Participant Information Sheet

A single centred feasibility study to evaluate and compare the implementation of an antigen-prioritising algorithm compared to standard care to arrange units for blood transfusion prior to selection by staff at NHSBT

Chief Investigators: Dr Sara Trompeter & Dr Nicholas Gleadall

Sponsor: NHS Blood and Transplant

Clinical Trial Team: Haem-Match study team

The study Sponsor is inviting you to take part in a clinical study that will involve using a decision support algorithm to suggest to scientists, blood that they may want to choose to allocate for patients with Sickle Cell Disorder (SCD). You do not have to take part if you do not wish to.

Before you decide whether to participate in this study it is important that you understand why this study is being conducted and what is involved. Please take time to read the following information carefully and discuss it with others if you wish.

There are nurses and doctors involved in the study who are happy to discuss any concerns or answer any questions you may have.

What is the purpose of the study?

Red cells used for blood transfusion have labels on their surface known as blood groups. There are over 300 blood group types currently known . When there is a mismatch between the blood group of the blood donor and the patient receiving the transfusion, there is a risk of blood group antibodies forming – this is called alloimmunisation. Patients living with SCD are the most likely patient group to suffer from alloimmunisation. These events can be life threatening and can limit the long-term treatment options for patients.

We want to better match blood to prevent these complications. But there are many, many blood groups and over 12,000 units a month of blood ordered by hospitals for patients in England with SCD. It is not possible for a human brain to sift through all this information, comparing the thousands of units in stock, all the blood groups of the donor and the patient and then repeat this thousands of times a month. Therefore, we have developed a decision-support algorithm (some computer code), known as "bloodMatcher," to scan through the thousands of available units and organise them in order of best matching. The current algorithm lists the units in order of oldest first. The new algorithm will arrange the order of units in order of best matching and will also understand the specific needs of the patient

and the rules around blood matching for sickle cell disorder. In addition, if there is blood available it will match further than current standards for three sets of additional blood groups. A senior scientist will then check the suggestions are in line with current rules around blood matching and then the routine team at NHSBT will select the units to send to the hospital. The units will then go through all the routine checking procedures at NHS Blood and Transplant and also the hospital as they normally would.

In summary the new algorithm principally lists units by best matching and the current one by oldest first; there is an extra layer of checking in the study with all the usual checking still in place; otherwise, everything around your care will remain the same.

We have tested the new algorithm against previous orders and the stocks available that day and the data showed that it performed better than the current system, it met all the current rules about matching blood and was able to match for blood groups that we don't normally match for. We believe if this technology were used nationally within the NHS, the algorithm could reduce the chance of alloimmunisation in sickle cell patients significantly. We now want to test it in real-time.

Why am I being asked to take part in this research?

You have received this information sheet because you have SCD and have been on a regular red cell exchange transfusion programme and have already received three consecutive transfusions.

Do I have to take part?

You do not have to take part if you do not wish to — it is completely up to you. Your decision has no influence on your care now or in the future.

You will be asked to sign a consent form to confirm that you understand the study and that you agree to take part. You will also be given this information sheet and a copy of the consent form to keep. You are free to withdraw at any time, without giving a reason.

You will receive three of your red cell unit transfusion episodes whilst taking part in the study. These red cell units will have been suggested by the decision support algorithm, bloodMatcher and then selected by a senior scientist at NHSBT. They will have gone through all the routine checking processes as a normal transfusion would. The rest of your clinical care will remain the same as normal. There will be no extra tests, examinations nor hospital visits.

How long will I be in the study and where will it take place?

You will take part in the study from your first routine exchange transfusion after you have given consent. Your participation will continue until the routine blood test carried out before your fourth exchange transfusion. This means you will receive three routine exchange transfusions as part of the study. The study will take place during your usual transfusion appointments at UCLH. There will be no additional hospital visits. Each appointment will last the same amount of time as your standard transfusion

visits.We will compare the transfusions you receive on the study to your three previous exchange episodes that took place prior to your study involvement. In doing this we will collect data on several factors including how well the blood units were matched, how the bloodMatcher algorithm performed, and how using this algorithm might impact the hospital and NHS Blood and Transplant processes.

We are aiming to publish the results from this study and get further funding for a larger study, with the overall aim of using the bloodMatcher technology in the NHS as part of routine clinical care.

What tissue samples will be used and what will happen to them?

As part of this study, we will use blood samples that are already taken as part of your routine clinical care for transfusion.

A pregnancy test may be required for women who could be pregnant. No additional blood samples or other tissue will be taken specifically for this study.

If samples are no longer required, they will be disposed of safely in line with NHS policies.

What are the possible benefits of taking part?

We cannot guarantee any direct benefits to you from taking part in the study. It is hoped that the results of this study will benefit patients receiving blood transfusions in the future, which may include yourself, by better matching and better allocation blood.

What are the possible disadvantages of taking part?

The only change to your usual clinical care is that the red cell units transfused during your time on the study may have been identified by the bloodMatcher algorithm. Senior clinical scientists at NHSBT will check this suggestion of which red cell units will be used for the transfusion, they will ensure that the units meet the current standards and guidelines for transfusion in sickle cell disorder and if they do, they will pass this information onto the team at NHSBT who usually pick the units for you. They will still do all their checking too – in fact, all the regular checks and processes that are in place normally both at NHSBT and within the Hospital will still happen. The rest of your clinical care will remain the same as normal. Therefore, we do not think there will be any disadvantage to you to taking part in this study. If any information comes to light that might affect your continued participation in the study a member of the research team will contact you to discuss this.

What if there is a problem?

NHS Blood and Transplant, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participating in this study. NHS indemnity operates in reports of the clinical treatment which is provided.

You should be aware that, in the unlikely event that you lose capacity to make decisions during the study, you would be withdrawn from the study. However, the research team would retain any tissue samples and personal data already collected and may use them for future research, as explained in this information sheet.

You can ask more questions about the trial at any time, and you can contact the following people for more information:

Research Team:

Email: **uclh.haem-match@nhs.net**

For independent advice on taking part in a clinical study please contact the UCLH Patient Advice and Liaisons Service (PALS):

- Tel: 0203 447 3042
- Email: uclh.pals@nhs.net
- Address: PALS

  Ground Floor Atrium

  University College Hospital

  235 Euston Road

  London NW1 2BU

They are able to help you with health-related questions and can resolve concerns you have about your health care as well as helping you to raise a complaint if you feel it is necessary. UCLH PALS is available Monday to Friday between 09:00 and 16:00.

If you are seen by a doctor outside of the study, you should remind them that you are taking part in this study. In case of an emergency, you should act in the same way as you would if you were not in the study.

How do I withdraw if I want to?

You can withdraw from the study at any point. If you decide to withdraw, the research team will retain any data that we have gathered up to the point you withdraw for the study. Please contact the study team and let us know if you wish to withdraw.

Who is organising the study?

This study is being run by Dr Sara Trompeter from UCLH, UCL and NHS Blood and Transplant and Dr Nicholas Gleadall from the University of Cambridge and NHS Blood and Transplant. Dr Trompeter is also acting as the Principal Investigator at UCLH.

The study is being funded by the Department of Health and Social Care, NHS Blood and Transplant and UCLH Biomedical Research Centre.

What if new information becomes available?

The study staff will let you know if any new information relating to the study becomes available and discuss it with you. Depending on what the information is, you may wish to withdraw from the study or

your doctor may advise you to withdraw, in which case you would continue to be seen as per your normal clinical care. If you decide to continue in the study you may be asked to re-consent.

A special group of experts who are independent of the study staff and doctors, will be set up as a safety oversight group to oversee and review the study on a regular basis. They make sure any issues are looked into properly and that the patients taking part are informed about any relevant new information. The information sheet and other study documents will also be updated with any new details.

How will we use information about you?

We will need to use information from you and from your medical records for this research project.

This information will include:

- your name
- NHS number
- date of birth
- contact details
- relevant clinical information related to your sickle cell disorder and blood transfusions

People will use this information to do the research or to check your records to make sure that the research is being done properly. Some of this data may contribute to a PhD research project.

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 instead.

NHS Blood and Transplant is the sponsor of this research and is responsible for looking after your information.

We will share your information related to this research project with the following types of organisations:

- NHS Blood and Transplant
- NHS hospitals involved in your care
- The study research team
- Regulatory authorities and auditors who check that research is carried out correctly

We will not share your information with other organisations unless this is required for the purposes of the study or by law.Due to the way trials are regulated in the UK, the research team will keep identifiable information about you from this trial for 25 years after the trial has finished. The study data will then be fully anonymised and securely archived or destroyed.

International transfers

Your data will not be shared outside the UK.

How will information about you be kept confidential?

We will protect your privacy at all times and will keep all information about you safe and secure. The steps we take to ensure this are as follows:

- Your consent to take part in the study will be recorded on the consent form. A copy of the consent form will be returned to you, a copy will be stored in your hospital file, and a copy will be kept in the study file. These forms are stored in a secure location separate from the study data.
- The information we record about you will be stored using a unique identification number and will not contain any personal identifying information.
- People who do not need to know who you are will not be able to see your name or contact details.
- All study data will be stored in a restricted-access, study database. This study database will not be connected to any database containing your personal details.
- The study database will be used only by named researchers working on this study under the direct supervision of the research team.
- Your information will not be shared outside the United Kingdom.
- After the research we will write our reports in a way that no-one can work out that you took part in the study.

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
- If you choose to stop taking part, we would like to continue collecting information about your health from your hospital records until the study ends. If you do not want this to happen, please tell us and we will stop.
- you have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study, including storage in approved research repositories.

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

You can find out more about how we use your information:

- by going to the Health Research Authority website: www.hra.nhs.uk/patientdataandresearchby asking one of the research team

by sending an email to the UCLH Data Protection Officer: UCLH.IGQueries@nhs.net

How will we use information about you after the study ends?

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.

We will keep your study data for **25 years**. The study data will then be fully anonymised and securely archived or destroyed.

Who has reviewed the study?

The study has been reviewed and approved by the South Birmingham Research Ethics Committee, which has given a favourable opinion to conduct this study in the UK.

Contact for further information

General contact (study team):	**Email:** **uclh.haem-match@nhs.net**

Thank you for taking the time to read this participant information sheet. If you decide to take part in the study, we will ask you to sign a consent form. You will be given a copy of the signed consent form and this participant information sheet.

Thank you for reading the Haem-Match participant information sheet

Please ask if there are any questions.