# Taking it to the Streets! Prehospital Infusion of Plasma

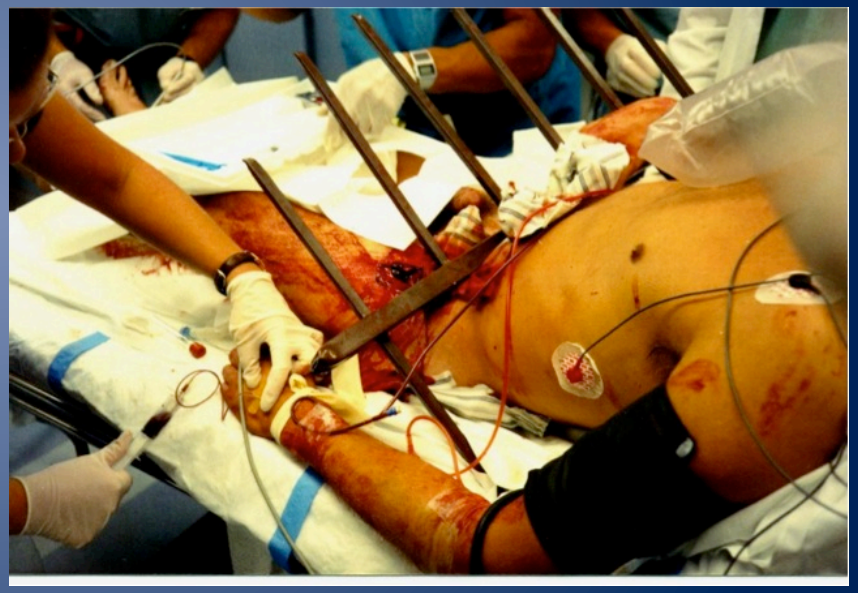
Christopher B. Colwell, M.D.

Denver Paramedic Division and
Denver Fire Department

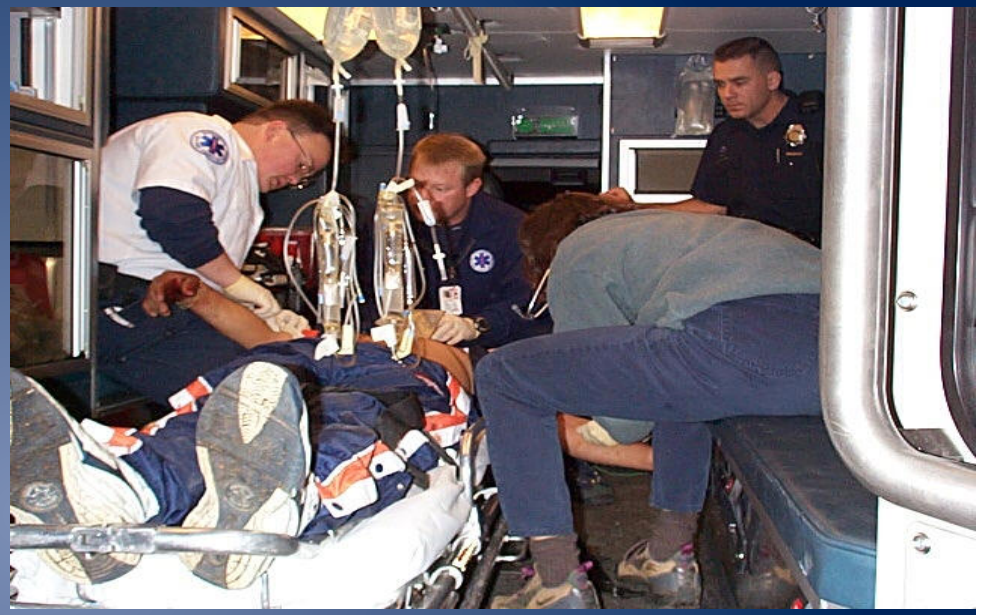
# Pepe's Preparation

# Current State

- Blood loss associated with trauma carries potential complications
- Current therapy
  - Salt solutions
    - Volume



# Prehospital Trauma Study




## Prehospital Randomization


Receives Crystalloid

Receives PolyHeme

**Primary Endpoint**

Increased Survival at 30 days

**Secondary Endpoints**

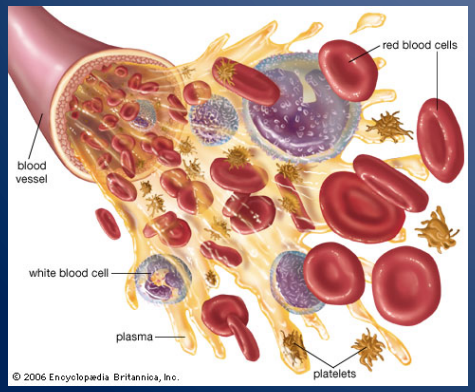
Reduce use of stored blood

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




# COMBAT Study Design

**Inclusion:**

Age ≥ 18 years

Presumed Acute Blood Loss

- SBP ≤ 70 mm Hg
- SBP 71 – 90 + HR > 108

**Exclusion:**

Pregnancy

Prisoner

Unsalvageable ( CPR at the Scene)

Objection to Blood Products

GSW Head

# Trial Design : Before the Hospital

Severely injured trauma patients with life-threatening bleeding ( SBP < 70 mmHg or SBP < 90 with HR > 108 / min ) = 1 in 4 chance of dying

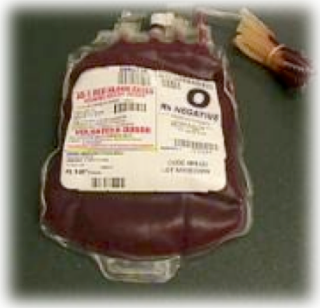
assigned to either one of two groups at random

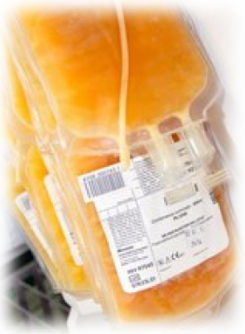
50% Standard Group: Receive normal saline as first treatment fluid

50% Experimental Group: Receive FP24 as first treatment fluid

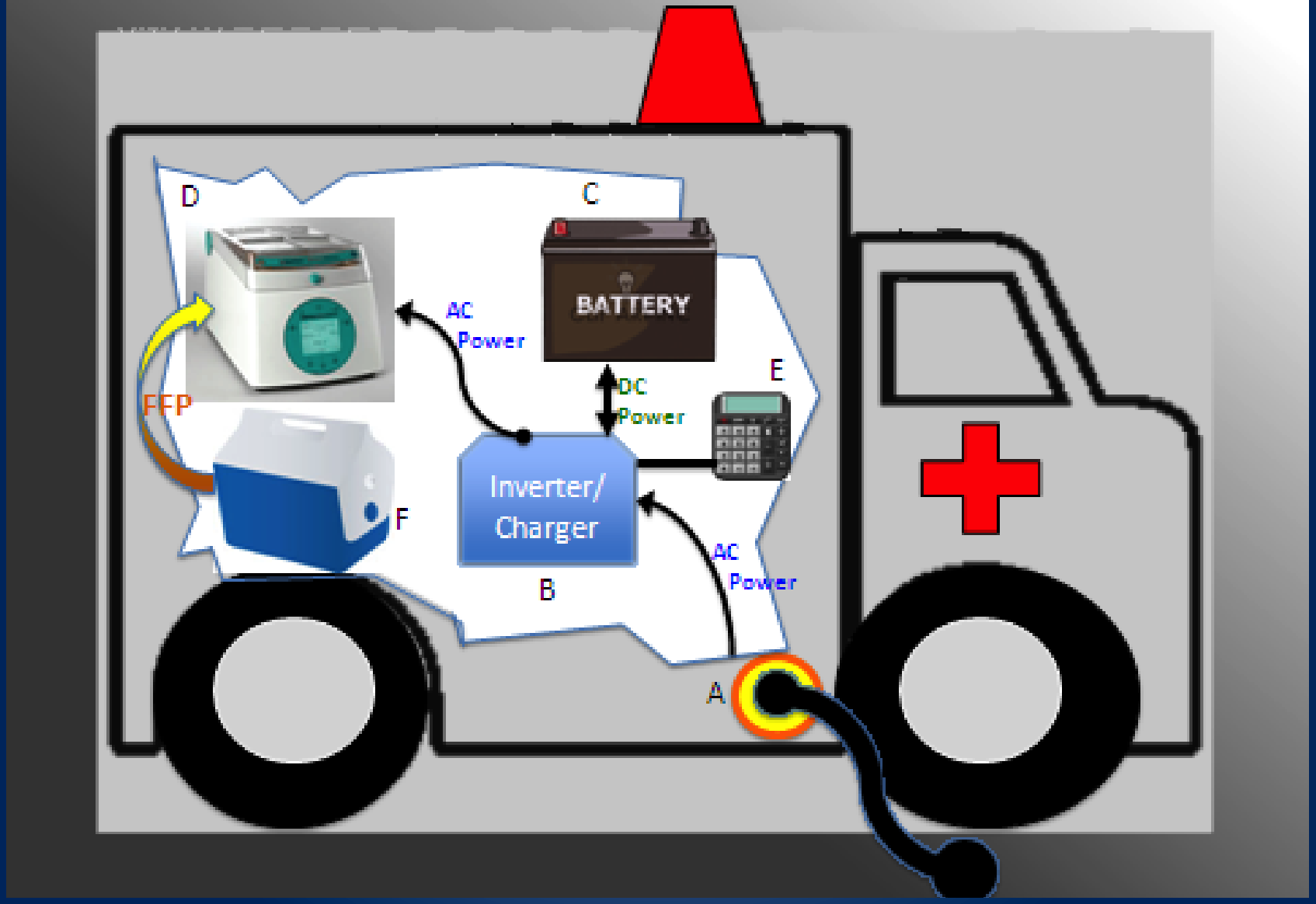
# Standard vs. Experimental Group

| Standard | Test |
|---|---|
| 1. Normal Saline | 1. Plasma Transfusion |
| 2. RBC Transfusion | 2. Normal Saline |
| 3. Plasma Transfusion | 3. RBC Transfusion |





# Components of a Ambulance-Mounted FFP Field Delivery System



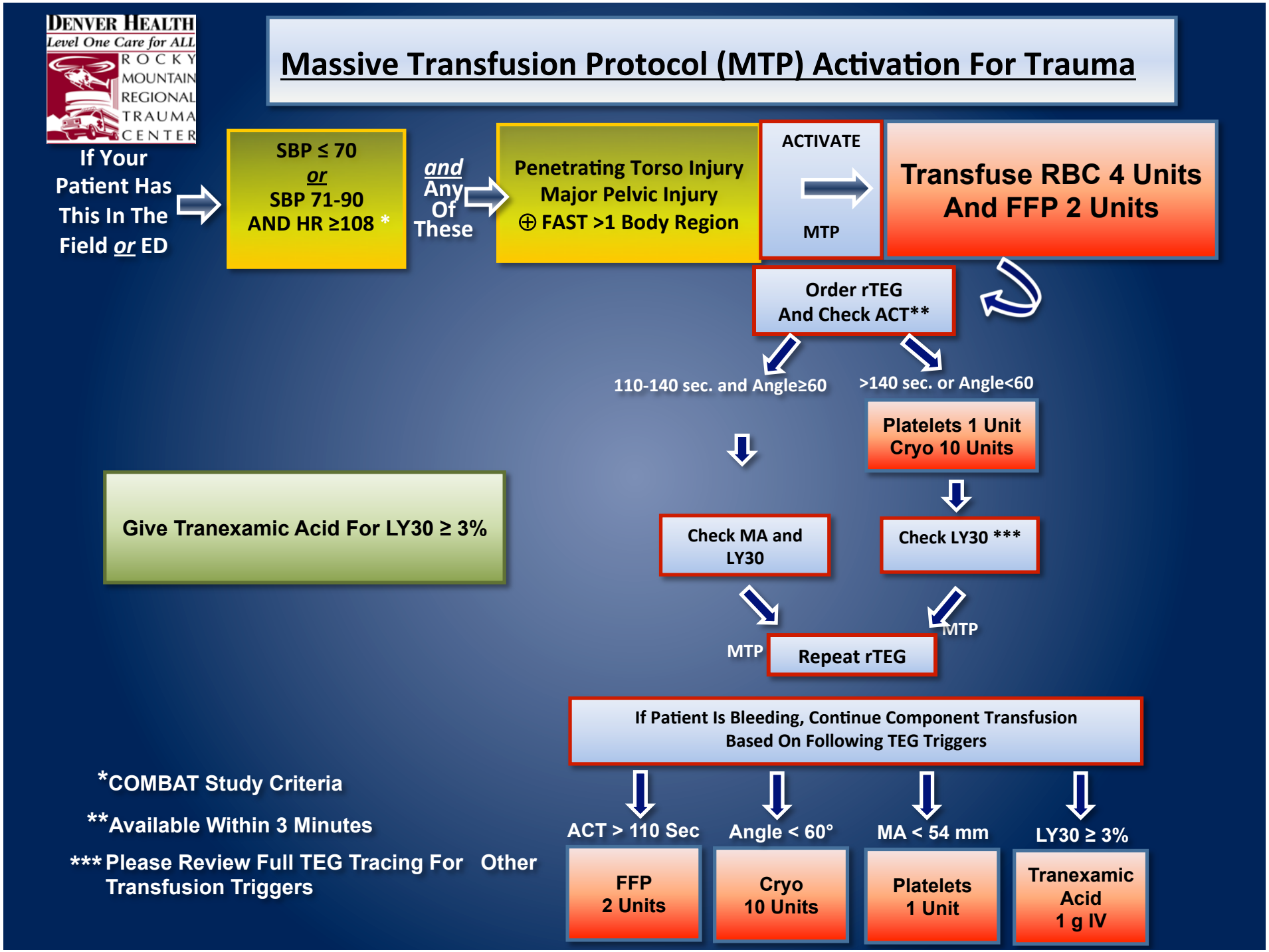
# COMBAT : FP24 Thawing

## 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**


DENVER HEALTH
Level One Care for ALL
ROCKY MOUNTAIN REGIONAL TRAUMA CENTER
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 *
and Any Of These
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
>140 sec. or Angle<60
Platelets 1 Unit
Cryo 10 Units
Give Tranexamic Acid For LY30 ≥ 3%
Check MA and LY30
Check LY30 ***
MTP
MTP
Repeat rTEG
If Patient Is Bleeding, Continue Component Transfusion
Based On Following TEG Triggers
ACT > 110 Sec
Angle < 60°
MA < 54 mm
LY30 ≥ 3%
FFP
2 Units
Cryo
10 Units
Platelets
1 Unit
Tranexamic Acid
1 g IV
*COMBAT Study Criteria
**Available Within 3 Minutes
*** Please Review Full TEG Tracing For Other Transfusion Triggers

# This Study is Done with an Exception from Informed Consent

**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"

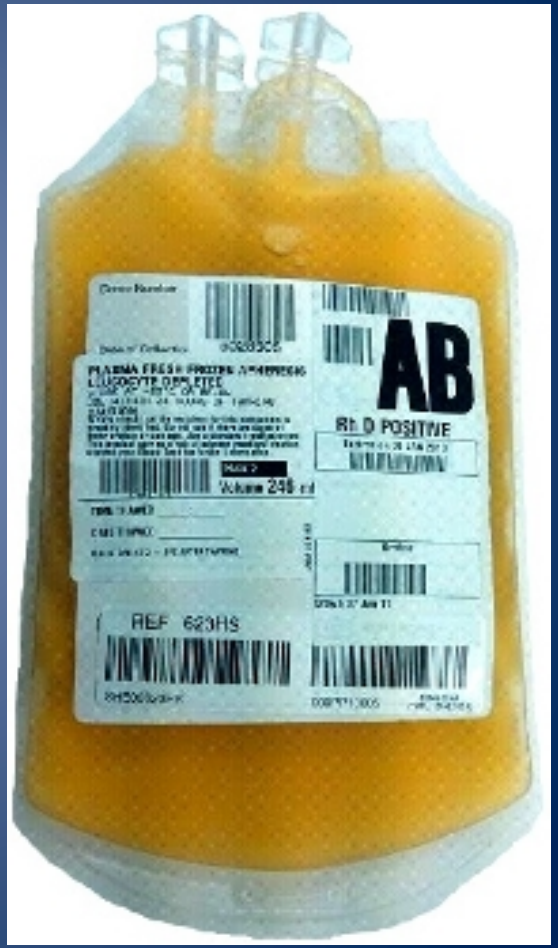
  These items can be requested ***free of charge*** from Denver Health

- **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.

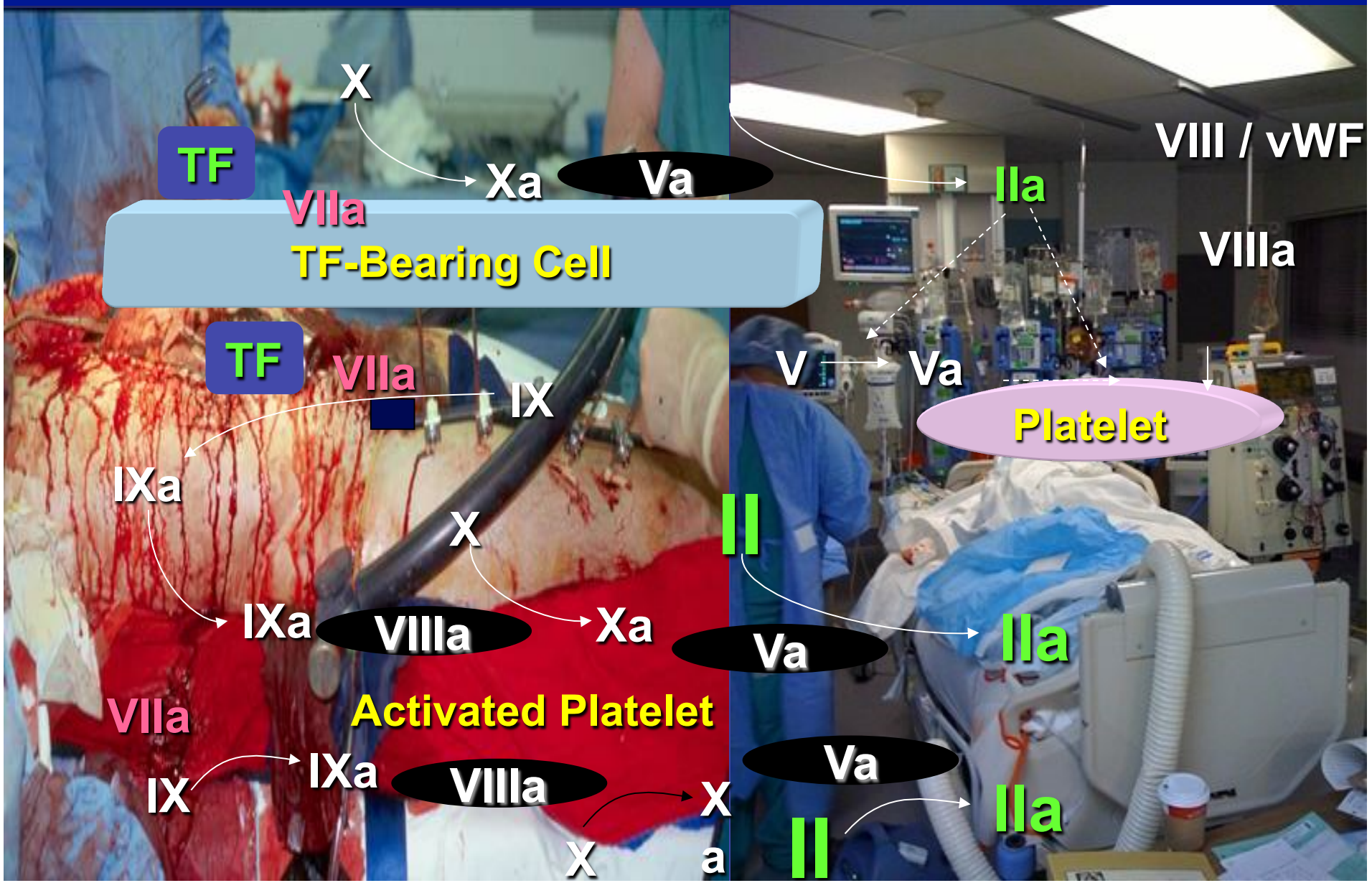
  – **www.DenverHealth/COMBATstudy**

# Study to Date

- Started enrollment in May, 2014
- 36 patients enrolled
- So far, so good!



# Thank you !!!


X
TF
Xa
Va
VIIa
TF-Bearing Cell
TF
VIIa
IX
IXa
X
IXa
VIIIa
Xa
VIIa
Activated Platelet
IX
IXa
VIIIa
X
X
a
VIII / vWF
IIa
VIIIa
V
Va
Platelet
II
IIa
Va
Va
IIa
II