

Title: Massive Transfusion in Children-2 (MATIC-2) Policy (NCBH)		Document Number: 56465
Document Type: <input checked="" type="checkbox"/> Policy <input type="checkbox"/> Procedure <input type="checkbox"/> Guideline <input type="checkbox"/> Other		Last Review/Revision Date: Not Set
Content Applies to Patient Care: (Select all that apply)	Content Applies to: (Select One)	Effective Date: Not Set
<input type="checkbox"/> Adults <input checked="" type="checkbox"/> Pediatrics (Under 18)	<input checked="" type="checkbox"/> Clinical <input type="checkbox"/> Administrative	
Scope: <input type="checkbox"/> Enterprise <input type="checkbox"/> MW Region <input type="checkbox"/> SE Region		
<input type="checkbox"/> WI <input type="checkbox"/> IL <input type="checkbox"/> Greater Charlotte Market <input type="checkbox"/> Navicent Market <input type="checkbox"/> Wake Market <input type="checkbox"/> Floyd Market		
<input checked="" type="checkbox"/> Entity Only (Entity Name): NCBH <input checked="" type="checkbox"/> Department Only (Department Name): Blood Bank		

I. PURPOSE

The MATIC-2 trial is a Bayesian, randomized, multicenter, adaptive platform phase III trial. The trial will include injured children with hemorrhagic shock anticipated to require massive blood transfusion, who will be randomized to receive either LTOWB or CT and Tranexamic Acid or placebo.

The primary objectives are to

1. Determine the effectiveness of LTOWB to reduce all-cause 24-hour mortality compared to CT in children with traumatic life-threatening hemorrhage.
2. Determine the effectiveness of TXA to reduce all-cause 24-hour mortality compared to placebo in children with traumatic life-threatening hemorrhage.

II. SCOPE

This document applies to NCBH Blood Bank Staff and Management

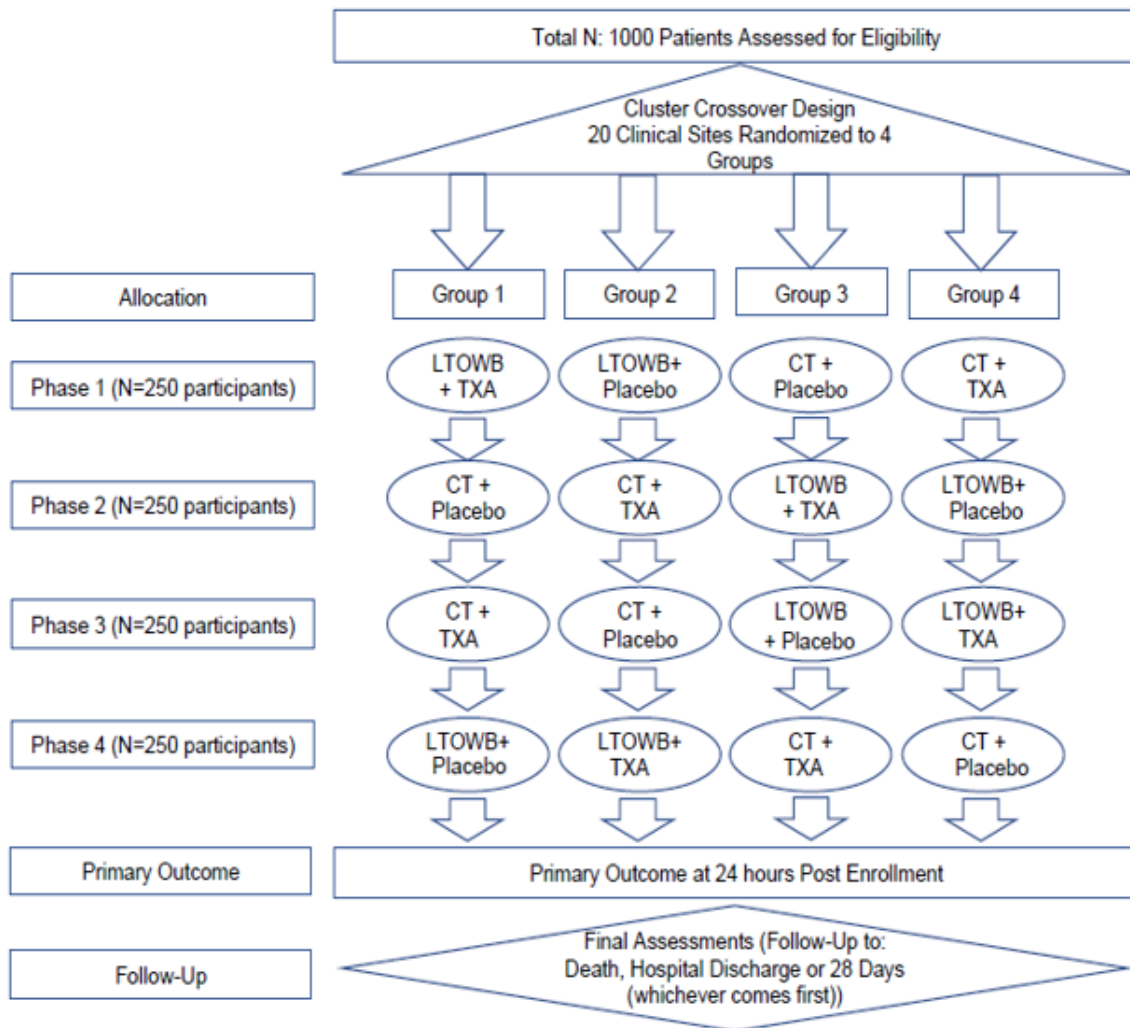
III. DEFINITIONS/ABBREVIATIONS

A. MATIC-2: Massive Transfusion in Children-2

IV. POLICY

- A. Blood Bank will be notified of a MATIC-2 Clinical Trial Patient via phone.
- B. Patients will receive either Low Titer O Whole Blood or Components based on a pre-defined randomization schedule.
 1. NCBH will start in the LTOWB group.
 2. After 250 patients have been enrolled in the trial, NCBH will give components for the next two phases (500 patients), before returning to whole blood for the final phase and last 250 patients.
 3. NCBH Blood Bank staff is blinded to TXA vs. placebo.

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4. No one is blinded to blood products.
5. Flags on Refrigerator 11 will indicate which phase of the trial we are in and what products to use.
 - a. Management will be responsible for keeping this signage updated.





- C. There is no limit to amount of LTOWB that can be given during phase 1 or phase 4 (when NCBH is randomized to LTOWB).
 - 1. There must be at least 5 LTOWB in stock to enroll a patient.
 - 2. If there are less than 5 LTOWB in stock, notify management immediately. Management will notify the clinical team that we need to pause the clinical trial until inventory can be replenished.
 - 3. ARC is our primary LTOWB supplier.
 - 4. NYBC is an alternate supplier and can be used in case of low inventory.

- D. Liquid plasma (group AB) can be used for MATIC-2 patients during Phase 2 and 3.
 - 1. Liquid plasma is not routinely used in pediatric trauma (<50kg patients) but is approved for the clinical trial.

V. PROCEDURE / GUIDELINE

- A. Pack and issue products per routine SOP.

VI. CROSS REFERENCES

Not Applicable

VII. RESOURCES AND REFERENCES

MATIC-2 Protocol, current version

VIII. ATTACHMENTS

Not Applicable