Informed Consent for Participation in a Research Study

Title of Research Study: What is the ideal dose of whole blood in massively bleeding trauma patients?
Investigator: ***Babak Sarani, MD. Department of Surgery***

Key Information:

You are being asked to take part in a research study which seeks to determine how many units of whole blood should be transfused to help stop bleeding injured patients. This page will give you key information to help you decide whether or not you want to participate in this study. More detailed information can be found on the next pages. Ask the research team questions during the consent process, and use the contact information on this form to ask questions later.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THIS STUDY?

You have already received whole blood as a part of the initial transfusion you received when you arrived to the hospital. Study only asks your permission to write down how much blood you received, your lab test results, and your hospital outcome. There is no follow up for this study and you will not be contacted again by a member of the research team. This study will not impact any therapy you will receive in the future.

WHAT ARE THE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

By participating in this study, your information will be used to help determine how to best transfuse injured patients in the future.

WHAT ARE THE REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

There is a small risk that your information about your current hospital stay will be released. However, this risk is very small because all of the information will be entered into a password protected database.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

You do not have to take part in this research. It is your choice whether or not you want to take part. You can agree to take part and later change your mind. If you choose not to take part or choose to stop taking part at any time, there will be no penalty to you or loss of benefits to which you are otherwise entitled.

WHAT IF YOU HAVE QUESTIONS OR CONCERNS?

The person in charge of this study is Dr. Babak Sarani. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: 202-741-3188. 2150 Pennsylvania Ave, NW. 6B. Washington, DC 20037

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to them at 202-994-2715 or via email at ohrirb@gwu.edu if:

- You have questions, concerns, or complaints that are not being answered by the research team or if you wish to talk to someone independent of the research team.
- You have questions about your rights as a research subject.

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Detailed Consent Form:

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you received whole blood during your initial resuscitation after you were injured.

What should I know about a research study?

- Someone will explain this research study to you. You may ask all the questions you want before you decide whether to participate.
- Participation is voluntary; whether or not you take part is up to you.
- You can agree to take part and later change your mind.
- Your decision not to take part or to stop your participation will not be held against you.
- Your decision will not affect the medical care you receive from GW. If you decide not to take part, you can still receive medical care from GW.
- You may take this document home to read or to discuss with your family members or doctor before deciding to take part in this research study.

Who can I talk to if I have questions?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the Principal Investigator at 202-741-3188. 2150 Pennsylvania Ave, NW. 6B. Washington, DC 20037

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to them at 202-994-2715 or via email at ohrirb@gwu.edu if:

- You have questions, concerns, or complaints that are not being answered by the research team or if you wish to talk to someone independent of the research team.
- You have questions about your rights as a research subject.

Why is this research being done?

The purpose of this study is to determine how much whole blood should be given to bleeding injured patients during their initial resuscitation.

How long will I be in the study?

We expect that you will be in this research study during your current hospital stay only. There is no follow up period and you will not be contacted by a research team member in the future.

How many people will take part in this research study?

We expect about ___200__ people will take part in the entire study.

What happens if I agree to be in this research?

We will record information about the amount of blood you received, your laboratory test results, and your hospital outcome in a research database. This study will not impact the actual care you receive in any way.

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What other choices do I have besides taking part in the research?

You can choose to not participate in this study. Doing so will not impact the care you receive in any way.

What happens if I agree to be in research, but later change my mind?

You may refuse to participate or you may discontinue your participation at any time without penalty or loss of benefits to which you would otherwise be entitled.

If you decide to leave the research, contact the investigator so that the investigator can stop collecting information about your laboratory test results and hospital course. 202-741-3188. 2150 Pennsylvania Ave, NW. 6B. Washington, DC 20037

Is there any way being in this study could be bad for me?

There is a small risk that your information about your current hospital stay will be released. However, this risk is very small because all of the information will be entered into a password protected database.

Will being in this study help me in any way?

You will not receive any benefits from participating in this research.

What happens to my information collected for the research?

To the extent allowed by law, we limit your personal information to people who have to review it. We cannot promise complete secrecy. The IRB and other representatives of this organization may inspect and copy your information.

How will my privacy and health information be protected?

The Health Insurance Portability and Accountability Act (HIPAA) requires that researchers and health care providers protect the privacy of information that identifies you and relates to your past, present and future physical and mental health or conditions, or the provision of health care. If you agree to participate in this research, protected health information will be used and shared with others for purposes of the study. Below is more detailed information about how your health information will be shared and protected. By signing this form, you are allowing the people and groups that are listed in the next paragraphs to use your health information for this research study. Your information will only be used or shared as explained in this authorization form

The use and release of protected health information is for the purpose of collecting data for this study.

Protected Health Information to be shared: medical record number, age, gender, race, date of medical procedures.

Who may disclose your protected health information: The researcher and the other members of the research team may obtain your individual health information from:

Hospitals: GW Hospital

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By signing this form, you allow the use, sharing, copying, and release of your protected health information in connection with this study by:

- The members of the research team;
- Other healthcare providers such as labs which are part of the study;
- A safety monitoring board {include only if applicable};
- Institutional officials who are responsible for compliance;

All of the tests in this study would have been done as part of your regular care. These test results will be used both to treat you and to complete this research. The test results will be recorded in your medical record.

Once your health information has been disclosed to others outside of the hospitals and medical practices, the information may no longer be covered by the federal regulation that protects privacy of health information.

Not signing this form or later canceling your permission will not affect your health care treatment outside the study, payment for health care from a health plan, or ability to get health plan benefits. However, if you do not give permission to use your health information, you may not take part in this study because your health information is needed in order to conduct this study.

This Authorization does not have an expiration date.

However, you may cancel this authorization at any time. Even if you cancel this authorization, the researchers may still use the protected health information they already have about you; however, no new health information or new biological specimens will be collected from you after you cancel your permission.

To cancel your permission, you will need to send a letter to Babak Sarani, MD stating that you are canceling your authorization. This letter must be signed and dated and sent to this address: Babak Sarani, MD. 2150 Pennsylvania Ave, NW 6B. Washington, DC 20037.

Are there any costs for participating in this research?

No

Will I be paid for my participation in this research?

No

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Signature Block for Adult

By signing below, you agree that the above information has been explained to you and you have had the opportunity to ask questions. You understand that you may ask questions about any aspect of this research during the course of the study and in the future. Your signature documents your permission to take part in this research. Your signature documents your permission to take part in this research.

_____

Printed name of subject

_____ _____

Signature of subject Date

_____ _____

Printed Name of Legally Authorized Representative/Next of Kin Date

(if applicable)

_____ _____

Signature of Legally Authorized Representative/Next of Kin Date

(if applicable)

_____ _____

Signature of person obtaining consent Date

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Data Collection Supplements

How many units of whole blood does your center have? _____
How many units of whole blood can you administer to one patient based on your blood bank policy?_____

Study Center: _____
Patient Number: _____

Demographics and injury characteristics

- Age (years)
- Gender (male, female)
- Race (C, AA, Latino, Asian, Other)
- Mechanism of Injury
    - MVC: motor vehicle collision
    - MCC: motorcycle collision
    - AVP: auto vs pedestrian
    - Fall
    - Assault
    - GSW: gunshot wound
    - SW: stab wound
    - Other: _____ (free text)
- ISS
- AIS (body region)
    - Head
    - Face/Neck
    - Chest
    - Abdomen/Pelvis
    - Extremity
- Height
- Weight
- BMI: auto calculated
- Comorbidities:
    - HTN: hypertension
    - DM: diabetes mellitus
    - Anticoagulant therapy (DOAC/Warfarin)
    - Antiplatelet medication use
    - MI/CHF
    - Stroke
    - Liver failure, cirrhosis
    - Renal failure
    - Other (fill in)
- Initial temp, HR, BP
- FAST positive in the abdomen? Yes / No / Not done / Indeterminate

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- Blood products given by EMS: PRBC, Plasma, WB (units)

Hospital Course

- Units of whole blood given in 2, 4, 6, and 12 and 24 hours and time when they were given
- Operations performed for hemorrhage control in the first 4 hours
    - Laparotomy
    - Thoracotomy (in the operating room)
    - ED Thoracotomy
    - Extremity exploration
    - Craniotomy/Craniectomy
    - Neck exploration
    - Other
- REBOA used: yes / no
- Angioembolization for hemorrhage control within the first 4 hours
- TXA Given: yes / no
- 4-factor PCC given: Yes / No

Outcomes

- Units of packed red blood cells given in 2, 4, 6, 12, and 24 hours and time they were given
- Units of plasma given in in 2, 4, 6, 12, and 24 hours and time they were given
- Units of platelets given in 22, 4, 6, 12, and 24 hours (single donor equivalent) and time they were given
- Units of cryoprecipitate given in 2, 4, 6, 12, and 24 hours and time they were given
- Lactate and Base Deficit
    - On arrival
    - 2, 4, 6, 12, and 24 hours (as available)
- Hospital length of stay (LOS), days
- ICU LOS, days
- Ventilation days
- TEG/ROTEM results (if available)
    - On arrival
    - At 4 hours
    - At 6 hours
    - At 12 hours
    - At 24 hours
- PT/PTT/INR results (if available)
    - On arrival
    - At 4 hours
    - At 6 hours
    - At 12 hours
    - At 24 hours

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- Morbidity
    - ARDS based on NTDB
    - Ventilator Associated Pneumonia based on NTDB
    - AKI based on NTDB
    - PE based on NTDB
    -
- In-hospital mortality - yes, no.
    - Date of death

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