Participant Information Sheet

Participant Information Sheet – Pre-randomisation
Version 4.0, 15th December 2011

'The ABLE Study: Age of Blood Evaluation Study'

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve, so please take time to read the following information carefully. Talk to others about the study if you wish.

Key Facts about this study

- You are currently unwell in the intensive care unit.
- Your doctor has decided that blood transfusions, which contain mainly red blood cells, are needed as part of routine treatment.
- At present blood transfusions are stored in the blood bank following donation for up to 35 days. They can be used for patients at any time during this period.
- At present the duration of storage of any red blood cell unit is determined by the blood bank, usually in order to ensure that as many of the donations as possible are used for patients, and none are wasted
- We are unsure if there is a difference in the effectiveness of red blood cell units stored for shorter periods (for example less than one week) versus longer periods (for example greater than 3-4 weeks).
- This might be important, especially for intensive care patients like you, in whom blood transfusions are often required to treat anaemia or bleeding.
- This research project, the ABLE trial, is designed to find out if the length of time blood donations are stored prior to use is important for critically ill patients.
- The ABLE trial is a large international research trial that is being undertaken in several countries world-wide.
- You are eligible to participate in this trial and we are approaching you for your permission to take part.

The name of this study is:
'The ABLE Study: Age of Blood Evaluation Study'
The title means looking at the length of time red blood cells have been stored and the effect this has on very ill participants.

What is the purpose of the study?
The aim of blood transfusions is to increase the ability of your blood to carry oxygen around the body to the organs and tissues, which need oxygen to function normally.

At present, the blood used for blood transfusions in the UK is stored in the blood bank for up to 35 days after being donated. This has been the case for many years, but we are not sure whether blood stored for longer periods is as effective as blood stored for shorter periods. This is particularly important for sick patients, like you for whom maintaining oxygen supply to the tissues is a key part of treatment.

The purpose of this study is to find out whether it makes a difference using blood that has only been stored for one week or less compared with the blood currently used in all UK hospitals, which has been stored anywhere between 2 to 35 days in the blood bank.
One group of patients who take part in the trial will receive blood stored for 7 days or less while the other will receive blood stored for the usual 2 to 35 days. We will then compare a range of measures for participants allocated to the 2 groups over the 12 months after entering the trial. Approximately 2,500 participants will be enrolled in hospitals in Canada, the UK, France, and some other countries.

Why are you being approached?
Your doctor has identified you as a potential participant for this study, because they have decided that you require a blood transfusion as part of your care. The number of blood transfusion units you will receive has been decided by your doctor.

Do I have to agree to participation?
No. There is no obligation to take part in this study. If you decide to participate you will be given this information sheet to keep and be asked to sign a consent form. If you decide to agree you are still free to change your mind at any time without giving a reason. A decision not to continue or to withdraw will not affect your standard of care.

What will happen if I agree?
You will be randomly allocated to one of two groups of trial participants:
One group receives blood that is stored 7 days or less whenever their doctor thinks a blood transfusion is needed; the other group receives blood stored according to the present standard practice (2 to 35 days) whenever their doctor thinks a blood transfusion is needed. This continues for the rest of their stay in the hospital or for 90 days, whichever is shorter.
The decision regarding which group is determined randomly by a computer. There is a 50/50 chance of being in either one of the groups. This is a “double blind study” which means that neither the medical staff nor you or your family know which group you are in. This is important to make sure that a fair comparison is made between the groups, so that the study results really give us an answer about whether the length of time blood donations are stored before being transfused to patients is important.

During your stay in hospital, we will review your progress to see how your organs are functioning. We will record information if any other problems arise, and also how long you stay in the intensive care unit and hospital. Participation in this study does not require any additional blood tests or examinations other than those carried out during routine care.

Once you leave the hospital, we will ask you to complete questionnaires in 6 and 12 months' time by post or phone. These questionnaires will ask how you are feeling and also about how much health care support you have needed. The questionnaires will take about 30 minutes to complete. There is no need to make any special visits to hospital or have any additional tests for the purpose of the study. We may look at registries and data bases to find out if anything has happened to you.

What is the procedure that is being tested?
The number of blood transfusions you receive will be determined by your doctors according to their clinical judgement and opinion. It will not change because of participation in this study. The only difference will be whether the blood transfusions are the current standard storage age or the shorter storage age.

What if I do not consent/agree to participation?
If you decide not to participate in the trial any blood transfusions you receive will be identical to those you would have received in the "standard storage age" group, because this is current normal practice. We know that on average these blood transfusions have been stored in the blood bank for about 3 weeks.

What are the possible risks of taking part?
All the blood transfusions that will be used in the ABLE trial have been approved for use in the UK and were treated for viruses and other pathogens according to normal procedures. As far as we know, there are no additional risks associated with participating in this trial.

What are the possible benefits of taking part?
There is no known direct benefit from participation in this study at the present time. Participants receiving blood transfusions stored for a shorter time might respond better, but at present we do not know if this will occur. This trial will clarify this for the future, so the information obtained may help future critically ill patients.

Will my family doctor/general practitioner know about this study?
Yes. We will write to your general practitioner/family doctor to tell him/her about the study and inform him/her that you are taking part.

What if new information becomes available?
Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the research team will tell you about it and discuss further participation in the study.

What if something goes wrong?
If you have any concern 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, you can do this through the usual hospital procedures.

The University has a policy in place that provides indemnity against legal liability for non-negligent harm caused to a research subject, arising from the conduct of the research. This policy includes a no fault compensation section for accidental injury that is neither expected or intended when within the terms or instructions of the trial

protocol. An insurance policy is also in place (which includes no fault compensation) for negligent harm caused by the investigators or the design of the study. Normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in this study be kept confidential?
Yes. All information obtained during the course of this study will be kept confidential. The data collected will be kept for 15 years after the end of the study under secure conditions.

In order to ensure proper research procedures are carried out it is possible that appropriately qualified members of the organisation sponsoring the research in the UK (Edinburgh University and NHS Lothian) or the trial office coordinating the international trial in Canada may inspect the research data and your medical records. All individuals viewing these records will be appropriately qualified and will ensure they are kept confidential.

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 of health professionals. It may take one to three years after the study is entirely completed for results to be published. You can request a copy of the published results from the Site Principle Investigator. You will not be identifiable in any publications or presentations resulting from this study.

Who is organising and funding the research?
The research is sponsored by NHS Lothian and Edinburgh University and has been funded in the UK by Health Technology Assessment Programme (HTA). The HTA programme produces independent research about the effectiveness of different healthcare treatments and tests for those who use, manage and provide care in the NHS. It identifies the most important questions that the NHS needs the answers to by consulting widely with these groups, and commissions the research it thinks is most important. .

Who has reviewed the study?
This study has been given a favourable ethical opinion for conduct in the NHS by the multi-centre research ethics committee (NRES Committee South Central -Oxford C)

Contact for Further Information
If at any time during the study you have questions or concerns regarding the study you can contact the local Principle Investigator, who is in charge of the research at your hospital:

Insert name and address of local PI

If you would like to speak to an independent doctor about this trial then please contact:

Name and address of local independent doctor

Thank you for taking the time to consider participation in the ABLE trial.