NHS
Blood and Transplant

Clinical Trials Unit

Annual Review 2019 / 2020

Director's Foreword

A lot has changed since our last annual report. The rise of the COVID-19 pandemic has highlighted the importance of good quality research when there are no known effective treatments for the disease. Our CTU has rapidly adapted to new working practices and we are working on major national (RECOVERY) and international trials (REMAP-CAP) on the use of convalescent plasma to treat patients who have been admitted to hospital with the infection.

Aside from COVID-19 we have been awarded a major grant for the assessment and treatment of maternal anaemia (PANDA). This has been highlighted as a public health risk for the UK by the World Health Organization as well as working on other new studies in organ transplantation and transfusion. We have shown our ability to rapidly adapt to changing circumstances and we will continue to grow throughout this year and the next.

Dr. Lise Estcourt
CTU Director

Health research has never been more important than now, in the current coronavirus pandemic. Despite the obvious and necessary disruption to our portfolio of studies, NHSBT CTU continues to deliver high quality clinical trials in the fields of transfusion medicine, organ donation and transplantation, tissue and stem cell transplantation. In the last year, we have been making great progress in our portfolio of studies, such as recruitment of over 500 patients to CRYOSTAT-2, a trial looking at better ways to deliver a fibrinogen-rich blood component prepared from plasma to bleeding trauma patients in A&E.

Looking ahead, there will be a further expansion of our activities with new trials coming on board in 2020/21, including studies to increase the number and quality of liver & kidney transplants, and a study to evaluate iron supplementation in the prevention of anaemia during pregnancy.

The CTU is a skilled, enthusiastic and committed team and I am excited by what we can achieve together in the next few years and I hope that you will collaborate with us, to benefit even more patients in the future.

Rachel Johnson
Assistant Director
Statistics & Clinical Studies

Mission Statement

“To deliver excellence in the design, conduct and dissemination of clinical trials in transfusion medicine, blood donor health, cellular therapies, therapeutic apheresis donation, and transplantation of organs and tissues, thereby providing evidence that benefits donors and patients locally, nationally and internationally.”

NHS
Blood and Transplant

www.nhsbt.nhs.uk

OUR YEAR IN REVIEW

4 new grants

ONE THOUSAND AND ELEVEN
PARTICIPANTS HAVE TAKEN PART IN ONE OF OUR CLINICAL TRIALS

THREE studies opened to recruitment

GO

31 TEAM MEMBERS

THATS TWO MORE THIS YEAR!

FIVE
new publications

12
active clinical trials
involving over **150** hospital teams across the UK, Ireland, Netherlands, New Zealand and Australia

£3.2 MILLION
GRANT FUNDING AWARDED

PUBLIC ENGAGEMENT

Over the past year, we have continued to engage with the public and to promote NHSBT CTU through conference attendance and presentations. Here are just a few of the highlights:

An article about the SONAR study was published in Kidney Life. This magazine is produced by the National Kidney Federation, an independent charity which provides vital support for kidney patients across the UK.

Find the full article here:
www.kidney.org.uk/News/kidney-life

BTS British Transplantation Society

In early March the CTU supported the first ever 'Dragons Den' event at the British Transplantation Society (BTS) congress. This collaborative session was set-up to support surgical and medical trainees to develop their own research ideas.

Trainees submitted their research ideas in advance, and the top six were selected to present in front of the 'dragons' on the day. The CTU team were there to offer advice and comment on the proposals before a final vote selected the top proposal. We are now working with the winner to develop a funding application for their study.

ICTMC2019

International Clinical Trials Methodology Conference

BE PART OF RESEARCH

The NHSBT team continued to support the annual 'Be Part of Research' campaign, which raises awareness of the benefits of research and the positive impact it has on people's lives.

Every year, more than half a million people help the NHS to improve healthcare and develop life-saving treatments by taking part in health research.

Find out more at: **bepartofresearch.nihr.ac.uk**

NIHR | National Institute for Health Research

QUALITY ASSURANCE

The GCP Quality Project Specialist (QPS) is a dedicated QA resource for the CTU, providing an in depth knowledge of Good Clinical Practice (GCP) and the required regulations. This specialist retains independence from CTU by reporting to the established Quality Assurance directorate within NHSBT, having the advantage of providing access to a large team of QA professionals and an established Quality Management System.

The QPS promotes a risk based approach to safety and quality culture, striving to support CTU to find solutions which are innovative, flexible and recognise risk, while allowing CTU to move forward maintaining and improving regulatory compliance in all its trials.

On a day to day basis the QPS supports CTU by reviewing procedures and trial documents for GCP compliance and consistency, keeping abreast of the latest regulations; ensuring appropriate risk assessments are in place; leading on change controls, incident investigations and quality review meetings; advising on audit strategy and conducting internal audits. The QPS is an active member of the UKCRC CTU QA Forum, a national network of QA professionals in CTUs across the country, and is a member of RQA, the Research Quality Association.

Katie Keen

Katie has a BSc (Hons) in Biological Sciences from the University of Birmingham. She joined the QA team in July 2019 specifically to provide Quality Assurance support to the CTU by ensuring compliance with Good Clinical Practice (GCP) and the regulatory environment for clinical research.

Prior to NHSBT, Katie worked in safety and quality support at Cambridge University Hospitals specialising in applying the principles of root cause analysis to the investigation of serious patient incidents in areas of oncology, haematology and imaging.

Katie has over 10 years' experience in clinical data management and clinical research gained in the biotechnology industry and contract research organisations, primarily in the fields of oncology and haematology.

SPOTLIGHT ON

PANDA

Primary prevention of maternal ANaemia to avoid preterm Delivery & other Adverse outcomes

Chief Investigators: Professor Simon Stanworth and Professor Marion Knight

In September 2019, NHSBT secured an NIHR Programme Grant for Applied Research. The research programme involves five interlinked work streams (WS) with the aim of improving maternal & infant outcomes by evaluating prevention of anaemia during pregnancy with oral-iron supplementation.

1

A qualitative study - a) interviews with 26 pregnant women & 13 Healthcare Professionals to understand factors influencing preventative oral iron use during pregnancy; b) designing behavioural interventions to improve uptake & ongoing adherence to oral-iron.

2

A clinical trial - to select an optimal preventative oral iron dose schedule & pilot the behavioural intervention developed in WS1. 240 pregnant women will be randomised to one of three dosing schedules: single-daily dose; alternate-daily; three-times/week, taken up to 28-weeks gestation.

3

A definitive clinical trial - to establish clinical & cost effectiveness of preventative oral iron, 11020 pregnant women will be enrolled into a two-arm trial of placebo vs oral iron supplementation, using the dosage regimen defined in WS2. The behavioural intervention will be delivered to all participants to optimise recruitment & oral iron adherence.

4

Process evaluation study - to assess fidelity of intervention delivery, adherence and acceptability using observations, interviews and surveys.

5

Long-term follow-up - to seek consent from women participating in WS3 to support future data collection including from national databases to evaluate long-term maternal & infant outcomes.

CTU RESPONSE TO COVID-19

The COVID-19 pandemic is affecting the public and health services around the globe.

NHSBT CTU is involved in the delivery of convalescent plasma treatment via two national clinical trials (REMAP-CAP and RECOVERY). These adaptive trials are investigating a variety of potential treatments for COVID-19.

For our ongoing trials, we have been working closely with study teams, participating sites, and partner organisations to find ways of minimising any additional strain on the clinical teams and ensuring the safety of study participants.

CTU are supporting NHSBT front line colleagues in Blood Donation by helping to triage donors as they arrive at the Oxford and Cambridge Blood Donor Centres.

Looking ahead 2020/2021

Continue to support current and new COVID research

Publish three studies which have recently completed, or are due to complete soon

Collaborate with researchers on new funding applications for COVID and non-COVID trials

Set-up two recently awarded grants (NIHR i4i and Wellcome Trust)

Adapting to the "new normal" for clinical research. This will involve finding new ways to enable Patient and Public Engagement, remote data collection and monitoring procedures

Recruit new staff to support COVID studies and the wider CTU portfolio

KEEP UP TO DATE WITH ALL OUR TRIALS:

nhsbt.nhs.uk/clinicaltrialsunit
cryostat2.co.uk
pithia.org.uk
sonartrial.org.uk
treatt.org
pluto-study.co.uk

Recent Publications

Estcourt L, McQuilten Z, Powter G, Dyer C, Curnow E, Wood E, Stanworth S; TREATT Trial Collaboration (provisional). The TREATT Trial (TRial to EvaluAte Tranexamic acid therapy in Thrombocytopenia): safety and efficacy of tranexamic acid in patients with haematological malignancies with severe thrombocytopenia: study protocol for a double-blind randomised controlled trial. **Trials. 2019 Oct 15;20(1):592. doi: 10.1186/s13063-019-3663-2**

Richards J, Hossain M, Summers D, Slater M, Bartlett M, Kosmoliaptsis V, Wilson E, Lagaac R, Sidders A, Foley C, Laing E, Hopkins V, Fitzpatrick-Creamer C, Hudson C, Thomas H, Turner S, Tambyraja A, Somalanka S, Hunter J, Dutta S, Lawman S, Salter T, Aslam M, Bagul A, Sivaprakasam R, Smith G, Moinuddin Z, Knight S, Gibbs P, Motallebzadeh R, Barnett N, Pettigrew G; SONAR trial group. Surveillance arterioveNous fistulAs using ultRasound (SONAR) trial in haemodialysis patients: a study protocol for a multicentre observational study. **BMJ Open. 2019 Jul 23;9(7):e031210. doi: 10.1136/bmjopen-2019-031210.**

Curry N, Foley C, Wong H, Mora A, Curnow E, Zarankaite A, Hodge R, Hopkins V, Deary A, Ray J, Moss P, Reed MJ, Kellett S, Davenport R, Stanworth S; The application of a haemorrhage assessment tool in evaluating control of bleeding in a pilot trauma haemorrhage trial. **Transfus Med. 2019 Dec;29(6):454-459. doi: 10.1111/tme.12644. Epub 2019 Nov 3.**

Stanworth S, Killick S, McQuilten Z, Karakantza M, Weinkove R, Smethurst H, Pankhurst L, Hodge R, Hopkins V, Thomas H, Deary A, Callum J, Lin Y, Wood E, Buckstein R, Bowen D; Red cell transfusion in outpatients with myelodysplastic syndromes: a feasibility and exploratory randomised trial. **Br J Haematol. 2020 Apr;189(2):279-290. doi: 10.1111/bjh.16347. Epub 2020 Jan 20.**

Fustolo-Gunnink S, Fijnvandraat K, van Klaveren D, Stanworth S, Curley A, Onland W, Steyerberg E, de Kort E, d'Haens E, Hulzebos C, Huisman E, de Boode W, Lopriore E, van der Bom J; PlaNeT2 and MATISSE collaborators. Preterm neonates benefit from low prophylactic platelet transfusion threshold despite varying risk of bleeding or death. **Blood. 2019 Dec 26;134(26):2354-2360. doi: 10.1182/blood.2019000899.**

Our Team

LEADERSHIP

Lise Estcourt
Director

Rachel Johnson
Assistant Director - Statistics & Clinical Studies

QUALITY ASSURANCE

Katie Keen
GCP QA Specialist

DATA MANAGEMENT

Renate Hodge
Head of Clinical Data Services

Jo Mullings
Senior Clinical Data Manager

Rupa Sharma
Clinical Data Manager

Siobhan Martin
Clinical Data Manager

Lisha Gracias
Clinical Data Manager

Emily Arbon
Data Management Support Officer

Nikki Dallas
Data Management Support Officer

CLINICAL OPERATIONS

Alison Deary
Head of Operations

Claire Foley
Clinical Operations Manager

Claire Dyer
Clinical Operations Manager

Ana Mora
Clinical Operations Manager

Gillian Powter
Clinical Trial Manager

Heather Smethurst
Clinical Trial Manager

Anna Sidders
Clinical Trial Manager

Emma Laing
Clinical Trial Manager

Samaher Sweity
Clinical Trial Manager

Joanne Lucas
Clinical Trial Manager

Amy Evans
Clinical Trial Coordinator

Val Hopkins
Clinical Trial Coordinator

ADMINISTRATION

Jayne Gipp
Business Manager

Anna Welford
Clinical Trials Support Officer

Chloe Fitzpatrick
Clinical Trials Administrator

STATISTICS

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Head of Clinical Trial Statistics

Cara Hudson
Principal Statistician

Laura Pankhurst
Senior Statistician

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