

Participant Information Sheet: Patient and Blood Donor Representatives (Focus Group)

Study of Whole blood in Frontline Trauma (SWiFT) Implementation study

Chief Investigators (CI): Dr Laura Green, Professor Jason Smith

Co-investigator for the Implementation study: Dr Grazia Antonacci

Invitation to participate in research

You are being invited to take part in a research study. Before you decide on whether to take part or not, it is important you understand why the research 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.

Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study. If there is anything that is not clear or if you would like more information, please ask us. Take time to decide whether or not you wish to take part. Thank you for reading this.

PART 1: WHAT IS THE PURPOSE OF THE 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 (through whole blood) 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 patients are doing up to three months after the injury.

This study involves: an evaluation of clinical outcomes (a randomised controlled trial – RCT), an economic study and an implementation study. You have been invited to participate in the implementation study. The Implementation study will assess the acceptability and implementation of the intervention in patients with life-threatening haemorrhage in the context of the SWiFT trial.

Specifically, this study aims to:

- Gain a deeper understanding of the contexts of implementation and the impact of the intervention on local (hospitals) and central (blood service) processes and systems.
- Identify factors that influence acceptability of the intervention from the perspective of healthcare professionals and its routine incorporation in everyday life.
- Inform future adoption and implementation of the WB pathway in other settings by identifying potential strategies for sustainable implementation.

The design of the Implementation study involves: (i) up to 40 interviews with operational staff, (ii) 4 focus groups with operational staff (up to 20 participants), (iii) one focus group with patient representatives and donors (10 participants), and (iv) one focus group with patient representatives, donors and operational staff (up to 10 participants).

Through our research we hope to provide practical recommendations to service providers and policy makers to support future implementation and spread of the whole blood (WB) pathway in other settings.

Why have I been invited?

As patient representative or blood donor, we are interested in learning your views on this. We might also contact you over the next months to participate in another focus group as part of this study. We are seeking 7-10 patient and blood donor representatives to participate in a focus group as part of this study.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason by sending an email to Dr Grazia Antonacci (g.antonacci@imperial.ac.uk).

PART 2: WHAT WILL HAPPEN TO ME IF I TAKE PART?

If you chose to participate in this study, a researcher from the study team will contact you directly to agree date and time for the focus group meetings. The focus group will be conducted face-to-face or using online communication technologies depending on the evolution of the Covid-19 pandemic and preferences of participants.

This focus group is aimed at reviewing and consolidating findings emerging from interviews and focus groups about operational staff perspectives on acceptability and implementation of the intervention, previously conducted as part of this study. During the focus groups we will present findings from interviews and focus groups with operational staff and will prompt discussion about the patient and blood donor perspectives about acceptability and implementation issues in order to understand what is important for services to be aware of if this treatment is implemented on a wider scale. The focus group will last 2-3 hours. This programme of research will last from August 2022 to July 2024.

What do I have to do?

If you choose to participate, you will be asked to attend the focus group at the date and time agreed. During the focus group you will be invited to answer a number of questions which you can respond to or decline as you see fit. You will receive £75 for participating in the focus group. Travel expenses will also be covered if the focus group is conducted face-to-face.

What are the possible disadvantages and risks of taking part?

There are no anticipated disadvantages or risks to taking part in this study.

What are the possible benefits of taking part?

Participation in the focus group is entirely voluntary. There may be benefits to participation, such as helping to shape management and policy recommendations resulting from this work aimed at informing future adoption and implementation of the WB pathway in other settings.

What if something goes wrong?

There are no anticipated risks to taking part in this study. If you would like to make a complaint or comment about the study conduct or impact on you please contact the Chief Investigators directly, Dr. Laura Green (laura.green@nhsbt.nhs.uk) and Professor Jason Smith (jasonesmith@nhs.net, or via SWiFT@nhsbt.nhs.uk).

What will happen to the results of the research 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. You will not be identifiable in any publications or presentations resulting from this study.

In any dissemination activity, confidentiality will be maintained by removing all personally identifiable information from the focus group transcripts. Any verbatim quotes used in the reports and publications will be anonymised and referred to only by the date of the focus group and/or the type of role of the participant. To maximise confidentiality of individual participants generic role such as patient or donor representative.

Who is organising and funding the research?

The research is sponsored by NHS Blood and Transplant and co-funded by: NHS Blood and Transplant, 10 Air Ambulance Charities and the Ministry of Defence.

Who has reviewed the study?

This study has been approved by the **South Central – Oxford C** Research Ethics Committee and the Health Research Authority.

How will we use this information about you?

NHS Blood and Transplant (NHSBT) is the sponsor and data controller for the SWiFT trial and has commissioned Imperial College London to conduct the Implementation study. Imperial College London will process data for this part of the study, on behalf of NHSBT. This means that we are responsible for looking after your information and using it properly. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

We will need to use information from you for this research project. This information will include your:

- Name
- Initials
- Contact details (email address and phone number)
- Generic role (e.g. patient representative or donor representative).

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number or participant ID instead. Focus groups will be audio recorded and professionally transcribed. Audio recordings will be deleted once transcribed.

We will keep all information about you safe and secure.

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

Legal Basis

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the [UK Policy Framework for Health and Social Care Research](#)

Sharing your information with others

For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, we will share your personal data with certain third parties. Other College employees, agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your 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 you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- the HRA leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to dpo@imperial.ac.uk
- by ringing us on 020 7594 9173.

Complaint

If you wish to raise a complaint on how we have handled your personal data, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO).

Contact for Further Information

Grazia Antonacci – g.antonacci@imperial.ac.uk, 020 75949173.