Emergency Medicine Cape Town

Clinical Practice Recommendations (EM-CPR)

Title: Practice Recommendations for the Use of Tranexamic Acid (TXA) in Paediatric Trauma

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Scope and Purpose

These clinical practice recommendations provide interim guidance on the use of tranexamic acid (TXA) as an adjunct in paediatric trauma within the Western Cape. Although TXA has established efficacy in adult trauma and surgical settings, the evidence for its use in children with major trauma remains limited. Given the high burden of trauma in South Africa, delays in definitive haemorrhage control, and the favourable safety profile of TXA, these recommendations aim to support pragmatic, context-specific decision-making for its cautious use. This guidance was developed through structured expert consensus and contextual appraisal of the available evidence and local practice patterns.

Summary of key recommendations:

1. Consider TXA in critically injured children with suspected major haemorrhage, particularly where access to definitive care may be delayed (e.g. rural or prehospital settings).
2. Use TXA as an adjunct, not a primary intervention. Prioritise haemorrhage control, airway management, and resuscitation.
3. Suggested dosing: 15 mg/kg IV loading dose (max 1g). Do not exceed this dose. An infusion is not recommended at present.
4. Administration should not delay transfer to definitive care.
5. Ensure alignment with local referral centres and maintain consistency of practice across prehospital and facility-based settings.
6. Document all TXA administration. Monitor as a quality marker for ongoing audit and evaluation.
7. Do not mandate TXA via formal guidelines at this stage. Instead, allow provider discretion through a clear position statement acknowledging limited evidence.

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1. Clinical Question: Concise statement describing the clinical dilemma

Uncontrolled haemorrhage remains a leading cause of preventable mortality in children with major trauma.[1–3] While robust evidence supports the early use of tranexamic acid (TXA) in adult trauma[2,4] to reduce haemorrhage-related mortality, equivalent paediatric-specific evidence is sparse. Most data are extrapolated from elective paediatric surgeries or observational studies[2,5], with only limited and inconclusive data from trauma contexts. Despite this, some tertiary trauma centres and prehospital providers in South Africa have begun using TXA in children with suspected major trauma, leading to inconsistent practice and uncertainty about indications, safety, and dosing.

In the absence of clear guidance in the national Standard Treatment Guidelines (STGs) and Essential Medicines List (EML), frontline providers in both urban and rural settings face a clinical dilemma: whether and how to administer TXA to a critically injured child, particularly when faced with long transfer times or limited access to definitive surgical care.

These recommendations aim to address this gap by providing interim, consensus-based guidance for the use of TXA in paediatric trauma within the Western Cape, balancing the limited evidence base with pragmatic considerations of safety, feasibility, and equity.

2. Structured PICO

Component	Description
Population	Children (under 18 years) with major trauma and risk of significant haemorrhage, in prehospital or facility-based emergency care settings
Intervention	Administration of tranexamic acid (TXA), as an adjunct to standard trauma care
Comparator	Standard trauma care without TXA
Outcome(s)	Primary: all-cause mortality. Secondary: transfusion requirement, progression of shock, need for surgical intervention, adverse events (e.g. seizures, thromboembolism)

3. Evidence Synthesis Approach

These recommendations were developed through a structured, tiered process, combining evidence appraisal with expert consensus:

1. **Literature review:** A focused review of available literature on TXA use in paediatric trauma and surgery was conducted. The review included systematic reviews, observational studies, and pilot RCTs. Findings were appraised pragmatically for clinical relevance, methodological rigour, and applicability to the South African context.

2. **Expert** consensus: A multidisciplinary group of emergency medicine specialists, academic clinicians, and senior registrars from the University of Cape Town, Stellenbosch University, and the Western Cape Department of Health convened to discuss the evidence and contextual factors. Consensus was reached through structured discussion, with explicit consideration of safety, feasibility, equity, and implementation.

3. **Contextual adaptation:** In the absence of definitive paediatric trauma data, recommendations were adapted using a pragmatic lens. Factors influencing this adaptation included current variation in practice across regional centres, the high trauma burden in South Africa, rural–urban disparities in access to care, and the widespread availability of TXA in adult emergency care settings.

Consensus meeting date: 22 May 2025

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4. Summary of Evidence and Contextual Considerations

These recommendations are based on a pragmatic synthesis of the available evidence, expert consensus, and contextual realities within the Western Cape emergency care system. Key considerations are outlined below.

4.1 Safety and Pharmacological Profile

TXA has a well-established safety record in children undergoing elective surgery, with demonstrated reductions in blood loss and transfusion requirements across multiple surgical settings. Reported adverse effects are rare and typically mild. These include:

- **Gastrointestinal symptoms** (e.g. nausea, vomiting)
- **Hypotension** with rapid infusion
- **Seizures**, noted primarily in high-dose cardiac surgery settings
- **Thromboembolism**, although not shown to be increased in TXA-treated groups

Given its pharmacokinetic profile and widespread use in adult trauma, TXA is considered safe for cautious use in paediatric trauma, particularly when administered as a single bolus dose if there are no contraindications to TXA use. Contraindications for use include: known coagulopathy, active thrombosis, hypersensitivity to TXA, subarachnoid haemorrhage and in those with recent seizures.

4.2 Evidence for Use in Paediatric Trauma

Tranexamic acid (TXA) has a well-established safety and efficacy profile in elective paediatric surgeries, particularly in cardiac, craniofacial, and orthopaedic contexts.[1,2,4–6] A 2021 meta-analysis by Wei et al. demonstrated that TXA significantly reduces perioperative blood loss and transfusion requirements in children, with a safety profile comparable to adult populations.[6] Similarly, a review by Borgman and Nishijima (2023) highlighted that TXA use in children, including those undergoing non-trauma procedures, is widely accepted and well tolerated, with rare adverse effects.[4,7]

However, the evidence for TXA in paediatric trauma remains limited and inconclusive. The most frequently cited study in support of its use is the **PED-TRAX study** (Eckert et al., 2014), a retrospective analysis of paediatric trauma patients in a combat setting.[8] This study showed an association between TXA use and reduced mortality in children with abdominal and extremity trauma, but its findings may not be generalisable to civilian or LMIC settings.

A 2022 systematic review and meta-analysis by Kornelsen et al. evaluated the effectiveness and safety of TXA in paediatric trauma.[5] The authors included only observational studies and found no statistically significant reduction in mortality, although they emphasised the overall low certainty of evidence. Notably, the same review was cited twice in previous summaries (reflecting its centrality to the debate), reinforcing that available evidence remains weak and underpowered.

The **TIC-TOC trial**, a 2022 pilot randomised controlled trial led by Nishijima et al., aimed to test the feasibility of a large-scale RCT.[7] Although not designed to assess clinical outcomes, it demonstrated that a randomised trial of TXA in children with trauma is feasible, which may pave the way for future high-certainty data. No large RCT has been published to date.

Other data come from smaller observational or descriptive studies. For instance, Thomson et al. (2021) reported low complication rates with TXA in an urban trauma centre retrospective review, and Gendler et al. (2023) used a propensity-matched analysis of Israeli Defense Forces registry data, showing a mortality benefit with prehospital TXA administration in paediatric trauma.[3,9] These studies support the hypothesis of benefit but are limited by their design.

Global practice patterns suggest that TXA is increasingly used off-label in paediatric trauma despite the lack of definitive data. A U.S.-based survey by Cornelius et al. (2021) found that the most common practice involved a 15 mg/kg loading dose, with or without infusion.[1] Similarly, Beno et al. (2014) called for a reconsideration of the hesitation to use TXA in children, arguing that the biological plausibility, low risk, and extrapolated adult benefits justify cautious use in the absence of paediatric-specific trials.[2]

In summary, while high-certainty evidence for TXA use in paediatric trauma is lacking, the overall literature supports a favourable safety profile and plausible benefit. The evidence is strongest for elective surgical indications and combat trauma settings. The existing gap highlights the need for

further research, but also creates an opportunity for permissive, pragmatic use in high-risk trauma scenarios where definitive care may be delayed.

Reference	Design	Key Findings
1. Cornelius et al. (2021) – *US TXA practices survey*[1]	Descriptive survey	Widespread but varied TXA use in paediatric trauma; 15 mg/kg most common dose
2. Beno et al. (2014) – *TXA in paediatric trauma: rationale*[2]	Narrative review	Argues for extrapolating adult TXA data to children; low risk and potential benefit
3. Gendler et al. (2023) – *Israeli Defense Forces registry*[3]	Propensity-matched observational	Prehospital TXA associated with improved outcomes in combat paediatric trauma
4. Borgman & Nishijima (2023) – *Review of TXA in paediatric haemorrhagic trauma*[4]	Expert review	Supports use as pragmatic adjunct in LMICs; evidence gap acknowledged
5. Kornelsen et al. (2022) – *Systematic review and meta-analysis*[5]	Systematic review/meta-analysis	No definitive mortality benefit; studies limited to observational design
6. Wei et al. (2021) – *TXA in paediatric surgery*[6]	Systematic review/meta-analysis	Demonstrated reduction in surgical bleeding and transfusion in elective paediatric surgeries
7. Nishijima et al. (2022) – *TIC-TOC pilot RCT*[7]	Pilot RCT	Feasibility of TXA RCT in paediatric trauma shown; not powered to assess mortality benefit
8. Thomson et al. (2021) – *Urban trauma centre chart review* [9]	Retrospective chart review	Low complication rate with TXA; support for use in selected paediatric trauma cases
9. Eckert et al. (2014) – *PED-TRAX study (combat setting)*[8]	Retrospective observational	Lower mortality with TXA in children with abdominal/extremity trauma in a combat zone

4.3 Current Practice in the Western Cape

There is currently no national or provincial policy guiding TXA use as an adjunct in managing paediatric trauma. However, clinical practice varies:

- **Tertiary paediatric trauma centres** (Red Cross and Tygerberg) currently use TXA in selected trauma cases, guided by expert opinion.
    - Dosages vary between 10–15 mg/kg (max 1 g), with no infusion used.
- **Public sector emergency departments and EMS providers** do not routinely use TXA in children.
- **Private EMS providers** report case-by-case TXA use, although protocols are not standardised.

Facility Type	TXA Use in Paediatric Trauma	Dose Used
RCWMCH (Tertiary)	Yes – selective use	15 mg/kg (max 1 g), no infusion
Tygerberg Hospital	Yes – selective use	10 mg/kg (max 1 g), no infusion
District hospitals	No standard use	Not applicable
Provincial EMS	No routine use	Not applicable
Private EMS (select providers)	Yes – occasional/individual use	Variable

This variation highlights a gap in guidance and risks inequity in care, particularly in rural and under-resourced settings.

4.4 Ethical and Equity Considerations

Children with major trauma represent a highly vulnerable population. In South Africa, the following contextual factors strengthen the case for cautious TXA use:

- **Delays in definitive haemorrhage control** are common in rural or low-resource areas.
- TXA is **inexpensive, widely available, and familiar** to clinicians due to its inclusion in adult trauma protocols.
- A **single-dose approach** is operationally feasible, requires minimal training, and poses low risk.
- Caution is warranted to avoid introducing new practice variation or medico-legal uncertainty; hence the need for a clear, permissive position statement rather than a binding guideline.

5. Suggested Dosing and Clinical Use

These recommendations outline a pragmatic approach to TXA use in children with suspected major trauma. TXA should only be considered where there is clinical concern for significant haemorrhage and a delay in access to definitive haemostatic care.

5.1 Indications for Use

Consider TXA as an adjunct to standard resuscitation for children with suspected major trauma *and* any of the following:

- Signs of haemodynamic compromise (e.g. hypotension, tachycardia, delayed capillary refill)
- Evidence or suspicion of active bleeding (e.g. open fractures, penetrating trauma, abdominal distension)
- High-risk mechanism with prolonged transfer to surgical care (e.g. rural EMS)
- Polytrauma with potential for occult bleeding

Important: TXA must not delay life-saving interventions (e.g. airway management, haemorrhage control, fluid resuscitation).

5.2 Dose and Administration

Component	Recommendation
Loading Dose	15 mg/kg IV (maximum 1 gram)
Route	Intravenous (slow push or diluted in 100 mL NS over 10 minutes)
Infusion	Not recommended at present
Repeat Dose	Not indicated
Timing	Administer as early as possible, preferably within 3 hours of injury

5.3 Practical Considerations

- Use pre-calculated weight-based dosing (e.g. Pawper tape, Broselow tape or digital aids) to avoid delays.
- If IV access is delayed, prioritise life-threatening interventions over TXA administration.
- Avoid rapid bolus infusion to minimise risk of hypotension.
- Co-administer with fluid resuscitation and haemostatic measures as indicated.

6. Contextual and System-Level Considerations

These recommendations recognise that decisions about TXA use in paediatric trauma occur within complex systems of care, often under significant time pressure and resource constraints. The following considerations informed the guidance provided:

Factor	Consideration
Risk–Benefit	TXA has a favourable safety profile and potential benefit in reducing haemorrhage-related mortality. Given the low risk of a single-dose regimen and the high trauma burden, cautious use is justified.
Feasibility	TXA is readily available in most emergency centres and prehospital settings. Administration is simple and requires minimal additional training.
Cost and Resources	TXA is inexpensive and listed on the EML for adult trauma. Its use in children does not impose additional procurement burdens. No infusion pumps or special monitoring are required for the recommended single-dose regimen.
Acceptability	Emergency clinicians are already familiar with TXA use in adults. The recommendation supports clinical discretion rather than a prescriptive protocol, which is likely to enhance acceptability.

Factor	Consideration
Equity	These recommendations aim to reduce disparities in care by supporting access to TXA in rural and under-resourced settings where delays to surgery are more likely. The permissive nature of the guidance allows flexibility while promoting consistency.
Practice Variation	Current variation across referral centres creates confusion and medico-legal uncertainty. A clear advisory position helps standardise practice without enforcing rigid guidelines.
Implementation	Introduction should be supported through case-based learning, clinical governance discussions, and integration into trauma audits. Ongoing monitoring will help inform future guidance.
Monitoring and evaluation	Explicit development of local audit tools and a shared learning platform to capture outcomes and inform future updates by the tertiary trauma centres currently using TXA in major paediatric trauma. Further, consider routine trauma audits, debriefs and referral handovers to include use of TXA to ensure continuous learning and alignment across prehospital and hospital care.
Guideline Alignment	These recommendations are not intended to replace national STGs/EMLs but to provide interim direction in areas where no formal guidance exists. Alignment with local referral centre practices is strongly encouraged.

7. Summary of Recommendations

These interim recommendations provide structured, context-sensitive guidance on the use of tranexamic acid (TXA) as an adjunct in management of major paediatric trauma. They support cautious use in selected cases where there is clinical concern for major haemorrhage and delayed access to definitive care.

1. **TXA may be considered for critically injured children** with suspected significant haemorrhage, particularly in settings where definitive care may be delayed (e.g. rural EMS, interfacility transfer).
2. **Use TXA as an adjunct, not a core intervention.** It must not distract from priority actions such as haemorrhage control, airway management, and fluid resuscitation.
3. **Suggested dosing:**
    - 15 mg/kg IV loading dose (maximum 1 gram)
    - Dilute and administer slowly over 10 minutes
    - Do not repeat or continue with an infusion
4. **Timing:** Aim to administer within 3 hours of injury. Earlier administration is preferable.
5. **Do not delay transfer** or compromise stabilisation efforts to administer TXA.
6. **Align with local referral centre practices** and promote shared protocols where feasible.
7. **Use clinical discretion.** TXA use should be based on clinician judgement, guided by injury severity, haemodynamic status, and anticipated delays to surgical care.

8. **Do not formalise into national or provincial guidelines at this stage.** Instead, implement through a permissive position statement that supports decision-making while minimising medico-legal exposure.
9. **Monitor TXA use through clinical governance processes**, trauma audits, and quality improvement initiatives. Document all cases clearly.
10. **Educate teams on appropriate indications and dosing**, and ensure TXA is included in trauma discussions and training, particularly for EMS personnel and clinicians in rural or district facilities.

These recommendations are **conditional** and reflect **low-certainty evidence**, extrapolated from non-trauma paediatric settings, observational data, and adult trauma protocols. While TXA has demonstrated a favourable safety profile in children and is widely used in elective surgeries, its benefit in paediatric trauma remains **uncertain**, with no definitive mortality reduction proven in high-certainty studies.

The recommendations were developed through expert consensus, contextualised to the South African health system, and intended to support **pragmatic decision-making** in situations where delays to definitive haemorrhage control may increase the risk of preventable mortality. They are not prescriptive but offer **interim guidance** to reduce unwarranted practice variation and support safe, equitable care in resource-limited and high-risk settings.

Clinicians should exercise **judgement on a case-by-case basis**, prioritising haemorrhage control, airway, and resuscitation, with TXA considered an adjunct. Further research, including prospective studies and routine audit of TXA use in paediatric trauma, is strongly recommended to inform future updates.

8. Endorsement and Approval

These recommendations were developed by a multidisciplinary panel through a structured consensus process. They reflect a balance between available evidence, clinical expertise, and the contextual realities of emergency care delivery in South Africa. This guidance is intended to support safe, equitable, and pragmatic decision-making in the care of children with major trauma.

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