NHS
South Western
Ambulance Service
NHS Foundation Trust

Patient Group Direction

INDIVIDUAL PRACTITIONERS MUST BE AUTHORISED BY NAME, UNDER THE CURRENT VERSION OF THIS PGD BEFORE WORKING ACCORDING TO IT.

Practitioners must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of Trust PGDs can be found at http://intranet.swast.nhs.uk/patient-group-directions.htm

Clinical Publication Category	**MANDATORY - No deviation from document permissible**
PGD	**TRANEXAMIC ACID**
Version	5.0
Legal category	POM • The use of tranexamic acid in severe haemorrhage following trauma and in head injury is off label. However its use is supported by national JRCALC. • The use of tranexamic acid in children under 1 year of age is off label. However its use is supported by national JRCALC guidelines. • Intraosseous route supported by national protocols.
Approved by	Medicines Governance Group
Date Issued	30-03-2020
Review date	29-03-2022

Staff Characteristics	
Qualifications and professional registration	• Professional registration with HCPC as a Paramedic. • Professional registration with NMC as a Nurse. • Current contract of employment within South Western Ambulance Service NHS Trust or SWAST commissioned service as a Paramedic (or specialist Paramedic) or Nurse.
Initial training	• The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate training as defined by the Trust and successfully completed the competencies to undertake clinical assessment of patient leading to diagnosis of the conditions listed. They must be competent to recognise and manage unintended but expected side effects including such as anaphylaxis.
Competency assessment	• Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions • Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required.
Ongoing training and competency	• Trust PGD or medication training as required • Annual anaphylaxis and resuscitation training. • Completion and submission of Continuous Professional Development (CPD) as required by HCPC or NMC
Decision to administer	• The decision to administer any medication rests with the individual registered practitioner who must abide by the PGD and any associated organisational policies.
Consent	• **In the context of the clinical scenario described in this PGD the patient may not be able to make an informed choice and consent to treatment. In this situation, the clinician should act in the best interests of the patient at all times and within their professional competency and code of conduct.**

Clinical Situation	
Clinical situation	Patients with signs of actual or suspected severe haemorrhage in the following clinical scenarios: • Injured patients triggering local network major trauma criteria. • Patients with a time critical injury, including pregnant women, where significant internal or external haemorrhage is known or suspected. • Head injury patients, age 18 and over with a Glasgow Coma Score (GCS) of 12 or less. • Post-partum haemorrhage after the administration of a uterotonic drug. N.B. A post-partum haemorrhage may start within 4 but up to 24 hours after delivery.
Inclusion criteria	**Trauma** Treatment of known or suspected severe traumatic internal or external haemorrhage as soon as clinically possible on arrival at the scene and within 3 hours of bleeding starting in adults and children who are considered to be at risk of significant haemorrhage. This may be demonstrated by one or more of: • Systolic blood pressure < 90mmHg or absent radial pulse or heart rate > 110 bpm believed to be due to bleeding in adults. In children this may be demonstrated by changes in the normal physiological parameters for age (see JRCALC page for age). • Any patient where haemostatic gauze, arterial tourniquet/s, chest dressing/s or pressure dressing/s have been applied. • Patient who has suffered a traumatic cardiac arrest. • The above would include women who have recently given birth but have suffered subsequent trauma. • Women who are pregnant and/or breastfeeding should have tranexamic acid administered in life threatening circumstances. **Traumatic Brain Injury (TBI)** Patients age 18 and over who have a known or suspected head injury where the following criteria are met: • GCS is 12 or less. • Injury has occurred within the last 3 hours. Administration should take place as soon as possible after injury to give greatest benefit.

	Post-Partum Haemorrhage Any of the following criteria: • PPH (bleeding from the genital tract >500ml) which usually occurs within 4 hours (but up to 24 hours) after delivery. This can be associated with haemodynamic instability. TXA should be given after the administration of a uterotonic drug. • Woman with a post-partum haemorrhage when uterine trauma (rupture) is suspected. Bleeding may be intra-abdominal. • Woman for whom uterotonic drugs are contraindicated (rare).
Exclusion criteria	• Known previous anaphylactic reaction to tranexamic acid; • Bleeding started more than 3 hours ago. Note that a PPH occurs within 4 hours (but up to 24 hours) **after delivery** but actual bleeding should not have started more than 3 hours ago; • TBI patients who warrant administration of TXA as per the findings of the CRASH-2 trial must be managed as trauma not TBI patients; • Obvious resolution of haemorrhage; • Post-partum haemorrhage without co-administration of a uterotonic unless uterotonic contraindicated (rare); • Critical interventions required (must only be given after critical interventions have been performed: i.e. airway managed; control or splinting of major haemorrhage etc and if does not delay transfer noting it may be administered en route).
Cautions	Contact the local senior on call clinician for advice on the below if required. • There are insufficient clinical data on the use of tranexamic acid in pregnant women. As a result, although studies in animals do not indicate teratogenic effects, as a precaution for use, tranexamic acid is not recommended during the first trimester of pregnancy. Limited clinical data on the use of tranexamic acid in different clinical haemorrhagic settings during the second and third trimesters did not identify deleterious effect for the foetus. Tranexamic acid should be used throughout pregnancy only if the expected benefit justifies the potential risk; • Patients with a known history of convulsions or convulsions from any cause during the incident. High dose regimes have been associated with convulsions; however, in the low dose regime recommended here, the benefit from giving tranexamic acid for severe haemorrhage outweighs the risk of convulsions. An increase in convulsion rate may be due to the antagonistic effect of tranexamic acid on GABA receptors. Treat convulsions which may be caused by treatment with tranexamic acid as per JRCALC and Trust guidance (management not covered under this PGD);

	• Patients with a known history of acute venous or arterial thrombosis. In the low dose regime recommended here, the benefit from giving tranexamic acid for severe haemorrhage outweighs the risk of thrombotic events. This information should be passed to the receiving hospital; • Patients with known severe renal impairment (eGFR <30ml/min 1.73m^2). There is a risk of accumulation of tranexamic acid. In the low dose regime recommended here, the benefit from giving tranexamic acid for severe haemorrhage outweighs the risk of accumulation. This information should be passed to the receiving hospital.
Side effects	• Gastro-intestinal disorders: nausea, vomiting and diarrhoea. • Cardio-vascular disorders: rapid intravenous administration may cause hypotension and loss of consciousness. • Arterial or venous thrombosis at any sites. • Nervous system disorders: dizziness, convulsions. • General disorders: hypersensitivity reactions including anaphylaxis
Interactions	• Do not administer through the same line as blood products or penicillin antibiotics (including co-amoxiclav). • Patients receiving oral contraceptives may have an increased risk of thrombosis. In the low dose regime recommended here, the benefit from giving tranexamic acid for severe haemorrhage outweighs the risk of thrombotic events. If known that patient is currently taking an oral contraceptive this information should be passed to the receiving hospital. • A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website or BNF: www.medicines.org.uk https://bnf.nice.org.uk/
Action if excluded	If patient meets exclusion criteria: • Explain reason to patient/carer • Record reason in patient's clinical record (PCR) • Convey all patients with an ATMIST alert who present with exclusion criteria.
Action if patient declines treatment	• If patient declines treatment convey immediately with an ATMIST alert to the receiving unit. • Document advice and actions in PCR. • Ensure patient or representative signs refusal section on PCR.

Description of Treatment

Generic name

- Tranexamic acid

Presentation

- 500 milligrams in 5ml solution for injection

Route

- Intravenous
- Intraosseous

Method

☒ Administration ☐ Supply

- The IV/IO dose should be administered by slow injection over 10 minutes – can be given in 10 aliquots 1 minute apart. Rapid intravenous injection may cause dizziness and/or hypotension.
- After administration flush with 0.9% sodium chloride.

Dose

Traumatic Haemorrhage and TBI IV/IO

AGE	DOSE	VOLUME 100mg/ml
Adults and children aged 12 years and over	1000mg	10ml
11 years	500mg	5ml
10 years	500mg	5ml
9 years	450mg	4.5ml
8 years	400mg	4ml
7 years	350mg	3.5ml
6 years	300mg	3ml
5 years	300mg	3ml
4 years	250mg	2.5ml
3 years	200mg	2ml
2 years	200mg	2ml
18 months	150mg	1.5ml
12 months	150mg	1.5ml
9 months	150mg	1ml
6 months	100mg	1ml
3 months	100mg	1ml
1 month	50mg	0.5ml
Birth	50mg	0.5ml

	Post-partum haemorrhage IV/IO • 1000 mg (10ml) administered by slow IV/IO injection over 10 minutes – can be given in 10 aliquots 1 minute apart. Rapid intravenous injection may cause dizziness and/or hypotension. Under this PGD, if the patient is still bleeding 30 minutes after the first dose is administered, a second dose can be administered if there is delay in reaching the destination hospital. A maximum of two doses may be administered in 24 hours. • After administration flush with 0.9% sodium chloride.
Frequency	**Traumatic haemorrhage and head injury** • Single dose permitted under this PGD. **Post-partum haemorrhage** • A second dose can be administered under this PGD if bleeding continues after 30 minutes of the first dose being administered and there is delay in reaching the destination hospital. A maximum of two doses may be administered in 24 hours.

Follow Up	
Referral arrangements and safety netting	• Inform receiving hospital staff that a loading dose of tranexamic acid has been administered and ensure that this is clearly recorded within the medicines section of the Patient Clinical Record.
Advice to patients	• Explain treatment. • All patients must be admitted to hospital.
Management of and reporting procedure for adverse reactions (ADRs)	• The practitioner acting under this PGD must ensure that all necessary drugs and equipment are available for immediate treatment should a hypersensitivity reaction occur and must be trained to manage anaphylaxis. • Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk • Record all ADRs in the patient's medical record. • Report via organisation incident policy.

Records	Record: • name of individual, address, date of birth • name of practitioner • name of medication administered • date of administration • dose, form and route of administration • quantity administered • anatomical site of administration (if indicated) • advice given, including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • supplied via Patient Group Direction (PGD) • Records should be named/signed and dated (or a password controlled e-records). • All records should be clear, legible and contemporaneous. • A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.
References	• BNF online accessed 18-10-2019 at https://bnf.nice.org.uk/drug/tranexamic-acid.html • WOMAN Trial Collaborators. Published online April 2017 at http://dx.doi.org/10.1016/S0140-6736(17)30638-4 'Effect of early tranexamic acid administration on mortality, hysterectomy, and other morbidities in women with post-partum haemorrhage (WOMAN): an international, randomised, double-blind, placebo-controlled trial'. • CRASH 2 Collaborators. Effects of tranexamic acid on death, vascular occlusive events, and blood transfusion in trauma patients with significant haemorrhage (CRASH-2): a randomised, placebo-controlled trial. Published online June 15 2010 and accessed 18-10-2019 at https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(10)60835-5/fulltext • CRASH 3 Collaborators. Published online 14-10-2019 and accessed 18-10-2019 at https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)32233-0/fulltext 'Effects of tranexamic acid on death, disability, vascular occlusive events and other morbidities in patients with acute traumatic brain injury (CRASH-3): a randomised, placebo-controlled trial.'

Authorisation				
Chief Executive Officer	Name	Ken Wenman		
	Signature		Date	19 02 2020
Medical Director	Name	Dr Phil Cowburn		
	Signature		Date	19 02 2020
Pharmaceutical Advisor	Name	Sue Oakley		
	Signature		Date	19 02 2020

- This patient group direction must be signed by the Chief Executive Officer, Medical Director and Pharmaceutical Advisor to be legally valid.

Individual Authorisation (Staff Copy)				
Individual	Name			
	Signature		Date	
Authorising officer	Name			
	Signature		Date	

- I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this document.

- PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.

- This signed page must be retained by the member of staff, together with the full PGD, which must be available in clinical practice.

Individual Authorisation (Trust Copy)				
Individual	Name			
	Signature		Date	
Authorising officer	Name			
	Signature		Date	

- I have read and understood the Patient Group Direction and agree to supply this medicine only in accordance with this document.

- PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.

- This signed page must be returned to the Divisional Training Administrator who will update the Electronic Staff Record. This copy must be retained by the Trust Training Department.