

Bristol BTRU in red cell products PPI/E Strategy - v2 2017

Brief Background

This BTRU will conduct 1) a clinical trial in research participants to compare laboratory produced reticulocytes (immature red blood cells) with standard human donated red blood cells (RBCs) 2) work to develop new technology to allow the production of enough RBCs to treat adult patients, and 3) work to create a bank of cell types to provide blood for patients with rare blood groups.

Patient and public involvement will be embedded throughout our research programme.

PPI/E Strategy

The NIHR Bristol BTRU in Red Blood Cell products and their partners organisations, firmly believe that user involvement in the design, adoption and use of innovative health technologies or solutions is a key priority. The development of laboratory grown RBCs has the potential to offer significant health benefits. However, the production of clinical products from stem cells is a complex and easily misunderstood area of work.

Aim

We will deliver effective public involvement and engagement in each of the BTRU's themes with the aim of ensuring that the patient, donor and public perspective is appropriately taken into account in all areas of our work and in its dissemination. We will work with People in Health West of England (<http://www.phwe.org.uk/>), along with the University of Bristol (UOB) and NHSBT to develop PPI/E in the BTRU.

To deliver the above aim the BTRU has appointed a dedicated PPI lead (Dr Andy Gibson) who is the academic lead for People in Health West of England. He will attend the BTRU management committee and will lead a programme of PPI/E activity throughout the lifecycle of the BTRU. He will draw on the networks of our partner organisations to establish a public advisory group (PAG) with a membership of up to 12 people. PAG membership will include the public, regular blood donors and also people who are patients that regularly receive blood transfusions and who will be the potential beneficiaries of the BRU's work. This group will advise the BTRU on all aspects of PPI/E as outlined below.

Objectives:

1. In **theme 1**, the clinical trial, members of the PAG will be involved in the trial set up phase. They will review the protocol and ethics applications, participate in the development of participant information and consent sheets and advise on the development of a trial participant recruitment strategy. They will also help us develop lay summaries of the findings and help disseminate them to appropriate patient groups.
2. In **the science themes** the PAG will help ensure that our research processes are acceptable and transparent. We believe it will be invaluable to work with a group of patients and donors during this developmental phase to provide the project with an independent lay perspective on the acceptability of work proposed, making adjustments to the programme if necessary. PAG members and patient group representatives (e.g. Sickie Cell Society) will also advise how to engage with specific patient groups. This will help us to ensure that our research direction reflects the hopes and concerns of all stakeholders.

3. Qualitative work package: The BTRU will collect new data to investigate what diverse patient and public groups think about the concept and use of laboratory grown red blood cells. The PAG will contribute to the qualitative work package led by Prof Julie Kent by participating in the development of research instruments, for example interview schedules and questionnaires. As with the clinical trial they will be involved in reviewing the ethics application for this work and developing information and consent forms. Members of the PAG will also be invited to support the analysis of the qualitative data and in developing a dissemination plan for this work.

4. Dissemination of research findings to lay audiences

The strategy for dissemination of research findings and information about the BTRU will be guided by the PAG. The NIHR BTRU will have a dedicated website that will host information about the clinical trial and our research. It will be written with input from our PAG and will be easily accessible to patients and the public. Written material will be produced for inclusion in patient and blood donor newsletters and leaflets. The BTRU will liaise with appropriate patient support groups via representatives from bodies such as the Sickle Cell Society and Thalassemia Society. When appropriate, media including print press, radio and television will be used to engage with the general public and the harder to reach patient and carer populations. The BTRU will work in partnership with the NHSBT communications team, making full use of the communications systems available through NHSBT including their website, intranet, magazines and NHSBT patient groups. All research outputs will be published in open access journals wherever possible and will be communicated via the BTRU, UOB and NHSBT in an accessible way.

Involvement in the management of the BTRU

Dr Gibson, as PPI lead, will be a member of the BTRU Management Committee. All members of the PAG will be invited to participate in meetings of this group on a rotation basis. They will update the Management Committee on the progress of our PPI/E work. They will also participate in decisions about the development and dissemination of the BTRU's work as appropriate. Two PAG contributors will also join the clinical trial steering group

Capturing Impact of PPI

All researchers at the BTRU who receive input from PAG members will be asked to provide a brief summary of the changes made to their work as a result of this feedback, or reasons why suggestions were not acted upon. This information will be collated by Dr Gibson and fed back to members of the PAG. It will also be reported to the NIHR via the annual report for the BTRU. This PPI section is also published online by NIHR for all to read.

Support and training to PAG members and BTRU Researchers

Dr Gibson will convene the PAG and will liaise with members of the BTRU to facilitate appropriate and timely PPI input. PAG members will be paid travel and other reasonable expenses as well as £20 per hour for their time. Appropriate training will be provided to PAG and BTRU researchers by People in Health West of England and facilitated by Dr Gibson, as required.

Public engagement

The BTRU will be active in public engagement. We will make transcripts of activities that we run in these areas available through the dedicated BTRU website and the University of Bristol main website. The BTRU will host and contribute to Science cafes, public lectures and in the training of early career scientists. We will also engage with the media (TV, newspapers, online articles, and blogs) in an honest, accessible and responsible way. We will involve members of the PAG in the development of an engagement strategy based on their experience of involvement with the project and on the findings from the qualitative work led by Prof Julie Kent. Members of the PAG will work with University of Bristol Centre for Public Engagement and groups such as Explore@Bristol and members of the research team to deliver our engagement strategy. Members of the team already have significant experience in this area of work and these routes of engagement will continue and expand. For example, Theme lead and BTRU Deputy Director Dr Toyne has given two Science Café talks on the

topic of growing blood for transfusion and engineering red blood cells, talked at the Southmead NHSBT Apheresis Unit and has given school talks and given "Hot topic" talks on growing red cells to the Biochemistry undergraduates at the University of Bristol. Dr Toye has spoken on Bristol local radio and the Director Prof. Anstee has spoken on BBC Radio 4 Science programme "Frontiers" devoted to alternative sources of blood. Most recently Director Prof Anstee and Dr Toye have separately appeared on TV programs including Horizons (BBC worldwide) and on Children's BBC (Operation Ouch- Extraordinary eyes episode).

Dated: November 2017