogenital tract with existing or potential sources of bleeding (implanted bladder catheter)	Severe arteriosclerotic vessel degeneration, cerebrovascular diseases
Cavernous pulmonary diseases, e.g. open tuberculosis or severe bronchitis	Mitral valve defects or atrial fibrillation
Aortic dissection	Diabetic retinopathy increase risk of local bleeding

Repeat treatment with streptokinase administered more than 5 days and less than 12 months after initial treatment may not be effective. This is because of the increased likelihood of resistance due to antistreptokinase antibodies.

If the patient is under active heparinisation, it should be neutralised by administering protamine sulphate before the start of the thrombolytic therapy. The thrombin time should not be more than twice the normal control value before thrombolytic therapy is started. In patients previously treated with coumarin derivatives, the INR (International Normalized Ratio) must be less than 1.3 before starting the streptokinase infusion.

9. Urokinase

Dosing information extracted from Summary of Product Characteristics and BNF. Urokinase is licensed for:

a. **Thrombosed intravascular catheters and cannulae**

- Dissolve 5000 to 25000 units Urokinase in a volume of sodium chloride 0.9% required to fill the catheter lumen only. Label the line with 'urokinase line lock' date, time and dose, and leave for 20 to 60 minutes then aspirate the lysate. Repeat if necessary.
- Alternatively, up to 250 000 units may be instilled directly into the catheter or cannula lumen **only.** Dissolve dose in sodium chloride 0.9% to a concentration of 1000–2500 units/mL and infuse over 90–180 minutes into the catheter or cannula.

b. **Acute occlusive peripheral arterial disease with limb threatening ischemia**

- A solution of 2,000 units/ml (500,000 units of urokinase dissolved in 250 ml solvent) should be infused into the clot with angiographic monitoring of progress of treatment. It is recommended that the rate of infusion should be 4,000 units/minute for 2 hours when angiography should be repeated. Following this, the catheter should be advanced into the occluded segment of vessel and urokinase infused at the same rate of 4,000 units/minute for another 2 hours. The process can be repeated up to 4 times if flow has not been achieved. Once a channel has been created through the blocked segment, the catheter may be withdrawn until it lies proximal to the remaining thrombus. Infusion should continue at the rate of 1,000 units/minute until the clot has completely lysed. Usually, a dose of 500,000 units over 8 hours should be sufficient. If the length of the clot has not been reduced by more than 25% after the initial dose of 500,000 units and further reductions of 10% by subsequent infusions of 500,000 units, discontinuation of treatment should be considered. Liaise with Pharmacy to ensure sufficient supply is available before commencing

c. **Acute Deep Vein Thrombosis Catheter Directed Thrombolysis:**

- A solution of 2,000 units/ml (500,000 units urokinase dissolved in 250 ml solvent) should be infused into the clot with angiographic monitoring of progress of treatment.
- It is recommended that the infusion rate be 50,000 units per hour for 20 hours when angiography should be repeated.
- This is an unlicensed indication.
- Liaise with Pharmacy to ensure sufficient supply is available before commencing

Urokinase has also been recommended by BTS as an alternative to alteplase for intrapleural treatment of pleural infections:

d. **Pleural Infection (unlicensed indication)**

- Urokinase 100,000 units to given twice a day intrapleurally for 3 days alongside dornase alfa as a recommended option from the British Thoracic Society in view of ongoing shortages.

e. **Unblocking indwelling pleural catheters**

- Urokinase 100,000 units is also used by the pleural specialist team to unblock IPCs but should only be done within the pleural service.

Urokinase is also licensed for management of acute massive pulmonary embolism and acute proximal deep vein thrombosis however due to the volumes required, this should not be first line choice. If this is to be considered, please discuss with the pharmacy team to review availability.

Appendix 1

National Patient Safety Alert

Department of Health & Social Care | NHS England

Shortage of alteplase and tenecteplase injections

Date of issue:	3-Aug-22	Reference no:	NatPSA/2022/006/DHSC

This alert is for action by: All organisations using alteplase and tenecteplase injections

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) and supported by the Pharmacy department and clinical leaders in stroke medicine, respiratory medicine, renal, cardiology, and emergency medicine.

Explanation of identified safety issue:

There will be supply constraints facing alteplase (Actilyse®) 10mg, 20mg and 50mg injections for the remainder of 2022. Tenecteplase (Metalyse®) 10,000unit injections will go out of stock in the coming months. At present the situation is expected to improve in early 2023.

Alteplase is licensed for thrombolytic treatment of acute ischaemic stroke, acute myocardial infarction (MI) and acute massive pulmonary embolism (PE) with haemodynamic instability. Tenecteplase is licensed for the management of acute MI.

Boehringer Ingelheim is the sole supplier of both these products in the UK. There are manufacturing constraints causing global issues with the supply of these products.

Availability of stock

Boehringer Ingelheim has put restrictions in place for alteplase injection to conserve supplies until further stock is available. Trusts will have access to:

- Alteplase 50mg – approximately normal demand
- Alteplase 20mg – approximately half of normal demand
- Alteplase 10mg – approximately two thirds of normal demand

Demand is calculated at trust level based on historical orders and stock available in trusts and will be coordinated by Boehringer Ingelheim and the Regional Pharmacy Procurement Specialists.

Boehringer Ingelheim has also put restrictions in place for tenecteplase to ensure stock is not depleted earlier than anticipated.

Actions required

Actions to be completed by
10/08/2022

1. Assess stock holding of alteplase and tenecteplase injections to ensure current stock levels are correctly recorded in pharmacy systems.
2. Centralise stock in pharmacy where appropriate to do so.
3. Alteplase stock should be conserved for patients with acute ischaemic stroke, given the lack of an alternative and the significant risk of harm without receipt of treatment.
4. Consider the feasibility of alternative therapeutic options to alteplase and tenecteplase where they exist.
5. Reduce wastage by selecting appropriate vial sizes and using the most appropriate doses, giving consideration to rounding down to the nearest whole vial.
6. Pharmacy staff should order alteplase injections in line with their allocations and order tenecteplase injection in line with historic order patterns; unusual orders will be challenged.
7. Pharmacy staff should liaise with their Regional Pharmacy Procurement Specialist to manage allocated stocks of alteplase. Ensuring proactive stock management and prompt liaison should stock levels become critically low.

For any enquiries about this alert contact: DHSCmedicinesupplyteam@dhsc.gov.uk 1/2

Failure to take the actions required under this National Patient Safety Alert may lead to CQC taking regulatory action

Additional information:

Alternative thrombolytic treatments

Stroke

Only alteplase is licensed for the treatment of ischaemic stroke. Stroke teams may also have experience of using tenecteplase from participation in clinical trials, though this would be an unlicensed use. Mechanical thrombectomy is also used to treat some patients with acute ischaemic stroke but should be used in conjunction with alteplase in the majority of patients. There are no other therapeutic options for the treatment of acute ischaemic stroke.

Myocardial Infarction and dissolution of thrombi and emboli

Streptokinase

- The 1,500,000 IU strength is licensed for the treatment of acute MI within 12 hours of onset with persistent ST-segment elevation or recent left bundle-branch block.
- The 250,000 and 750,000 IU strengths are licensed for intravascular dissolution of thrombi and emboli in: acute massive pulmonary embolism, acute, sub-acute or chronic (not older than 6 weeks) occlusion of peripheral arteries, extensive deep vein thrombosis, and central retinal venous or arterial thrombosis (arterial occlusions not older than 8 hours, venous occlusions not older than 10 days).

Repeat treatment with streptokinase administered more than 5 days and less than 12 months after initial treatment may not be effective due to increased likelihood of resistance as a result of antistreptokinase antibodies. Also, the therapeutic effect may be reduced in patients with recent streptococcal infections such as streptococcal pharyngitis, acute rheumatic fever and acute glomerulonephritis.

Urokinase

Urokinase is licensed for:

- thrombosed intravascular catheters and cannulae,
- extensive acute proximal deep vein thrombosis,
- acute massive pulmonary embolism, and
- acute occlusive peripheral arterial disease with limb threatening ischaemia

Supplies of urokinase 10,000 units and 25,000 units are not available however, urokinase 100,000 units is meeting demand and can support a small increase in use; please refer to the Medicine Supply Notification which includes link to Dear HCP letter regarding dilution of this high strength product.

Off label uses

For the thrombolytic treatment of occluded central venous access devices including those used for haemodialysis; please refer to Medicine Supply Notification the issued for the shortage of alteplase (Actilyse Cathflo®) 2mg powder for solution for injection vials. For paediatric use, alteplase should only be used as rescue therapy to preserve vascular access in children on haemodialysis when other agents have been ineffective. For prophylaxis of central venous line occlusion in paediatrics, alteplase should only be used for the highest risk patients i.e. infants and small children.
For other off label uses, discuss locally with the relevant specialist noting the advice contained within this alert.

References

SmPC alteplase
SmPC tenecteplase
SmPC streptokinase
SmPC urokinase
NICE guideline for stroke and transient ischaemic attack in over 16s: diagnosis and initial management
NICE guidelines for management of acute coronary syndromes
NICE guideline for the diagnosis and management of atrial fibrillation

Stakeholder engagement

The following stakeholders have been engaged in the management and consulted in the drafting of this alert: Specialist Pharmacy Service Medicines Information, Medicine Shortage Response Group, NHS England National Clinical Directors for stroke, heart disease and respiratory, and specialist renal clinicians.

Advice for Central Alerting System (CAS) officers and risk managers

This is a safety critical and complex National Patient Safety Alert. In response to CHT/2019/001 your organisation should have developed new processes to ensure appropriate oversight and co-ordination of all National Patient Safety Alerts. CAS officers should send this Alert to the executive lead nominated in their new process to coordinate implementation of safety critical and complex National Patient Safety Alerts, copying in the leads identified on page 1.

Monitoring

Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the Policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: *(Responsible for also ensuring actions are developed to address any areas of non-compliance)*	Frequency of reporting:
	WHAT?	**HOW?**	**WHEN?**	**WHO?**	**WHERE?**	**WHEN?**
	These are the 'key' parts of the process that we are relying on to manage risk. We may not be able to monitor every part of the process, but we MUST monitor the key elements, otherwise we won't know whether we are keeping patients, visitors and/or staff safe.	What are we going to do to make sure the key parts of the process we have identified are being followed? (Some techniques to consider are; audits, spot-checks, analysis of incident trends, monitoring of attendance at training.)	Be realistic. Set achievable frequencies. Use terms such as '10 times a year' instead of 'monthly'.	Who is responsible for the check? Is it listed in the 'duties' section of the Policy? Is it in the job description?	Who will receive the monitoring results? Where this is a committee the committee's specific responsibility for monitoring the process must be described within its terms of reference.	Use terms such as '10 times a year' instead of 'monthly'.
	Prescribing, dose, administration, adverse drug reactions, side-effects	Analysis and monitoring of incidents	On-going	Medicines Safety Officer	Medicines Safety Committee, Thrombosis Committee	Quarterly (unless trend identified)

References

1. University Hospitals Plymouth NHS Trust. Rapid Trust-wide Guidelines. Thrombolytic Options in view of global Alteplase shortage. Accessed 18/8/22

2. National Patient Safety Alerting Committee, 2022. Shortage of alteplase and tenecteplase injection available via: https://www.cas.mhra.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=103211 (Accessed 05/08/2022)

3. SPC: Tenecteplase. https://www.medicines.org.uk/emc/product/3013 (accessed 10/8/2022) SPC: Syner-LINASE 100,000 IU powder for solution for injection/infusion. Available from: https://www.medicines.org.uk/emc/product/7565/smpc (accessed 05/08/2022)

4. BNF Online accessed via https://www.medicinescomplete.com/#/content/bnf/ (accessed 05/08/2022)

5. *European Heart Journal*, Volume 41, Issue 4, 21 January 2020, Pages 543- 603, https://doi.org/10.1093/eurheartj/ehz405 (accessed 09/08/2022)

6. Anderson C.S et al for the ENCHANTED Investigators and Coordinators. Low-Dose versus Standard-Dose Intravenous Alteplase in Acute Ischemic Stroke. *The New England Journal of Medicine*, V375, Issue 24, 16th June 2016, pages 2313-23 https://www.nejm.org/doi/full/10.1056/NEJMoa1515510 (accessed 18/8/22)

7. Summary of Product Characteristics: Streptokinase https://www.medicines.org.uk/emc/product/4255/smpc (accessed 18/8/22)

8. British Thoracic Society. BTS response to the national shortage of alteplase in relation to pleural infection management 17th August 2022. https://www.brit-thoracic.org.uk/news/2022/bts-response-to-the-national-shortage-of-alteplase-in-relation-to-pleural-infection-management/ (accessed 22/8/22)

9. Konstantinides SV, Meyer G, Becattini C, et al. 2019 ESC Guidelines for the diagnosis and management of acute pulmonary embolism developed in collaboration with the European Respiratory Society (ERS): The Task Force for the diagnosis and management of acute pulmonary embolism of the European Society of Cardiology (ESC), European Heart Journal, Volume 41, Issue 4, 21 January 2020, Pages 543–603, https://doi.org/10.1093/eurheartj/ehz405

10. RCUK Quick Reference Handbook, Resus Council. https://www.resus.org.uk/sites/default/files/202207/RCUK%20QRH%20complete%20March%202022%20-%20final.pdf. Accessed 15.09.2022

Contribution List

Contribution List

This key document has been circulated to the following individuals for consultation;

Designation
All WAHT consultants

This key document has been circulated to the chair(s) of the following committee's / groups for comments;

Committee
Trust Thrombosis Committee
Medicines Safety Committee

Supporting Document 1 - Equality Impact Assessment Tool

To be completed by the key document author and included as an appendix to key document when submitted to the appropriate committee for consideration and approval.

Please complete assessment form on next page;

Herefordshire & Worcestershire STP - Equality Impact Assessment (EIA) Form
Please read EIA guidelines when completing this form

Section 1 - Name of Organisation (please tick)

Herefordshire & Worcestershire STP		Herefordshire Council		Herefordshire CCG	
Worcestershire Acute Hospitals NHS Trust	x	Worcestershire County Council		Worcestershire CCGs	
Worcestershire Health and Care NHS Trust		Wye Valley NHS Trust		Other (please state)	

Name of Lead for Activity	

Details of individuals completing this assessment	**Name**	**Job title**	**e-mail contact**
	Keith Hinton	Clinical Team Lead Pharmacist	keith.hinton1@nhs.net
Date assessment completed	15.09.2022		

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	**Title:** Thrombolytic options in view of global alteplase shortage rapid Trust-wide Guidelines				
What is the aim, purpose and/or intended outcomes of this Activity?	As above				
Who will be affected by the development & implementation of this activity?	x x ❑ ❑	Service User Patient Carers Visitors	x ❑ ❑ ❑	Staff Communities Other _____	
Is this:	❑ Review of an existing activity x New activity				

	❑ Planning to withdraw or reduce a service, activity or presence?
What information and evidence have you reviewed to help inform this assessment? (Please name sources, eg demographic information for patients / services / staff groups affected, complaints etc.	See reference list
Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)	CMO and Deputy CMO Countywide consultant body
Summary of relevant findings	

Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale**. Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Age		x		
Disability		x		
Gender Reassignment		x		
Marriage & Civil Partnerships		x		
Pregnancy & Maternity		x		
Race including Traveling Communities		x		
Religion & Belief		x		
Sex		x		

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Sexual Orientation		x		
Other Vulnerable and Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)		x		
Health Inequalities (any preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)		x		

Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Timeframe
	Shortage of alteplase/tenecteplase	See risk register	Trust Thrombosis Committee	Weekly review of stock position
How will you monitor these actions?				

When will you review this EIA? (e.g in a service redesign, this EIA should be revisited regularly throughout the design & implementation)	

Section 5 - Please read and agree to the following Equality Statement

1. Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation

1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing EIA	Keith Hinton
Date signed	15.9.2022
Comments:	
Signature of person the Leader Person for this activity	
Date signed	
Comments:	

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	No
2.	Does the implementation of this document require additional revenue	No
3.	Does the implementation of this document require additional manpower	No
4.	Does the implementation of this document release any manpower costs through a change in practice	No
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	No
	Other comments:	Nil

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval.