This Patient Group Direction (PGD) must only be used by registered Paramedics who have been named and authorised by their organisation to practice under it. The most recent and in-date final signed version of the PGD must be used.

Patient Group Direction

For the administration of

Tranexamic Acid

by Paramedics for

Treatment of severe haemorrhage

in South East Coast Ambulance Service NHS Foundation Trust

Date Issued:	**02/11/2022**
Issued By:	
PGD Reference:	**PGD-006 v5.00**
Review Date:	**02/05/2025**
Expiry Date:	**01/11/2025**

Upon issue of this version of the PGD, all previous versions must be removed from use. No supply or administration may be made under the terms of this PGD after the expiry date above.

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Change history

Version number	Change details	Date
0.01	Routine update	27/07/2017
0.02	Review and transfer to new template	28/07/2017
1.00	Published version	18/10/2017
1.01	Revised PGD reference number. Updated Yellow Card Link. Reviewed records to be kept	05/02/2018
2.00	Approved and Published version	06/02/2018
2.01	Revised by	12/03/2019
2.02	Revised by	07/05/2019
3.00	Approved and Published version	27/06/2019
3.01	Required to resign as version 3.00 hard copy misplaced	17/10//2019
3.02	Amendment to the use of TXA in Head Injuries and CRASH3 reference included	05/03/2020
3.03	Age amended to match misoprostol by Nurses removed from PGD	18/08/2020
3.04	Reviewed by	30/11/2020
3.05	Formatting checked in preparation for Trust Approval	03/12/2020
3.06	signature added	20/02/2021
3.07	Dosing clarification	25/05/2021
4.00	Approved and Published	27/05/2021
4.01	Update in line with National PGD: IM administration	25/10/2021
4.02	Minor amendments following PGDWG suggestions	25/10/2021
4.03	Antepartum haemorrhage (APH) added to exclusions	05/11/2021
4.04	Update following national updates and Trust discussions	18/02/2022
4.05	Pregnancy and breastfeeding section updated in line with National PGD update	15/03/2022
4.06	Accepted changes and minor amendments following feedback from PGDWG	24/03/2022
4.07	Review and update of references, formatting	06/05/2022
4.08	CADJ review and update of inclusion criteria and comments made on PGD review	03/10/2022
5.00	Trust Approved for Use	02/11/2022

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PGD development

Name	Job title and organisation	Date
Lead HCP		10/06/2017 17/10/2022
Lead Doctor		
Lead Pharmacist		01/12/2020
Other Paramedics/ Nurses involved in development/ review		18/08/2019

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Training and competency of Paramedics

	Requirements of registered Paramedics and Nurses working under the PGD
Qualifications and professional registration	Professional registration with HCPC as a Paramedic. Current contract of employment with SECAmb as a Paramedic (or specialist Paramedic).
Initial training	Paramedics must have undertaken appropriate training and successfully completed the competencies to undertake clinical assessment of patient leading to diagnosis of the conditions listed. Paramedics must be competent to recognise and treat unintended but expected side effects including loss of airway reflexes, respiratory depression and anaphylaxis.
Competency assessment	Paramedics should self-declare that they are competent to use this PGD, assuring themselves that they have the necessary clinical skills and knowledge for treatment of the conditions included and use of the drugs involved. Support for self-assessment will be provided by • Trust Standard Operating Procedures (SOPs) and training for the use of PGDs Paramedics should also understand the legislation surrounding use of PGDs and their responsibilities as a PGD user.
Ongoing training and competency	Paramedics must meet the requirements of the current prevailing level of education required for PGD use at this level of practice. This must include completion of the Trusts SOPs for medicine management and regular peer review. All ongoing regular training requirements (e.g. statutory and mandatory training) as required by the Trust for this role must be completed. The clinician is responsible for keeping him/herself aware of any changes to the recommendations for the medicine listed. It is the responsibility of the individual to keep up to date with continued professional development and to work within the limitations of their own individual scope of practice. Ensure compliance to Trust policies and process relating to medicines.

Clinical condition

Clinical condition or situation	Patients with signs of actual or suspected severe haemorrhage resulting from: • Major traumatic injuries, where significant internal or external haemorrhage is known or suspected. • Post-partum haemorrhage within 24 hours of delivery, which has not responded to the administration of an uterotonic drug.

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	• Patients aged 18 and over with known, or suspected head injury, with a GCS of 12 or less, within 3 hours of injury.
Inclusion criteria	**<u>Traumatic Haemorrhage</u>** **Treatment of known or suspected traumatic internal or external haemorrhage, where bleeding started less than 3 hours ago.** • In trauma: the clinician should assess the extent of traumatic haemorrhage using a combination of patient physiology, anatomical injury pattern, mechanism of injury and the patient's response to initial resuscitation. The above would include women who have recently given birth but have suffered subsequent trauma. • Children aged under 12 years old who have known or suspected severe haemorrhage from major traumatic injuries - if in doubt, these cases can be discussed with the duty senior on call clinician who can be contacted via the Critical Care Desk (CCD) in EOC. **<u>OR</u>** **<u>Post-Partum Haemorrhage (PPH)</u>** • 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. Tranexamic acid should be given after the administration of a uterotonic drug (misoprostol / syntometrine) except in individuals for whom uterotonic drugs are contraindicated (rare). • Woman with a post-partum haemorrhage when uterine trauma (rupture) is suspected. Bleeding may be intra-abdominal. **<u>Or</u>** **<u>Head Injuries</u>** • Tranexamic acid should be administered to any patient aged 18 years and over, who have a known or suspected head injury with a GCS of 12 or less, where the injury has occurred within the last 3 hours
Exclusion criteria	• Any haemorrhage condition not listed in the inclusion criteria • Known allergy to tranexamic acid or any of the excipients (water for injection) • Bleeding started more than 3 hours ago

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	• Obvious resolution of haemorrhage • Post-partum haemorrhage before the administration of a uterotonic drug unless uterotonic drug is contraindicated or if trauma is the suspected cause. • Critical interventions required (must only be given after critical interventions have been performed: i.e. airway managed; control or splinting of major haemorrhage etc. May be administered en route to hospital). • Antepartum haemorrhage.
Cautions **(including any relevant action to be taken)**	Where a caution is present the practitioner should be aware of the possible effects of administration but should continue to administer where the benefit outweighs risk – contact the duty senior on call clinician for **advice** via the Critical Care Desk (CCD) in EOC if in doubt about administering. Patients with a history of convulsions. 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 seizure rate may be due to the antagonistic effect of tranexamic acid on GABA receptors. Treat seizures as per JRCALC and Trust guidance. Patients with a 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 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. This information should be passed to the receiving hospital. Patients with severe renal impairment. 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. Patients with massive haematuria. Avoid if risk of ureteric obstruction. Rapid injection may cause hypotension and loss of consciousness. Do not administer through the same line as blood products or penicillin antibiotics (including co-amoxiclav).

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Pregnancy and breast feeding	Tranexamic acid has been subject to some controlled clinical studies in pregnancy. Tranexamic acid does cross the placenta, but it is unknown what the effect on the baby is. There is no evidence of teratogenicity in animal studies; however only use if potential benefit outweighs risk. Tranexamic acid's safe use during lactation has not been established. There is a small amount present in breast milk, although any antifibrinolytic effect in the infant is unlikely. The benefits of administration must outweigh any potential risk.
Arrangements for referral for medical advice	Patients who receive tranexamic acid should be fully monitored (ECG, NIBP and SpO2) and conveyed to the nearest appropriate hospital or handed over to an enhanced care team who are able to manage a patient who has had tranexamic acid administered. OR in the cases of patients where life extinct is recognised (ROLE) patients may be left in the community in the normal way. The receiving clinical team must be verbally informed, and the patient record should clearly show: • At what time the patient had tranexamic acid administered. • How much tranexamic acid the patient has had administered. • Whether the patient had capacity to provide informed consent.
Action to be taken if patient excluded	Ensure exclusion is recorded in patient records.
Action to be taken if patient declines treatment	Ensure the patient understands the information and rationale for the proposed administration and is therefore able to make an informed choice. It may be possible in the context of severe haemorrhage, that the patient will not be able to make an informed choice. Therefore, the clinician should act in the best interests of the patient at all times.

Details of the medicine

Name, form and strength of medicine	Tranexamic acid 500mg/5ml solution for injection ampoules
Legal category	POM

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Route / method of administration	Intravenous injection (IV) Intraosseous injection (IO) *Intramuscular injection (IM) The IV or IO dose should be administered **slowly over 10 minutes**. *Where IV access is not achievable promptly, and the IO route is not appropriate, the IM route can be considered into a large muscle as below. Where two or more injections need to be administered, they should be given at separate sites, preferably in a different limb, they should be administered at least 2.5cm apart. **IM Injection Sites and Appropriate Volumes** **Site** / **Maximum volume in Adult P** **Deltoid** 0 **Ventrogluteal** **Rectus Femo** **V** **IM Needle Length** The length of needle required is dependent upon the injection site chosen by the clinician. For intramuscular injections in infants, children and adults a 25mm (1 inch) long needle should be used. In larger adults or obese patients a 38mm (1.5 inch) long needle may be required.
Dose and frequency	**<u>Traumatic Haemorrhage</u>** Single dose administration only. **In adults and children aged 12 years and over**: • **1g** (10ml) administered over 10 minutes when administering IV/IO. **In children under 12 years of age:** estimate the patient's weight (refer to JRCALC 'age page'):

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- **15mg/kg** (maximum dose 1g (10ml)) administered over 10 minutes when administering IV/IO.

These cases can be discussed, if advice is needed, with the duty senior on call clinician who can be contacted via the Critical Care Desk (CCD) in EOC.

Note: The dose shown in this table is rounded to the nearest 50mg for ease of administration

Birth	**3.5kg**	50mg	0.5mls	100mg/ml
3mths	**6kg**	100mg	1mls	100mg/ml
6mths	**8kg**	100mg	1mls	100mg/ml
9mths	**9kg**	150mg	1.5mls	100mg/ml
12mths	**10kg**	150mg	1.5mls	100mg/ml
18mths	**11kg**	150mg	1.5mls	100mg/ml
2yrs	**12kg**	200mg	2mls	100mg/ml
3yrs	**14kg**	200mg	2mls	100mg/ml
4yrs	**16kg**	250mg	2.5mls	100mg/ml
5yrs	**19kg**	300mg	3mls	100mg/ml
6yrs	**21kg**	300mg	3mls	100mg/ml
7yrs	**23kg**	350mg	3.5mls	100mg/ml
8yrs	**26kg**	400mg	4mls	100mg/ml
9yrs	**29kg**	450mg	4.5mls	100mg/ml
10yrs	**32kg**	500mg	5mls	100mg/ml
11yrs	**35kg**	500mg	5mls	100mg/ml

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	Head Injury (adults aged 18 years and over only) Single dose administration only. • **1g (10ml)** administered over 10 minutes when administering IV/IO. **<u>Post-partum Haemorrhage (</u>in adults and children 12 years and over)** • **1g (10ml)** administered slowly when administering IV/IO. A second dose can be administered under this PGD for PPH if bleeding continues after 30 minutes of the first dose being administered. Any further doses are not permissible under this PGD within 24 hours.
Quantity to be administered and/or supplied	Visually inspect solution to ensure solution is clear and free from particulate matter prior to administration. **<u>Doses UNDER 500mg</u>** **IV / IO / IM administration:** Draw up the contents of **ONE 500mg in 5ml ampoules** into a labelled 5ml syringe **(100mg/1ml)**. **<u>Doses OVER 500mg</u>** **IV / IO administration:** Draw up the contents of **TWO 500mg in 5ml ampoules** into a labelled 10ml syringe **(100mg/1ml)**. **IM administration:** Draw up the contents of **TWO 500mg in 5ml ampoule** into **TWO** labelled 5ml syringes **(100mg/1ml)**. **TWO 5ml syringes** are required to administer the total **1g dose** across separate injection sites.
Maximum or minimum treatment period	**<u>Traumatic Haemorrhage and Head Injuries</u>** Single dose permitted under this PGD. **<u>Post-partum haemorrhage</u>** A second dose can be administered under this PGD if bleeding continues after 30 minutes of the first dose being administered. Any further doses are not permissible under this PGD within 24 hours.

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Administration details	Tranexamic acid is for administration by intravenous or intraosseous injection. Where IV access is not achievable promptly, and the IO route is not appropriate, the IM route can be considered into a large muscle. The IV/IO dose should be administered over 10 minutes. This can be given as 10 aliquots administered 1 minute apart where practicable. After administration flush with **0.9% Sodium Chloride**. Do not administer through same line as blood products or penicillin antibiotics. All patients must be fully monitored including SpO2, ECG and BP. Rapid injection may cause hypotension and loss of consciousness. Resuscitation equipment should always be available
Adverse effects Adverse effects should be reported via the Yellow Card scheme, and via Datix (DIF1)	**Common side effects**: • Nausea • Vomiting • Diarrhoea **Uncommon**: • Dermatitis allergic **Unknown frequency:** • Hypersensitivity reactions including anaphylaxis • Convulsions - particularly in case of misuse • Visual disturbances including impaired colour vision • Malaise • Hypotension, with or without loss of consciousness (generally following a too fast intravenous injection, exceptionally after oral administration) • Arterial or venous thrombosis at any sites Report adverse effects at: https://yellowcard.mhra.gov.uk/

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Record to be kept (*in cases where the patient lacks the ability to communicate or does not have capacity this may be omitted if reasonable efforts have failed to obtain this information)	• Record that valid, informed consent was given by the patient. • In cases where the patient lacks mental capacity, a record of how mental capacity was assessed and how the administration of this medicine was in the best interest of the patient. • CAD incident number. • Patient's name, address, date of birth • Contact details of GP (if registered) • Diagnosis or working diagnosis • Patient's estimated weight when under 12 • Dose given and route given by • Batch number and expiry date of drugs given • Time of administration • Advice given to patient • Signature and name of staff who administered medication • Details of any adverse reactions and action taken • Details of any telephone advice calls to the senior on call clinician must be stored on the CAD or on CCP base by the Critical Care Desk CCP. • Supplied via Patient Group Direction (PGD)
Indicate any off-label use (if relevant)	Tranexamic Acid's use in severe haemorrhage following trauma is currently off label. However, its use is supported by national and internationally recognised guidelines (4, 5), a large scale randomised controlled trial (6) the military (7) and other well established prehospital critical care systems. Its use in paediatric trauma is supported by national consensus statement (8) and recent papers (12). Tranexamic acid's use in post-partum haemorrhage is evidenced by a recent randomised, double-blind, placebo-controlled trial (9) and national obstetric guidance (10). Intraosseous injection of tranexamic acid has been reported in a recent paper from the British Defence Medical Services with both military and civilian casualties receiving IO administration of tranexamic acid in 82 patients with no associated complications (11). Intravenous administration is preferable but if there is only IO access treatment should proceed without delay.

Patient information

Written information to accompany the patient	The patient record must show: • Which medications have been administered. • The strength of medications administered.

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	• The dose of the medications administered. • The batch number of medications administered. • What time medications were administered. • The effect (intended or unintended) of medications administered The patient record must demonstrate that informed patient consent has been gained. If the patient lacks mental capacity a record of how the administration of the medicine is in the best interest of the patient. In cases where the patient has mental capacity: • Consent had been gained to administer medication. • The patient must be informed why treatment is required and what the intended effects of the medication are • Potential side-effects of the medication must be explained
Follow-up advice to be given to patient or carer	Patients who have received tranexamic acid should be conveyed to the nearest appropriate hospital or handed over to an enhanced care team who are able to manage a patient who has had tranexamic acid administered; OR in the cases of patients where life extinct is recognised (ROLE) patients may be left in the community in the normal way. The receiving clinical team must be verbally informed, and the patient record should clearly show: • Which medications have been administered. • How much tranexamic acid the patient has had administered. • Whether the patient had capacity to provide informed consent.

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Appendices

Appendix A Key references

1. Specific Product Characteristics Tranexamic Acid 100mg/ml solution for injection – ADVANZ Pharma. Last updated 20 April 2021 Tranexamic Acid 100mg/ml Solution for Injection - SPC. Accessed online May 2022.
2. British National Formulary by NICE Tranexamic Acid. Accessed online March 2021 https://bnf.nice.org.uk/drug/tranexamic-acid.html
3. British National Formulary for Children by NICE Tranexamic Acid. Accessed online March 2021 https://bnfc.nice.org.uk/drug/tranexamic-acid.html
4. National Institute for Health and Care Excellence (2016) Major trauma: assessment and initial management, NICE guideline [NG39]
5. Spahn et al. The European guideline on management of major bleeding and coagulopathy following trauma. (2019) Critical care, 23(98)
6. Crash-2 Collaborators. (2011). The importance of early treatment with tranexamic acid in bleeding trauma patients: an exploratory analysis of the CRASH-2 randomised controlled trial. The Lancet, 377(9771), 1096-1101.
7. Morrison, J. J., Dubose, J. J., Rasmussen, T. E., & Midwinter, M. J. (2012). Military application of tranexamic acid in trauma emergency resuscitation (MATTERs) study. Archives of surgery, 147(2), 113-119.
8. Royal College of Paediatrics and Child Health (RCPCH) and Neonatal and Paediatric Pharmacists Group (NPPG) (2012) Evidence Statement: Major trauma and the use of tranexamic acid in children.
9. Collaborators, W. T. (2017). 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. The Lancet, 389(10084), 2105-2116.
10. Royal College of Obstetricians and Gynaecologists. Postpartum haemorrhage, prevention and management (Green Top Guideline No. 52) (2016)
11. Lewis, P., & Wright, C. (2014). Saving the critically injured trauma patient: a retrospective analysis of 1000 uses of intraosseous access. Emerg Med J, emermed-2015.
12. Beno, S., Ackery, A. D., Callum, J., & Rizoli, S. (2014). Tranexamic acid in paediatric trauma: why not? Critical Care, 18(4), 313.
13. Brown, S. N., Kumar, D., Millins, M., & Mark, J. (Eds.). (2016). UK ambulance services Clinical practice guidelines JRCALC 2016. Bridgwater: Class Professional
14. Patient Group Directions. Medicines Practice Guide NICE August 2013. Updated March 2017
15. World Health Organisation (2017) WHO recommendation on tranexamic acid for the treatment of postpartum haemorrhage. Accessed March 2021.
16. Updated WHO Recommendation on Tranexamic Acid for the Treatment of Postpartum Haemorrhage (2017)
17. Crash 3 Trial Collaborators (2019). 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. Lancet; 394: 1713-1723

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18. National PGD : **https://www.sps.nhs.uk/wp-content/uploads/2021/10/Tranexamic-acid-National-PGD-template-V1.2-November-2021.doc** Last updated 16 November 2021
19. SECAMb Risk Assessment for the Use of Tranexamic acid administered via the intramuscular route.