

# Pragmatic, Randomized Optimal Platelet and Plasma Ratios



**(PROPPR)**

**Los Angeles County + University of Southern California  
(LAC+USC Medical Center)  
Community Consultation**

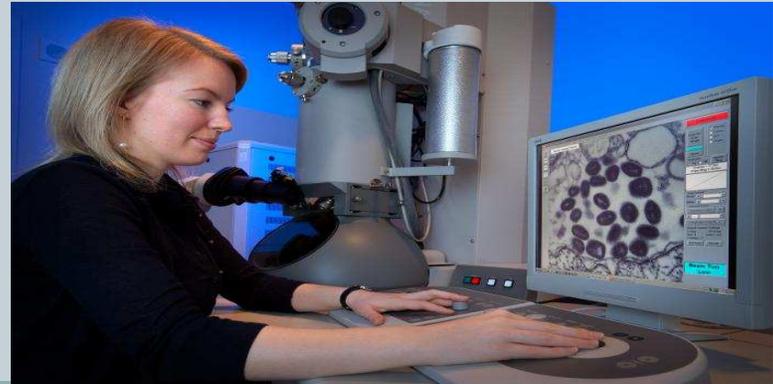
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**Sponsored by National Heart Lung and Blood Institute  
(NHLBI),  
and the National Institutes of Health (NIH)**

# What is Research?



- Research is a systematic study designed to contribute to generalizable knowledge. This means that researchers want a study to draw conclusions or find an answer to a question that applies to many people.
- Research is important as it allows doctors to make new advances in clinical care.
- Standard clinical care is performed by your doctor based on his/her expertise. Research follows a specific set of guidelines and rules.
- Clinical care always comes first, but with ongoing research, one can positively impact clinical care.



# What is Trauma?

- Trauma refers to a “a body wound or shock produced by sudden physical INJURY, from violence or accidents.
- It is the leading cause of death in people under the age of 45.
- People who have suffered trauma may require specialized care, including BLOOD TRANSFUSIONS and surgery.



# Background



- Nearly 50% of trauma deaths occur before the patient reaches the hospital and few of these deaths are preventable.
- About 40% of patients that reach the hospital will experience major bleeding problems and require a massive transfusion of at least 10 units of blood products.
- Complications from bleeding are the leading cause of early death in trauma patients.

# LAC+USC Facts



- LAC+USC is one of the largest Level 1 trauma center in Los Angeles, which is the highest level of trauma certification possible to provide emergency care
- Over 5,000 traumatically injured patients are taken to LAC+USC for care annually
- The doctors are faculty of the University of Southern California
- Surgeons are in the hospital 24/7
- Specialized trauma care is available at LAC+USC that is not offered at other local hospitals

# Study Focus



Study Question: What is the best blood product ratio to use for trauma patients who require a large amount of blood to save their lives?



# What is the PROPPR study?



- This study involves research.
- Locations: Includes at least 12 North American Level 1 trauma center sites. LAC+USC is the only site in Southern California.
- Purpose: Decide what the best ratio or amounts of blood products may provide the best outcomes for the patients.
- Plan: Enroll patients who are PREDICTED to receive large amounts of blood products into a research plan using two different amounts of red blood cells and other blood products
- The knowledge gained will likely impact the way in which massively bleeding patients are transfused and lower the amount of preventable deaths resulting from shock from massive blood volume loss

# Inclusion Criteria



## **You are eligible for PROPPR if:**

- Severely injured
- Estimated age 15 years or older. If the age is not known, the patient weighs more than 110 pounds
- Patient is predicted to receive a massive transfusion by using a scoring system or by the judgment of the senior trauma surgeon

# Exclusion Criteria



## **You are NOT eligible for PROPPR if:**

- Non-survivable injuries
- Prisoners directly admitted from jail
- Children under 15 years or if age is not known, patient weighs less than 110 pounds
- Obvious pregnancy
- Severely burned
- Had at least 5 minutes of CPR with chest compressions before arrival
- Known “Do Not Resuscitate” orders
- Patients who wear “PROPPR Ø” opt-out bracelet
- Religious objections to blood transfusions

# How are patients selected for this study?



- The trauma surgeon will use information collected when a patient first arrives to the LAC+USC Emergency Department to predict if he/she will require a large amount of blood products.
- For patients who are eligible for this study, the blood bank will be called and will randomize (a process like flipping a coin) the patient to receive one of two blood groups.

# What about other treatments and care?



- **People enrolled in the study will receive all other treatments and medical care given to anyone who is severely injured.** You will get the same treatment without being in the study.
- If you are not in the study, the only difference is that the combination of blood products given to you is decided by the doctors and not by the research plan.

# Is the blood safe?



Yes, the blood is safe.

- Blood products are processed through the LAC+USC Blood Bank
- Blood products are approved by the U.S. Food and Drug Administration and the American Association of Blood Banks
- Blood products are tested for infectious diseases
- LAC+USC has established policies to safely transfuse blood products

# What will be studied?



- We will collect one blood sample from all severely injured patients.
- We will collect small amounts of blood at various time points on all patients enrolled in the study.
- We will review your medical record daily.
- The 0 hour or first sample will be collected on all potential patients and stored for future tests. These tests do NOT include genetic testing.
- Patients in the study will be contacted one month after their admission to LAC+USC to find out how they are doing.

# Any Risks?



- Risks include: a chance of transmission of an infectious disease, low blood pressure, allergic reaction, shortness of breath, fever, and blood clotting problems.
- Because you needed a blood transfusion, you would have these risks whether or not you were in the study.

# What is the informed consent process?



- The consent process is when we ask for a person's permission to be in a research study. This process includes explaining the risks and benefits of the study, as well as answering any questions.
- For the PROPPR study:
  - Injured patients will be screened for enrollment into the study
  - Due to their injuries, when patients arrive in the LAC+USC Emergency Department they are unable to consent to the study
  - All eligible patients will be screened and entered into the study without providing informed consent
  - Blood samples will be taken without providing consent
  - Every attempt will be made to obtain consent from the legal representative and/or surrogate to continue or end participation in the study
  - Enrolled patients will be told about the study as soon as possible

# Exception From Informed Consent (EFIC)



Food and Drug Administration (FDA), Dept. of Health and Human Services (DHHS) and National Institute of Health (NIH) allow enrollment of patients into research with an EFIC when:

1. Subject has life threatening injuries, and
2. Obtaining informed consent is not feasible because:
  - (i) The subjects will not be able to give their informed consent as a result of their medical condition;
  - (ii) The intervention under investigation must be administered before consent from the subjects' legally authorized representatives is feasible; and
  - (iii) There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.
- (3) Participation in the research holds out the prospect of direct benefit to the subjects because:
  - (i) Subjects are facing a life-threatening situation that necessitates intervention;

# INFORMATION YOU SHOULD KNOW



- Patients and/or legal representatives/surrogates can decide at any time to withdraw from the study
- Patients will receive the same medical care and treatment whether they are in the study or not in the study
- There is no cost for being in the study and the patient will not be paid for being in the study

# INFORMATION YOU SHOULD KNOW



- Every effort will be made to make sure we maintain patient privacy
- All data reviewed for this study will be linked to identifiers (coded) during the study. That means we will remove your name and medical record number from the final data
- Members of the community may “opt-out” if they do not wish to be in the study. A colored, plastic bracelet with the word “PROPPR Ø” on it will be available for those who **DO NOT** want to take part in this study. If a patient arrives to the ED with this bracelet on, they will not be screened or enrolled in this study. An opt-out card for your wallet is available as well.

# Comments and Questions?



- For comments or questions about this study, please call:

Jay Zhu                      323-6960-OPT

Laura Sarmiento        323-6960-USC

Email: [proprr@usc.edu](mailto:proprr@usc.edu)

- For questions about informed consent, please call:

the Institutional Review Board (IRB)

323-223-2340; e-mail: [irb@usc.edu](mailto:irb@usc.edu)

- If you would like to “opt out” of the study, please call:

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**THANK YOU FOR YOUR TIME**

6/14/2012