Taking it to the Streets!
Prehospital Infusion of Plasma

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Pepe’s Preparation
Current State

• Blood loss associated with trauma carries potential complications

• Current therapy
  – Salt solutions
    • Volume
Prehospital Trauma Study

Prehospital Randomization

Control
Receives Crystalloid

Test
Receives PolyHeme

Primary Endpoint
Increased Survival at 30 days

Secondary Endpoints
Reduce use of stored blood
Reduce multiple organ failure
Reduce adverse events
Control of Major Bleeding after Trauma (COMBAT)

Prospective, randomized study of fresh frozen plasma versus crystalloid as initial prehospital fluid resuscitation
**Inclusion:**
- Age $\geq$ 18 years
- Presumed Acute Blood Loss
  - $SBP \leq 70 \text{ mm Hg}$
  - $SBP 71 - 90 + HR > 108$

**Exclusion:**
- Pregnancy
- Prisoner
- *Unsalvageable (CPR at the Scene)*
- Objection to Blood Products
- GSW Head
Severely injured trauma patients with life-threatening bleeding (SBP < 70 mmHg or SBP < 90 with HR > 108 / min) = 1 in 4 chance of dying

assigned to either one of two groups at random

- **Standard Group:** Receive normal saline as first treatment fluid
- **Experimental Group:** Receive FP24 as first treatment fluid
### COMBAT Research Study

#### Standard vs. Experimental Group

<table>
<thead>
<tr>
<th>Standard</th>
<th>Test</th>
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<tbody>
<tr>
<td>1. Normal Saline</td>
<td>1. Plasma Transfusion</td>
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<tr>
<td>2. RBC Transfusion</td>
<td>2. Normal Saline</td>
</tr>
<tr>
<td>3. Plasma Transfusion</td>
<td>3. RBC Transfusion</td>
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</tbody>
</table>
COMBAT: FP24 Thawing

Plasma Storage = Dry Ice  -18°C

- Microwave (ArkBio) Standard = 6 minutes
- Water Bath (Permatherm) 2L = 2.5 minutes
FP 24 Water Bath Thawing

Terumo (Japan) = 2 liter bags
Massive Transfusion Protocol (MTP) Activation For Trauma

If Your Patient Has This In The Field or ED

- SBP ≤ 70
- or
- SBP 71-90
- AND HR ≥108

Penetrating Torso Injury
- Major Pelvic Injury
- FAST >1 Body Region

ACTIVATE MTP

Transfuse RBC 4 Units And FFP 2 Units

Order rTEG And Check ACT**

110-140 sec. and Angle≥60

Platelets 1 Unit
Cryo 10 Units

Check MA and LY30

Check LY30 ***

Repeat rTEG

If Patient Is Bleeding, Continue Component Transfusion Based On Following TEG Triggers

- ACT > 110 Sec
- Angle < 60°
- MA < 54 mm
- LY30 ≥ 3%

Give Tranexamic Acid For LY30 ≥ 3%

*COMBAT Study Criteria

**Available Within 3 Minutes

***Please Review Full TEG Tracing For Other Transfusion Triggers
Federal regulation (21 CFR §50.24) allows studies without consent.

- It is a **life-threatening situation** that needs urgent treatment.
- Patients **cannot give consent because of the condition** and the treatment must be given before a family member can be contacted.
- The treatment being studied **must possibly help the patient**.
- The study **cannot be done if a consent is required**.

It requires approval of:

- **Food and Drug Administration** (FDA)
- **Colorado Multiple Institutional Review Board**: Group of people not involved with the study whose main purpose is to protect human subjects of ANY study
- **Department of Defense**, Human Research Protection Office
Right of Refusal

• Potential subjects may opt out of this study by:

1. A bracelet stating “NO COMBAT STUDY”
2. A necklace ID stating “NO COMBAT STUDY”

These items can be requested free of charge from Denver Health.

• If a family member is present at the scene and not severely injured, easily accessible to paramedics, the paramedics will ask the family member if there is any objection to enrollment by saying ‘We are enrolling him/her in a research study where we are giving a blood product. We don’t have time to explain the study at this time. Is this okay?’ The paramedics will not be able to look for family members among a crowd of bystanders because of the importance of transporting the patient to the hospital as soon as possible.

www.DenverHealth/COMBATstudy
Study to Date

• Started enrollment in May, 2014
• 36 patients enrolled
• So far, so good!
Thank you!!!

TF-Bearing Cell

Activated Platelet

Platelet

VIIIa

VIIa

IXa

IX

IIa

Xa