

Research and Development Committee Meeting Minutes

11.00am – 16:00pm Monday 10th December 2018

**BJA Library space
The Royal College of Anaesthetists
Churchill House, 35 Red Lion Square
London, WC1R 4SG**

Committee Members

Paresh Vyas (Chair of RDC, Non-Executive Director)
Rob Bradburn (Finance Director)
Anthony Clarkson (Interim Director of Organ Donation and Transplantation)
Louise Fullwood (Non-Executive Director)
Daniel Hollyman (Head of IBGRL, Deputising for Director of Diagnostics and Therapeutic Services)
Greg Methven (Director of Blood Manufacturing & Logistics)
Gail Miflin (Medical & Research Director)
Jeremy Monroe (Non-Executive Director)
David Roberts (Associate Medical Director Blood Collections, Deputising for Director of Blood Donation)
Jonas Wadstrom (University of Stockholm, Sweden: External Expert)

Observers

Yomi Adebajju (National Research Manager, Minutes)
Ruth Allen (Operations Manager, NIHR BTRU in Red Blood Cell Products)
Emanuele Di Angelantonio (PI observer and Director of NIHR BTRU in Donor Health and Genomics)
Rachel Johnson (Assistant Director – Statistics and Clinical Studies)
Willem Ouwehand (PI Observer)
Rutger Ploeg (PI observer)
Chris Sims (Planning and Management Accountant, Group Services)
Ash Toyne (PI Observer and Director of NIHR BTRU in Red Blood Cell Products)
Nick Watkins (Assistant Director – Research & Development)

Apologies

Harvey Klein (NIH, USA: External expert)
Ellen van der Schoot (Sanquin, The Netherlands: External Expert)
Mike Stredder (Director of Blood Donation)
Huw Williams (Director of Diagnostic and Therapeutic Services)

1. Introductions, Apologies and Conflicts of Interest

PV opened the meeting, apologies and deputies were noted as above. NW noted that meeting is not quorate as 2 external committee members are unable to attend. They will review meeting papers offline and feedback comments to the group via the Research and Development Office. Any decisions made at the meeting will be ratified by the External Experts offline.

RJ was introduced as this is her first RDC meeting as Assistant Director – Statistics and Clinical Studies.

DR declared a conflict of interest in relation to items 6d and 6e.

2. Minutes of meeting held 12th June 2018

The minutes were approved with no amendments.

3. Update on Actions from 12th June 2018 meeting

NW reported that all actions were closed except action 6 (PI engagement and horizon scanning), which is ongoing.

4. R&D Strategy Update

NW gave an update on the current R&D strategy.

- Innovate UK grant: there was discussion around end point or goal of the project in 18 months and the feasibility of obtaining NHS data. One of the aims of this project is to use hospital data from multiple trusts to develop a model of supply and supply of platelets. The project will start with 2 hospitals with scope to expand (4-5). Committee reiterated the importance of developing a model suitable for implementation.
- There is positive development with implementation of EPIC (digital platform) at Cambridge although more work is needed.

Outcome: Committee congratulate NW on securing the funding from Innovate UK in partnership with Kortical

- There was a brief discussion on the Principal Investigator piece, it was noted previous interview panels for PIs have been gender balanced therefore the focus should shift to developing researchers at all levels.

5. Financial Report

CS gave an update on the current financial report.

- The results of the NIHR consultation on Research and Capability funding indicate that it will continue to decline and may fall to approximately £40k p.a. over the next 5 years.
- The 5-year plan presented is a worst scenario and does not include NIHR BTRU funding post September 2020.
- The future strategy must align with NHSBT's core values and take into account all operational areas: cells, blood cells, stem cells, organs and tissues.

- The leadership of the NHS wants to see innovation therefore it is important develop a clear strategy that addresses this, which in turn will help secure larger funding for innovation.
- External funding streams must be identified as well as areas of stability (i.e. UKRI), where we can apply for funding in development and innovation.
- Identify key stakeholders i.e. Chief Medical Officer, Directors of MRC and align our strategy with theirs (i.e. UKRI).
- There was discussion around ODT funding, with concerns being expressed around the lack of direct funding for research in ODT as Grant in Aid cannot be used for research (set by DoH). Discussions are ongoing with NIHR to increase the level of funding available for research in ODT. There was a recent call for studies focused on diagnostics in transplantation.

Outcome: Committee agreed on the importance of identifying external funders and the patient and public voice (patient and public involvement and engagement).

6. Items requiring decision

a. QQR and Horizon scanning

NW gave an update on QQR preparation and Horizon scanning for the 2020 – 2025 strategy and the research priorities identified.

Action: Executive team to review identified research priorities before the June 2019 RDC/QQR.

The following points were noted:

James Lind Alliance: There was discussion around a patient lead group similar to the James Lind Alliance for ODT, which is critical to external funding and would encourage alignment with patient groups.

Action: RP and AC to work with NHSBT Organ Donation Campaign forum to identify future research priorities.

Microbiology and virology: Question was raised regarding the nature of microbiology and Public Health England alignment. The teams work jointly with an NHSBT and PHE lead.

“Samples from deceased donors would be invaluable in validations and are ordinarily difficult to obtain.” statement in appendix 2 (Microbiology and virology) was queried.

Action: NW and RP to review the links with virology and ODT

Traditional Components: There was discussion around what direction this strategy should take: Small portfolio or differentiated and specific products. It was anticipated that the outcome of the universal plasma project led by Dr Cardigan would inform the future strategy. There needs to be an increase in collaboration and cross cutting

themes i.e. interactions with new products (stem cells for scaffolding, medium for growing new cells). There was discussion around whether development of blood products should focus on occasional users i.e. not patient specific but patient groups and the blood product use should be linked to patient outcomes.

To achieve this more evidence is needed and we need to be proactive rather than reactive. R&D needs to be clinically informed and integrate with the clinical community.

Cell Therapies: Closer links needed with charities like Anthony Nolan and more clinical trials are needed in this field. Funding streams for core blood and adult blood donation must be identified.

Advanced Blood Components: Immediate and long-term benefits to patients' lives must be clear. Is there a clear path to the changes needed in production techniques? Understanding donors will feed into changes in technology.

Organ Donation and Transplantation: During the 1st round of NIHR BTRU funding application, the conditions of funding meant that the number of partner sites was limited therefore it was not possible for a UK-wide consortium to apply.

Horizon scanning in ODT is being performed in partnership with the National Institute of Health Research Innovation Observatory (NIHRIO).
BAME recruitment and retention is also very important.

General comments: Several other areas were identified as potential future priorities:

- Un-transfusable patients (better matching of donors)
- Threats that would affect supply and demand
- Improving translation to operational service
- Managing sickle cell patients and long-term care of life long services users
- AI and Machine learning.

The priorities must have cross-cutting applications and be informed by discussions with key stakeholders (patient, donor and healthcare partners).

QQR template

Committee asked that the impact of research in terms of saving patient lives and sustaining safety of supply must be captured.

Action: NW and YA to feedback comments to the strategy groups and amend QQR template.

b. Future NIHR BTRU priorities

NW gave an update on the process and priorities for the next round of NIHR BTRUs. Additional information was provided on the planned stakeholder engagement and approach to finalising the list of priorities for NIHR BTRU funding.

Committee confirmed the need for a fair and robust process for finalising the list of NIHR BTRU priorities.

Action: GM and NW to present revised proposals for shortlisting to the Executive Team;

Action: NW and YA to arrange a further call with the RDC in March 2019 to update.

c. Defining an NHSBT Principal Investigator

NW presented proposals regarding the definition of an NHSBT PI

Outcome: Committee approved the proposed definition of PI and mechanism for considering candidates

d. WP15-11: The role of T regulatory cells in haematopoietic stem cell transplantation (Closure report)

NW/DR presented closure report for WP15-11

Outcome: Committee accepted the report and the study was formally closed.

e. WP18-02: Restless Legs Syndrome in Blood Donors (Funding application)

DR presented application for funding new project. The study will cost £81k per annum until the end of the current strategy and does not require any additional funding.

Outcome: Committee approved the proposal pending satisfactory external peer review

7. Items for discussion:

a. RESTORE update (Presentation)

AT presented an update on the RESTORE study

There was discussion on the potential amendment (major or minor) to the IMPD due to change of radioactive label source. The first set of data should be ready by July 2019. If Brexit takes place in March 2019 sponsors of clinical trials will require a legal representative (PI) in the UK in order collaborate with EU based research projects and vice versa. This arrangement will allow parties outside the UK to licence the use of data generated.

Outcome: Committee congratulates RESTORE team on progress so far.

Action: NW and YA to review the situation regarding sponsorship of clinical trials post Brexit

b. STRIDES update (Presentation)

EDA presented at update on STRIDES study. A tendering exercise for the isotonic tablets has been carried out through NHSBT procurement.

Outcome: Committee confirmed ongoing support for this study.

c. Update on Genotyping Platform (Presentation)

WO presented update on Genotyping platform. There was discussion around MHRA and legal regulations. Legal statute is delegated to MHRA, which is in turn delegated to NHSBT and regulated by MHRA.

Future implications for NHSBT if implemented include the ability to improve the current panel of tests and investment in IT systems. This will form part of the future Diagnostics strategy, which will include in-house serological programmes to help identify rare donors. Genotyping and serotyping will continue to run parallel.

Right blood to the right patient: there is a clinical need for this platform. Availability and costs needs to be considered. NHSBT aims to be at the forefront of providing this service.

Action: NW and GM to present a paper to ET in Q4 2018/19 to consider the best way forwards.

d. QUOD: Impact and future plans

RP presented an update on QUOD. Outputs include an increase in mechanistic research, support for the NIHR BTRU in ODT and the development of National clinical trials with CTU support. QUOD was recognised as a national and international resource.

The source of future funding was discussed, and a mixed model was proposed, with a plan to recover 50% of costs through charging for samples.

Action: NW and RP to present a business case for continuing financial support for QUOD to the ODT SMT.

e. Career Development in R&D

YA presented update of career development work

Outcome: Committee approves the proposal to work with Vitae to set up NHSBT Research Development Framework for NHSBT.

8. AOB:

The Chair expressed the Committees thanks to LF for her commitment to the RDC meetings as this will be her last meeting.

9. Date of next meeting:

- 3rd & 4th June 2019 (RDC and Review of R&D programme) – TBC, London
- 19th November 2019 – TBC, London