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SMaRT Blood: Single-unit versus Multiple-unit pRBC Transfusion in non-acute postpartum anemia

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UNIVERSITY OF PENNSYLVANIA RESEARCH SUBJECT INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	SMaRT Blood: Single-unit versus Multiple-unit pRBC Transfusion in non-acute postpartum anemia
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Why am I being asked to volunteer?

You are being invited to participate in a research study being conducted by Dr. Rebecca Hamm and Dr. Sindhu Srinivas, who are obstetricians at the Hospital of the University of Pennsylvania. You are being invited to participate because you delivered a baby during this admission and your doctor has recommended that you have a blood transfusion. This means receiving blood that was donated by other people. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

Blood transfusion is often recommended for women who have anemia (low blood counts) after delivering a baby. Currently, many doctors give 2 units, or packets, of blood because they expect that everyone will need 2. However, it may be better to only give 1 unit at a time to raise blood counts and relieve the symptoms of anemia, such as dizziness or feeling tired. The purpose of this study is to help us understand whether giving only 1 unit of blood at a time can reduce the total number of units of blood needed to raise low blood counts after delivery.

The study will compare the effects of giving 1 unit or 2 units of blood at a time. If you decide to participate, you will be in one of two groups – a group receiving 1 unit at a time or a group receiving 2 units at a time.

We are asking women to volunteer for the study if they are at least 18 years of age, they have delivered a baby, and have been recommended to receive a blood transfusion at the Hospital of the University of Pennsylvania.

How long will I be in the study? How many other people will be in the study?

You will participate in the study from today until a postpartum visit that will be scheduled 4 to 9 weeks from now. The study is expected to enroll 66 women and to take approximately 2 years. All participants will be from the Hospital of the University of Pennsylvania.

What am I being asked to do?

You are being asked to come back for a visit at 4 to 9 weeks after your delivery. This is recommended as standard of care for all postpartum patients. At this visit, we will ask you to complete three questionnaires about your mood, your relationship with your baby, and how tired you feel. We will also ask you about breastfeeding. The additional time needed for the study at this visit is about 20 minutes beyond the time needed for a usual postpartum visit.

You are being asked to allow us to gather information about your pregnancy and delivery by reviewing our computerized charting system. We will also review the records from your current hospital stay and any other hospital stay between now and your scheduled postpartum visit.

You are being asked to allow us to randomly assign you, like flipping a coin, to one of the two groups described below. Neither you nor the doctors working on the study will have any control over your group assignment.

The two groups are:

1. Single-unit blood transfusion, or 1 unit at a time. This means your doctor will order 1 unit of blood and your nurse will give you that blood through your intravenous (IV) line.

2. Multiple-unit blood transfusion, or 2 units at a time. This means your doctor will order 2 units of blood and your nurse will give you that blood through your IV line.

For both groups, a nurse will draw a blood sample 4 to 6 hours after the transfusion to look at your blood count. After the results come back, your doctor will see you, talk to you about the results, how you are feeling, and do a physical exam to help decide whether or not you need more blood. This exam and repeat blood count would be done with blood transfusions outside of the study as our standard of care. If your providers determine you need more blood after the first transfusion, you will be given additional units one at a time at the discretion of your provider.

What are the possible risks or discomforts?

Blood transfusion presents a risk of allergic reaction and infection. The study itself will not increase the risk. There will not be an increase in the number of exams or the number of blood draws if you participate in the study.

Questionnaires can sometimes make people feel embarrassed or uncomfortable. You may choose not to answer questions that make you uncomfortable.

There is also a risk of loss of confidentiality. However, all of our staff are well trained in protecting information about you and your baby and will take precautions to reduce the likelihood of this risk.

If you are randomized to the single-unit transfusion group, it is possible you will still need 2 units of blood, but over a longer period of time. This may lead to an extra night in the hospital. In addition, it may take more than one unit for your symptoms to improve. Finally, each unit of blood you are exposed to may increase the risk of developing an allergic reaction or antibodies against blood products.

Currently, both methods of blood transfusion are used at Penn; however, the method your own doctor would use is a matter of choice because there are no clear benefits to one method over another; physicians will use whichever method they prefer and feel is most appropriate for the patient.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available. However, based upon the nature of this study, we do not anticipate that this will happen.

What are the possible benefits of the study?

Receiving 1 unit of blood at a time might decrease the number of transfusions that you get and therefore might decrease your risk of an allergic reaction or an infection from blood. Receiving 2 units of blood at a time might help you feel better more quickly. However, this may not be the case. Participation in this study is for research purposes, and no health benefit is guaranteed for you. The results of this study could benefit future patients.

What other choices do I have if I do not participate?

You may choose not to participate in this study without affecting your present or future care at the University of Pennsylvania Health System. Your alternative to providing your consent is to not participate in this study. In that case you would still get a blood transfusion, with either 1 or 2 units being chosen at the discretion of your doctor. Both methods of blood transfusion being used in this study are also used routinely in clinical care.

Will I be paid for being in this study?

You will be paid $25 at the time of your discharge from this hospitalization and $25 at your postpartum visit after you complete the 3 surveys in the form of VISA gift cards.

Will I have to pay for anything?

You or your insurance will have to pay for any routine medical care that you receive, including all costs related to your labor and delivery, postpartum care, and blood transfusion because you would receive this care regardless of participation in the study. You will not be billed anything extra for your participation in this study.

What happens if I am injured from being in the study?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed on page 1 of this consent form.

When is the study over? Can I leave the study before it ends?

This study is expected to end after all participants have been recruited and all information has been collected. The study is expected to take four years. This study may also be stopped at any time by your physician, the University of Pennsylvania, or the Department of Obstetrics and Gynecology without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The study Principal Investigator, or the Department of Obstetrics and Gynecology has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care.

Who can see or use my information? How will my personal information be protected?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Your information will be held in a research database on a password protected computer in a locked office in the Department of Maternal Fetal Medicine. Only the principal investigator or study staff will have access to these files.

Electronic Medical Records and Research Results

What is an Electronic Medical Record?

What is an Electronic Medical Record and/or a Clinical Trial Management System?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are

participating in a University of Pennsylvania research study, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any information produced from your participation in this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.
Once placed in your EMR or in the CTMS, your information may be accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc.).

What information about me may be collected, used or shared with others?

The following personal health information will be collected and used for research but will NOT be disclosed during your involvement with this research study:

- Name, date of birth, medical record number
- Personal medical and obstetric history
- Information from your medical records regarding your labor and delivery
- Information from physical examination
- Results of tests and procedures you will undergo during this research study as described in the informed consent form.
- Your telephone number in order to contact you to schedule the end of study postpartum visit.

Why is my information being used?

Your information and results of tests and procedures are used to:

- do the research
- oversee the research to see if the research was done right.

We will not contact you after your postpartum visit.

Who may use and share information about me?

The following individuals may use your personal health information for this research study:

- The Principal Investigator and the Investigator's study team

- Authorized members of the workforce of the UPHS and the School of Medicine, and University of Pennsylvania support offices, who may need to access your information in the performance of their duties (for example: for research oversight and monitoring, to provide treatment, to manage accounting or billing matters, etc.).

At this time there are no plans to disclose specific information to anyone besides those persons listed above.

Who, outside of UPHS and the School of Medicine, might receive my personal health information?

As part of the study, the Principal Investigator and the study team may review your personal health information, including the results of the research study tests.

This information may be disclosed to those listed below upon request:

Individuals or organizations responsible for administering the study:

At this time, there are no plans for anyone besides the researchers involved at the Hospital of the University of Pennsylvania to receive your personal health information.

Regulatory and safety oversight organizations

- University of Pennsylvania Institutional Review Board
- Perelman School of Medicine's Office of Human Research
- U.S. Food and Drug Administration

Once your personal health information is disclosed to others outside of UPHS or the School of Medicine, it may no longer be covered by federal privacy protection regulations.

In the event that it becomes necessary to disclose information to others outside of UPHS, only de-identified information will be provided. In that case, you will be referred to by a study number. Your name, medical record number, date of birth, or any other information through which it would be possible to identify you as an individual will NOT be used. After we have collected all of your information, we will refer to you only as the random study number you are assigned, and not by anything else that could selectively identify you as an individual.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may UPHS and the School of Medicine be able to use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research repository (database). However, UPHS and the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization to do so
- The University of Pennsylvania's Institutional Review Board grants permission after ensuring that appropriate privacy safeguards are in place
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes, at any time you may withdraw your approval to allow the use and disclosure of your personal health information as described here. You must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, your personal health information that was collected before we received your written request may still be used and disclosed, as necessary for the study. If you withdraw your permission to use your personal health information, you will also be withdrawn from the research study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study. If you decide not to participate, you have the option of choosing to allow us to collect your information for data analysis. A checkbox is available for this option below.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. law. This web site will not include information that can identify you. At most, the web site will include a summary of the results. You can search this web site at any time.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations and people involved with the operations of this study.

A copy of this consent and HIPAA authorization form will be given to you.

_____	_____	
Name of Subject (Please Print)	Signature of Subject	Date
_____	_____	
Name of Person Obtaining Consent (Please Print)	Signature	Date

☐ I do not wish to participate in this study but am willing to have the information collected that is described in this consent form. My information will be used to compare the personal health information of those who participate in the study and those who do not.

When you select this option, you are declining to participate in this study but are agreeing to having your information collected. This means that you have read the consent form, your questions have been answered, and you have decided not to volunteer. Although you will not be randomly assigned to a transfusion method, you will allow your information to be collected. Your signature means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent and HIPAA authorization form will be given to you.

_____	_____	
Name of Subject (Please Print)	Signature of Subject	Date
_____	_____	
Name of Person Obtaining Consent (Please Print)	Signature	Date