

**Extrapolating Adult Evidence**  
***When not too: Massive haemorrhage***

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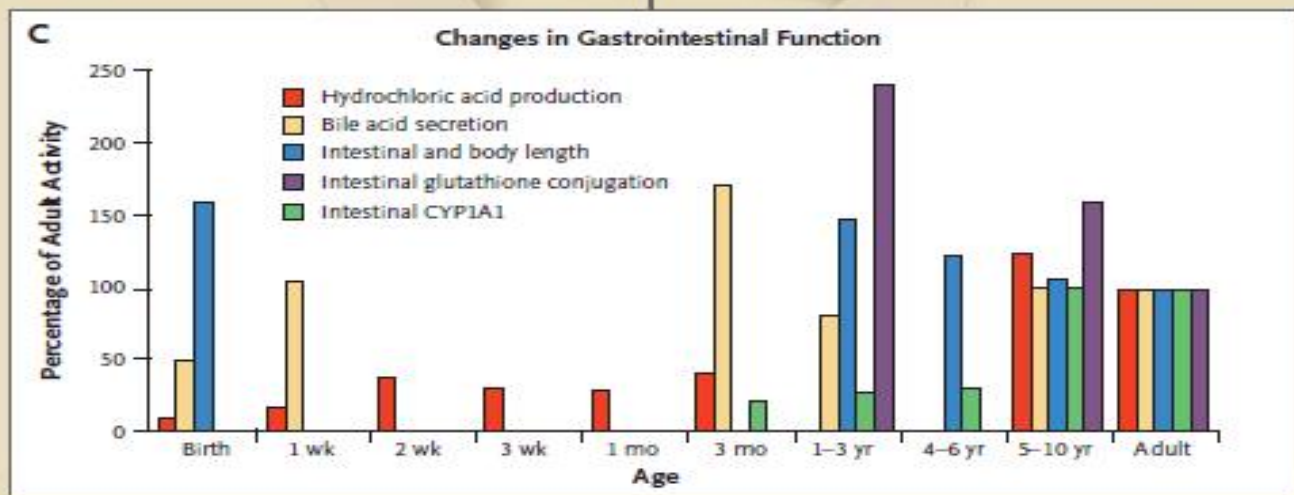
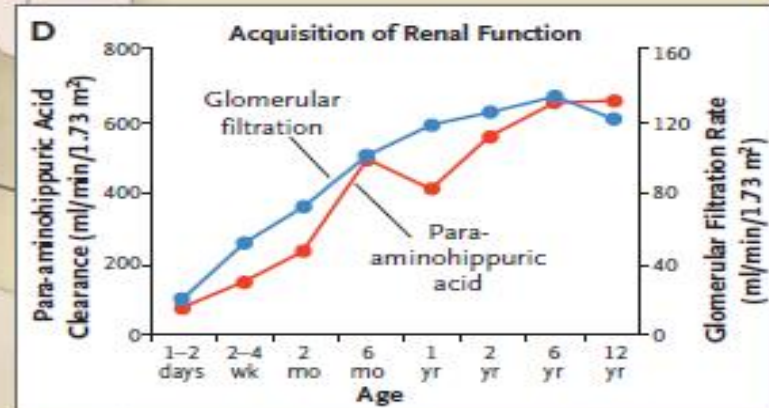
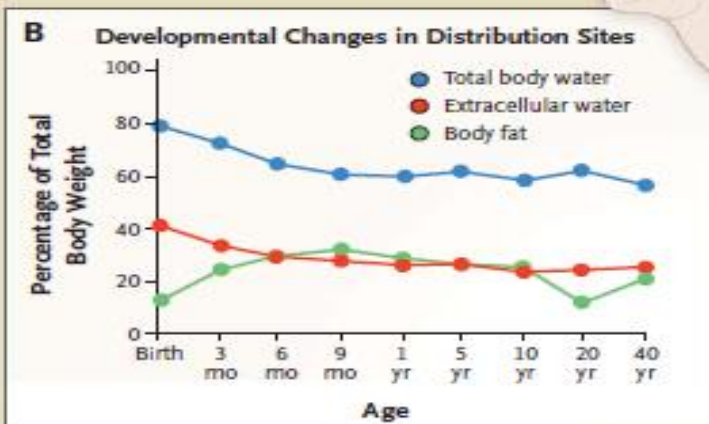
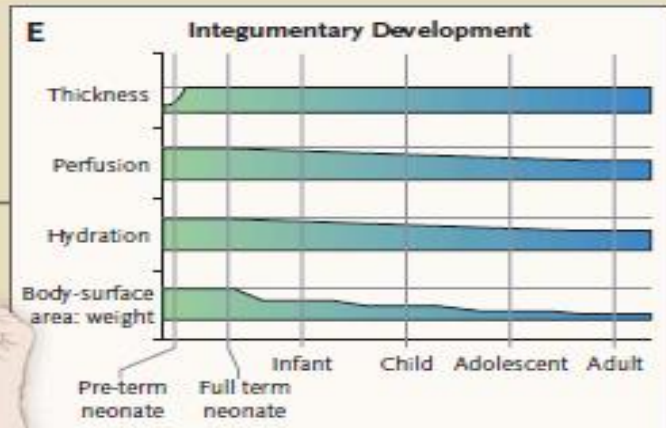
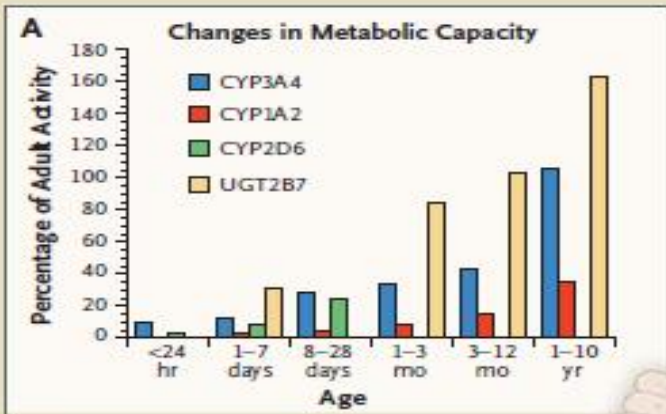
# Extrapolating Adult Evidence to Paediatrics

- Clinical research in children is often limited or lacking.
- The extrapolation of the benefit risk ratio from adults to children is performed during drug development and often implicitly used by paediatricians when prescribing off-label agents in children.

When considering extrapolation:

- Need to deliberate whether disease pathophysiology, natural history and disease severity and presentation are similar.
- Drug-drug interactions need to be considered.
- Drug metabolism according age groups (neonate, infants, children, adolescents) must be considered.
- Evidence of effectiveness & safety is available (RCTs ,case studies/series/observational studies etc.).

**Always look for data in the paediatric setting before considering extrapolation**



# New section added: Massive haemorrhage with massive transfusion

- During review it was identified that there was a need for the addition of new section on massive haemorrhage with massive blood transfusion to be added.

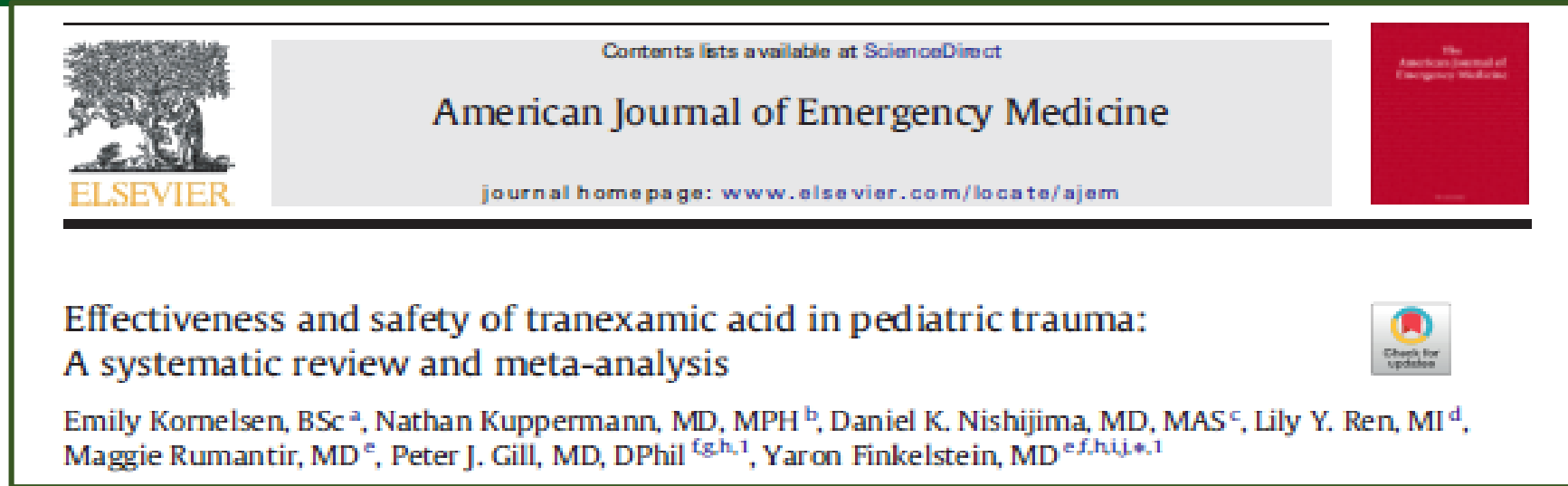
## 1.1.9 MASSIVE HAEMORRHAGE WITH MASSIVE TRANSFUSION OF BLOOD

### DEFINITION

Massive blood loss in children is recognised when a child requires a blood transfusion to replace 50% of total blood volume in 3–4 hours (40 mL/kg) or > 100% of total blood volume in 24 hours or receives replacement of 10% of total blood volume/minute. The rapid recognition is important to maintain tissue oxygenation by restoration of blood volume and haemoglobin.

- The Adult STGs and EML includes tranexamic acid for massive transfusion to expedite definitive control over bleeding.
- However for children this needed to be evaluated as there are concerns with efficacy (understanding statistics).

# Effectiveness and safety of tranexamic acid in paediatric trauma



- A systematic review and meta-analysis evaluating the effectiveness and safety of tranexamic acid in paediatric trauma found that the **benefits are unclear**.
- Tranexamic acid use was **NOT** associated with increased survival in paediatric trauma (adjusted odds ratio 0.61, 95% CI 0.3 to 1.22) after adjustment for patient-level variables such as injury severity.
- *Increased survival was only found in a subset of patients experiencing trauma in a combat setting. (not applicable in our setting).*

# Decision outcome

## Paediatric Expert Review Committee recommendation approved by NEMLC

- Tranexamic acid NOT included for massive haemorrhage with massive transfusion.
- Treatment recommendations included:

Facilities without access to blood bank	Facilities with access to blood bank
<ul style="list-style-type: none"><li>• Lyophilised plasma, IV<ul style="list-style-type: none"><li>○ 1 unit for each unit of emergency blood transfused</li></ul></li></ul>	<p>Massive transfusion pack to be requested</p> <p>Typically consisting of:</p> <ul style="list-style-type: none"><li>• Red blood cells</li></ul> <p>AND</p> <ul style="list-style-type: none"><li>• Lyophilised plasma OR Fresh frozen plasma (FFP)</li></ul> <p>AND</p> <ul style="list-style-type: none"><li>• Platelets</li></ul>

**Referral: All**

# Thank you