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Legal Representative Information Sheet

Title of Study: A Multi-Centre Randomised Controlled Trial of Pre-Hospital Whole Blood Administration versus Standard Blood Component Care for Traumatic Haemorrhage.

Chief Investigators: Dr Laura Green and Professor Jason Smith

Sponsor: NHS Blood and Transplant (NHSBT)

Introduction

This hospital is taking part in a research study to investigate different types of blood transfusion given to patients who are bleeding after suffering a serious injury.

Why am I being given this information?

Your relative/friend recently suffered from a severe injury and major bleeding. As part of their emergency care in the air ambulance (before they arrived at the hospital), they needed a blood transfusion. The doctors and paramedics agreed that it was appropriate for your relative/friend to enter a research study investigating treatments for bleeding in patients with severe injuries. This decision was made by your doctors on behalf of your relative/friend as they were too unwell to consider taking part at that time.

You are being given information about this research study because your relative/friend is currently unable to decide for themselves whether to participate in this study. We would therefore like to ask whether you think your relative/friend would like to take part. Please consider what you know about their wishes, feelings and their interests. Please let us know of any advance decisions they may have made about participating in research.

This research will help us improve the care of patients who suffer severe injuries in the future. Before you decide whether or not your relative/friend should continue in the study, it is important for you to understand why it is being done and what it will involve.

Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information.

If you decide that your relative/friend would not wish to continue in the study, it will not affect the standard of care they receive in any way.

What is the purpose of this study?

This study is investigating different blood transfusion treatments for patients with severe bleeding before they get to hospital. Every year, uncontrolled bleeding due to major injury accounts for more than 2 million deaths worldwide and 4,500 deaths in England.

Blood transfusion is an essential part of the treatment for severe bleeding, and any delay to starting transfusion can reduce the chances of survival. In the UK patients are often transfused blood at the scene of an incident, before they arrive at hospital. Transfusion may involve different blood components, red blood cells (important for carrying oxygen around the body), plasma (contains essential proteins to help blood clot) and platelets (small cells that are essential for blood clot formation).

Most UK air ambulances treat bleeding patients with a combination of red blood cells and plasma, which come in separate bags. Platelets are stored differently to other products and are more difficult to carry on air ambulances, so are only given after arrival at hospital.

However, carrying separate blood component bags introduces logistical challenges due to the additional weight the team needs to carry; increased complexity as several bags may need to be given to each patient; and a potential delay in transferring patients to hospital. Whole blood contains red cells, plasma and platelets all in one bag, as taken from a blood donor. Giving a blood transfusion of all of the components in a single bag could overcome these challenges.

In this study, one group of patients will be given transfusions of red blood cells and plasma. The other group of patients will receive transfusions of whole blood. The effects of the two different treatments will be compared by looking at survival in the two groups and the amount of blood needed over the first 24 hours after injury. We are also investigating how the patients are doing up to three months after their injury.

At the end of the study we will determine which of the transfusion types is better (or whether there is no difference between them) so that more patients in the future will get the best treatment.

What will happen to my relative/friend if they continue to take part?

If you agree for your relative/friend to continue to take part in the study, we are asking for your consent to:

- Allow us to collect routine clinical information about your relative/friend, the care they receive whilst they are in hospital and after they are discharged.
- Contact them to ask them to complete a questionnaire about their health three months after their injury.
- To contact their GP to find out about their health in three months' time, if we cannot contact them directly.

We are also asking for your consent to use their identifiable information to obtain more detailed medical information following their injury from different organisations. These organisations are the Trauma Audit and Research Network (TARN) and the Intensive Care National Audit & Research Centre (ICNARC). They collect complex data from

patients across the country. We will need to collect data from these organisations about your relative/friend's injuries and care. Their information will be stored securely on NHS computers by NHS Blood and Transplant, protected by password and only accessible by the research team. At the end of this study, all identifiable data stored will be destroyed.

What are the possible risks and benefits of taking part?

There are no known risks linked to/attributed to taking part in this study, and there are no known additional risks in participating in the study compared to the risk associated with transfusing blood components.

However, information collected as part of your participation in this trial may benefit patients in the future, even if you were randomly allocated to the standard treatment group.

What if there is a problem?

If you have any concerns about any aspect of this study, you should ask to speak to the researchers who will do their best to answer any questions. If you remain unhappy and wish to complain formally, or if you wish to speak to someone who is independent of this study please contact your local hospital Patient Advice and Liaison Service (PALS). You can speak to them on the telephone [local Trust PALS number here], via email at [local Trust PALS email here] or ask them for an appointment in person.

In the unlikely event that something does go wrong and your relative/friend is harmed during the research due to negligence then they may have grounds for a legal action for compensation against the NHS Trust, but they may have to pay legal costs. The normal National Health Service complaints mechanisms will still be available to them (if appropriate).

What will happen if I don't want my relative/friend to carry on with the study?

It is up to you to decide whether your relative/friend should continue to take part in the study or not. If you decide that your relative/friend should continue to take part you will be free to change your mind at any time, without giving a reason. If you did decide to withdraw them from the study it will not affect the care they receive now or at any time in the future. If you agree for your relative/friend to continue to take part in this study, you will be given this information sheet to keep and will be asked to sign a consent form. If you decide that your relative/friend should be withdrawn from the study, we will ask whether you agree for us to keep the data that has been collected so far. We would like to continue collecting information about their health from their hospital records and from central NHS records. If you do not want this to happen, tell us and we will stop.

Once your relative/friend has recovered we will approach them to inform them of the study and get their consent to continue in the study.

How will my relative/friend's information be used?

We will need to use information from your relative/friend's medical records for this study. This information will include their NHS number and date of birth. People will use

this information to do the research or to check their records to make sure that the research is being done properly.

People who do not need to know who they are will not be able to see their name or contact details. Their data will have a code number instead.

We will keep all information about your relative/friend safe and secure.

Once we have finished the study, we will keep some of their data so we can check the results. We will write our reports in a way that no-one can work out that your relative/friend took part in the study.

What are your choices about how your relative/friend's information is used?

- You can decide for your relative/friend to stop being part of the study at any time, without giving a reason, but we will keep information about them that we already have.
- We need to manage your relative/friend's records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about them.

Where can you find out more about how your relative/friend's information is used?

You can find out more about how we use your relative/friend's information:

- at www.hra.nhs.uk/information-about-patients
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to informationgovernanceteam@nhsbt.nhs.uk

Will my relative/friend's GP be informed of their participation in the study?

Yes, we will write to your relative/friend's General Practitioner to inform them that they are taking part. If we think that your relative/friend shows signs of extreme anxiety and depression during the study, we will contact their General Practitioner to let them know.

What will happen to the results of the study?

Once the study is completed the results will be published in scientific and medical journals and presented at meetings. We will also provide a summary of the results on a dedicated study website which can be accessed at: www.nhsbt.nhs.uk/SWiFT. Your relative/friend will not be identifiable in any publications or presentations resulting from this study.

Who is organising the research?

The study is being managed by NHS Blood and Transplant Clinical Trials Unit. The study has been funded by NHS Blood and Transplant, the Ministry of Defence and ten different Air Ambulance Services.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been approved by the South Central – Oxford C Research Ethics Committee and the Health Research Authority.

The information sheets for the study (like this one that you're reading) have also been reviewed by members of NHS Blood and Transplant's Patient and Public Advisory Group.

Who should I contact for further information?

If at any time during the study you have questions or concerns regarding the study you can contact the local Principal Investigator or Research Nurse, who is in charge of the research study at this hospital:

Principal Investigator	Research Nurse
[to be localised]	[to be localised]