SWIFT Aotearoa

NORTHERN RESCUE
NZBLOOD
Te Ratonga Toto O Aotearoa

Patient Information Sheet

Title of Study:	Study of Whole Blood in Frontline Trauma in Aotearoa (SWiFT Aotearoa): *A Randomized Controlled Feasibility Trial Assessing Prehospital Platelet-Rich Whole Blood versus Platelet-Poor Whole Blood in Traumatic Haemorrhage*
Chief Investigators:	Dr Alana Harper Dr Richard Charlewood
Sponsor:	New Zealand Blood Service

Introduction

The Northern Rescue Helicopter Limited (previously known as Auckland Rescue Helicopter Trust) and the New Zealand Blood Service are participating in a research study. The study investigates different types of blood transfusions given to bleeding patients suffering serious injuries. This study is similar to one underway in the United Kingdom (UK)and is trying to work out if people do better receiving red cells and plasma or whole blood (red cells, plasma and platelets).

Why am I being given this information?

You recently suffered from a severe injury and major bleeding. As part of your emergency care, the pre-hospital doctors and paramedics agreed you needed a blood transfusion before arriving at the hospital. Northern Rescue Helicopter Limited is currently part of a trial investigating treatments for bleeding in patients with severe injuries. The blood used in your emergency medical care was part of this trial.

Because you were unwell and not able to provide your own informed consent at the time you needed the blood transfusion, we have been given approval by the reviewing ethics committee for the pre-doctor and paramedic involved in your care to decide on your behalf if enrolment into this study would be in your best interest.

Following an assessment to decide if you were eligible to participate in the study, the attending doctor and paramedic agreed that at the time of your pre-hospital care, participation in the study was in your best interest. The agreement to enrol you in the study has been documented in your medical notes.

If available, we would have also discussed the study briefly with your family/Whānau or friends prior to your enrolment.

Now that you are well enough to make an informed decision, we are asking you to consider your ongoing involvement in the study and have given you with this information sheet to read over and discuss with your family/Whānau.

Please read the following information carefully and discuss it with others if you wish. Please ask us if anything needs to be clarified or if you want more information.

It is expected that this research will help us improve the care of patients who suffer severe injuries with major bleeding in the future. Before you decide whether you should take part in the study, you need to understand why it is being done and what it will involve.

If you decide that you would not wish to take part in the study, it will not affect the standard of care you receive in any way.

What is the purpose of this study?

Every year, over 2,000 New Zealanders suffer from significant trauma. Access to specialised care is an important factor in recovery, and the Northern Rescue Helicopter offers this care across a broad coverage of urban and rural areas.

Blood transfusion is an essential part of the treatment for severe bleeding. Any delay in starting a transfusion can reduce the chances of survival. Rapid access to blood is especially important for rural and remote locations with long travel times. Therefore, the Northern Rescue Helicopter often transfuses blood to patients at the scene of an injury or in transport before they arrive at the hospital.

In general, transfusion of patients suffering from severe trauma may involve different blood components. These components include red blood cells (carry oxygen around the body), plasma (contains essential proteins for clotting) and platelets (small cells that are also essential for clotting).

Until now, Northern Rescue Helicopter Limited has treated bleeding patients with whole blood that does not contain platelets as a filter removes these as part of standard blood processing. This is considered “whole blood” in New Zealand and is the standard treatment for anyone receiving a blood transfusion.

Platelets are stored differently from other products and are more difficult to carry on air ambulances, so they are usually only given after arrival at the hospital.

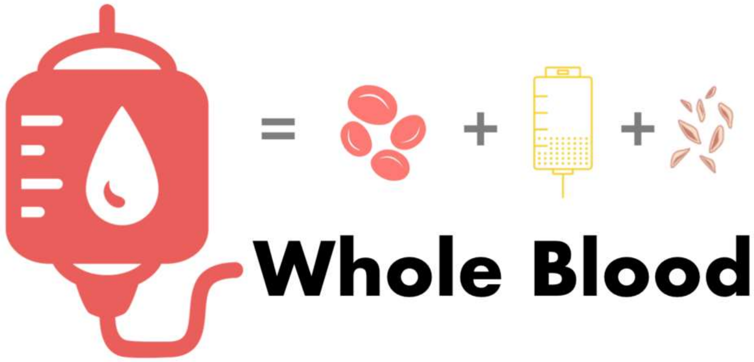
A new filter has been developed that does not remove the platelets from whole blood. Whole blood made using this new filter contains red cells, plasma, and platelets, all in one bag. Although this type of whole blood is not routinely used as standard of care in New Zealand, it is in the USA and Canada.

This SWiFT study investigates these two different blood transfusion treatments for patients with severe bleeding before they get to the hospital. Giving a blood transfusion of all the components in a single bag could improve patient outcomes and recovery. The platelets may improve clotting, decreasing the number and volume of blood transfusions.

In this study, one group of patients will be given a transfusion of red blood cells and plasma without platelets (the current standard of care). The other patients will receive a transfusion of red blood cells and plasma, and platelets. SWiFT Aotearoa will compare the effects of the two treatments by evaluating patient outcomes, including how much blood a patient needed. Patients will be randomised 1:1, meaning there is a 50% chance or receiving the current standard of care, and a 50% chance of receiving a transfusion containing platelets

This study is a “double blinded” study, meaning neither the patients or researchers will know which treatment each patient received. The reason for this is to improve the accuracy of the result by reducing any bias patients or researchers have towards a particular treatment. At the end of the study, if you would like to know what group you were treated as part of, we will tell you.

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 is the significance of this trial in New Zealand?

As mentioned at the start of this information sheet, a study similar to this has been run in the UK. However, unlike the UK, New Zealand has large areas of rural land with low numbers of people and a higher number of serious car crashes. In addition, the level care available across New Zealand varies due to different sized towns and hospitals. This combines to create a level of inequality of access to care. While this trial cannot address the underlying issues that give rise these inequalities, this trial aims to identify the best possible treatment in pre-hospital transfusion. Northern Rescue helicopters serve mainly rural areas, with car accidents which predominantly affect young men. This is a group known to be at risk of not receiving the healthcare they need. The people benefitting the most of this trial will be people living furthest from hospital. as pre-hospital transfusion makes the biggest difference when transport times are long.

What will happen to me if I take part?

You were enrolled in the study at the time of your blood transfusion and are being asked to consider providing your own consent to participate in the follow up for this study. There is no extra hospital visits or assessments needed as part of this study. Your consent to continue in the study will allow the study team to collect, routine clinical information about you and the care you receive in the hospital and after discharge.

If you are happy for us to keep following you up and collect information about your recovery, we will ask you to sign the consent form at the end of this information sheet.

What are the possible risks and benefits of taking part?

There are no known risks linked to/attributed to taking part in this study. There are no known additional risks in participating in the study compared to the risk associated with transfusing blood components. Information collected as part of this trial will improve transfusion practice in the future, regardless of the type of transfusion you received.

Participating in the trial will involve increased monitoring as members of the study team will be accessing your medical records. This is called “active surveillance” and means any adverse events may be recognised and responded to sooner. The standard of care in New Zealand is “passive surveillance” i.e. waiting for people to report adverse events.

What if there is a problem?

If you have any concerns about any aspect of this study, 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 want to speak to someone independent of this study, you can contact the Health and Disability Advocacy Service. Their details are included on page 9 of this information sheet.

If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.

What will happen if I don’t want to carry on with the study?

If you decided that you do not want to be involved, you can say NO and we will withdraw you from the study at this time. We will also remove any information we have collected about you, your treatment and care from the study notes unless you consent to allow that previously collected information to be used.

Your normal clinical care and follow-ups will continue and will not be affected by your decision.

What about my cultural beliefs?

NZBS understands that in Te Ao Māori, the body and blood are considered tapu and require special consideration and respect. NZBS respects these beliefs and values the sacredness of blood. The teams that handle blood do so respectfully. Where blood must be discarded, this is done respectfully, acknowledging the tapu nature of blood. This is part of the Blood Service's organisational values. If you'd like to discuss this further, we'd be happy to facilitate this.

If you need cultural support this can be provided. Please let the study team know and they will arrange this for you. Alternatively, you can ring the Cultural Support phone number at the bottom of this information sheet. Cultural support is different to knowing more about the study treatments. In these cases, the Transfusion Nurse Specialist can arrange a member of the study team to speak to you and your whānau.

How will my information be used?

Your identity as a participant in this study will remain strictly confidential. We will collect information (data') about you that is relevant to your study participation. This information will be used to complete separate study documents to communicate results with the sponsor and wider study team. Data in these separate study documents include basic demographics, a basic medical history, data about your laboratory test results, medications, and data collected during your time in hospital and any follow-up visits. If needed, additional information from your hospital records and your General Practitioner (GP) may also be collected. You cannot take part in this study if you do not consent to this information being collected.

Data collected will help the study team determine which of the transfusion types is better or whether there is no difference between them.

The data collected will be stored as either 'Identifiable Information' or 'De-identified Information':

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). This information is used to complete study specific documents that are held within NRHL, Health New Zealand | Te Whatu Ora and New Zealand Blood Service

The following people may have access to your identifiable information:

- Research team members, including the study doctor and Transfusion Nurse Specialists.
- Laboratory and radiology technicians – they will collect, process, analyse, and report any screening and follow-up tests you have.
- Study monitor (an authorized representative of the sponsor will be provided with access to review your medical records to check the accuracy of the information).

- The sponsor and its representatives, ethics committees, or government agencies from New Zealand, if the study or site is audited. Audits are done to make sure that participants are protected, the study is run properly, and the data collected is accurate.
- The Health and Disability Ethics Committee, for legal and regulatory purposes.
- Health, regulatory, or government agencies for legal and regulatory purposes.
- Your GP or other hospital doctors, if a study test gives an unexpected result (incidental finding) that could be important for your health. This allows appropriate follow-up to be arranged.
- The Medical Officer of Health, in the event of a positive result for a notifiable disease.

Rarely, it may be necessary for the Investigator to share identifiable data with people or groups not listed above – for example, in the event of a serious threat to public health or safety, or to the life or health of the participant or another person; or if the data is required for certain legal situations.

De-identified Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any study information sent to the sponsor. Instead, you will be identified by a unique study number, also known as a “code”. The research team will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

The following groups may have access to your de-identified and coded information as this will be sent and stored within NRHL and New Zealand Blood Service:

- Research team members, including your study doctor and Transfusion Nurse Specialist.
- The sponsor and study monitor, for the purposes of this study.
- People and companies working with or for the sponsor, for the purposes of this study (this may include approximately 10 people across 2 organisations)
- Disability Ethics Committee, to comply with legal and regulatory duties.
- Health, regulatory, or government agencies for legal and regulatory purposes, such as providing updates on the study and any adverse events.

Risks

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with de-identified and coded information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small but may increase in the future as people find new ways of tracing information.

Your de-identified information may be sent to the U.K. and combined with the study results from the SWiFT UK study. Other countries may have lower levels of data protection than New Zealand. There may be no New Zealand representation on overseas organisations which make decisions about the use of your information. There is a risk that overseas researchers may work with information in a way that is not culturally appropriate for New Zealanders, and there may be no New Zealand representation on overseas governance committees.

Security and Storage of Your Information

Your identifiable information is held at NRHL, Health New Zealand | Te Whatu Ora and New Zealand Blood Service during the study. After the study it is transferred to a secure archiving site and stored for at least ten years, then destroyed. Your coded information will be entered into an electronic database (RedCap EDC System) set up specifically for the study by the sponsor and stored on their internal servers. With this, your coded study information will be available through a secure server for the use of the sponsor. RedCap EDC System complies with international and national regulatory requirements in the countries where it is used. The de-identified data will be retained in secure cloud-based server by the sponsor for at least ten years, then destroyed by deleting the electronic files.

As deidentified data may be made available for use in the U.K. and Canada, it will be subject to the data protection laws of those countries, and not New Zealand. The research team acknowledges the cultural implications of sending Māori data overseas, with regard to the preservation of Māori Data Sovereignty principles. For further discussion and where to get support, please see the CULTURAL SUPPORT details on page 9.

Future Research Using Your Information

Your coded information may be used for future research related to treatment with blood transfusions. This is called “Future Unspecified Use” and is applicable to all data collected in this study. If you agree to participate in this study, your coded information may also be used for other medical and/or scientific research that is unrelated to the current study.

This future research may be conducted overseas. You will not be told when future research is undertaken using your coded information. Your coded information may be shared widely with other researchers or companies. Your coded information may also be added to information from other studies, to form much larger sets of data. You will not get reports or other information about any research that is done using your coded information. Your coded information may be used indefinitely for future research unless you withdraw your consent. However, it may be extremely difficult or impossible to access your information, or withdraw consent for its use, once your information has been shared for future research.

Information from this study may lead to discoveries and inventions or the development of a commercial product. The rights to these will belong to NRHL and New Zealand Blood Service. You and your family will not receive any financial benefits or compensation, nor have any rights in any developments, inventions, or other discoveries that might come from this information.

Incidental findings

An incidental finding is something extra that is found during a test or procedure and that is not expected. An example of this may be an unexpected blood result or a new diagnosis of a previously known condition. Any incidental findings discovered during the analysis of the study results will be passed on to your GP or the appropriate department of the hospital where a specialist appointment can be made with you to discuss these findings.

Rights to Access Your Information

You can request to have access to your medical records by contacting the study doctor or Transfusion Nurse Specialist. You may also request that any incorrect personal data be corrected. If you have any questions about the collection and use of the information about you, please speak to one of the Transfusion Nurse Specialists.

A description of this research study will be available on https://www.anzctr.org.au The identification number of the study is ACTRN12625000719437. These websites will not include information that can identify you. At most, the websites will include a summary of the results. You can search the websites at any time. All essential documents will be archived for at least ten years.

What are my choices about how my information is used?

You can decide to stop being part of the study at any time, without giving a reason. If you have previously agreed and now wish to stop being part of the study, we will keep information about you that we have already collected under your previous agreement. This is to protect the scientific integrity of the study.

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

The information will be used by the main study organisers in New Zealand. You can find out more about how we use your information in this trial:

- by asking one of the research team
- our leaflet available from www.clinicaldata.nzblood.co.nz/SWiFT

Will my GP be informed of my participation in the study?

Yes, we will write to your General Practitioner to inform them you are participating.

What will happen to the results of the study?

Once the study is completed, the information collected for all patients, including you, 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 at: www.clinicaldata.nzblood.co.nz/SWiFT. You will not be identifiable in any publications or presentations from this study.

By signing the consent form, you give permission for your de-identified information to be used in this way.

Who is organising the research?

The study is being managed by New Zealand Blood Service and funded by New Zealand Blood Service and Northern Rescue Helicopter Limited.

Who has reviewed the study?

This study has received ethical approval from the Northern A New Zealand Health and Disability Ethics Committee.

Members of the New Zealand Blood Service and Northern Regional Helicopter Limited have also reviewed the information sheet for the study that you're reading.

Who should I contact for further information?

If you require further information, have any questions, concerns, or complaints about the study at any stage, you can contact the one of the Principal Investigators or the Transfusion Nurse Specialist.

<table>
<tr><td>Principal Investigator:
Dr Richard Charlewood
☎ 027- 572-2547</td><td>Principal Investigator:
Dr Alana Harper
☎ 021-155-5134</td></tr>
<tr><td>Transfusion Nurse Specialist:
<Insert name>
☎<Insert contact number></td><td>Transfusion Nurse Specialist:
<Insert name>
☎ <Insert contact number></td></tr>
<tr><td colspan="2">You may also contact the Health and Disability Ethics Committee (HDEC) that approved this study on:
Email: hdecs@health.govt.nz</td></tr>
<tr><td colspan="2">If you have any queries or concerns regarding your rights as a participant in this research study, you can contact an independent Health and Disability Advocate.
This is a free service provided under the Health and Disability Commissioner Act
☎ NZ wide 0800 555 050;
Free Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz
Website: https://www.advocacy.org.nz/</td></tr>
<tr><td colspan="2">Māori cultural support
Please contact Steve Phillips for He Kamaka Waiora (Māori Health Team)
☎ 021425972</td></tr>
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