NHS
Blood and Transplant

Research and Development Committee Meeting Minutes

Monday 2nd December 2019
Boardroom, West End Donor Centre
26 Margaret St, Marylebone, London, W1W 8NB

Committee Members

Rob Bradburn (Finance Director)
Anthony Clarkson (Director of Organ Donation and Transplantation)
Harvey Klein (NIH, USA: External expert)
Greg Methven (Director of Manufacturing & Logistics)
Gail Miflin (Medical & Research Director)
Jeremy Monroe (Non-Executive Director)
Ellen van der Schoot (Sanquin, The Netherlands: External Expert)
Ella Poppitt (Assistant Director Operations - North & Chief Nurse Blood Donation, Deputising for Mike Stredder)
Paresh Vyas (Chair of RDC, Non-Executive Director)
Jonas Wadstrom (University of Stockholm, Sweden: External Expert)
Piers White (Non-Executive Director)

Observers:

Millie Banerjee (Chair, NHS Blood and Transplant)
Yomi Adegbaju (National Research Manager, Minutes)
Rachel Johnson (Associate Director Statistics and Clinical Studies)
Chris Sims (Assistant Director - Finance)
Nick Watkins (Assistant Director, Research & Development)

Apologies:

Mike Stredder (Director of Blood Donation)
Belinda Wright (Planning and Management Accountant, Group Services)
Huw Williams (Director of Diagnostic and Therapeutic Services)

PI Attendees (Open Session only):

Rutger Ploeg (Professor of Transplant Biology, Oxford)
Will Astle (Senior Lecturer in Statistical Science, Cambridge)
Emanuele Di Angelantonio (Donor Health and Genomics BTRU Director, Cambridge)
Ash Toye (Red Cell BTRU Director, Bristol)

Closed Session

1. **Introductions, Apologies and Conflicts of Interest**

PV opened the meeting, apologies and deputies were noted as above. No conflict of interest stated.

2. **Minutes and actions of meeting held 4th June 2019**

Minutes were accepted with no comments.

3. **Financial Report**

CS presented the report, with the following being noted:

- The forecast extends beyond the end of the current strategy but only as a planning exercise;
- Some of the forecast aligns with projects that have not yet been approved by the Committee;
- Many external grants are managed directly by academic partners and not by NHSBT finance;
- The conservative forecast of the BTRU funding is pending NIHR approval i.e. approval of extension applications.
- The numbers stated should reflect our current commitment and liabilities, with potential redundancy costs being taken into consideration where required;
- Committee requested that more information on risks being carried for projects that we are legally committed to;
- A proposal on an integrated approach to managing transfusion in sickle cell disease is being prepared for consideration against transformation funds (estimate £300k p.a.);
- It was confirmed that all WP applications are submitted to the RDC for review and approval, however, clarification on who makes the final decision (Exec Team or R&D Committee) is required;

Action: NW/CS/RB to revise how the R&D finances are presented to Committee to separate out commitments and available funding; R&D committee to approve how finances are presented.

Action: NW/CS to present a sensitivity analysis to the R&D committee to show future commitment;

Action: The Ex team to review the responsibility regarding whether R&D committee have a final sign-off of R&D finances;

4. **R&D Strategy**

   a. **NHSBT's Operating model**

GM presented an overview of the changes to organisational structure for information. It was noted that:

- Reference laboratory testing will be bought into the clinical directorate;
- The new Organ, Tissue and Eye services will now include the tissues and eye, organ reconditioning, and perfusion will benefit from tissue experts;
- Clinical services will be the interface between hospitals and NHSBT to ensure that we are meeting patient and customer needs;
- There is a need to work differently with the NHS in the future which the new structure will facilitate;
- The future R&D Programme must be fully aligned with the organisational strategy;
- The benefit of investment in R&D may be best captured through impact statements;
- Expertise in Social Science is required to address challenges around donor behaviour and targeting recruitment.

b. QQR Final Report

NW presented the final QQR report which included a response to the initial panel recommendations, including a preliminary gap analysis which had been prepared in discussion with members of the executive team.

During discussion of the Gap Analysis it was noted that:

For ODT/TES:

- There is a need for randomised controlled trials that maximise the performance of organs;
- More evidence is needed to support the deployment of perfusion technology;
- Optimal biomarkers for use prior to transplantation are required.
- SNODs are a good resource and we should make better use of them to deliver relevant research;
- The ODT Strategy includes a stream on Research and Innovation;
- There is a lack of research in living donation;
- Data needs to be used in a better way as there might be overlaps therefore collaboration is the most effective course of action;

Action: ODT to present an R&D strategy to R&D committee.

For Clinical Services:

- We are the experts and should provide clinical leadership to inform and advise service users;
- New therapies could be developed in partnership with industry;

- We have an important role in education to ensure that an educated and empowered workforce in hospitals have the right data, share best practise and alert us (NHSBT) to issues early;

For Blood supply:

- There was nervousness about using a single genotype provider for all service user, this should be open access and not commercialised;
- Data generated should be free from IP rights;
- We need to characterise donors and patients genetically to best match supply with demands;
- Genetic testing needs to be aligned with the testing platforms, large cohort studies and what the hospital want / can use to ensure compatibility of results;
- In the US the labelling distinction of 'black' and 'white' blood is becoming obsolete;

Action: There needs to be a gap analysis as with ODT and a paper presented on R&D strategy for the R&D committee to review.

Action: NW/GM to draft a public statement for review by Committee on NHSBT's corporate stance regarding genotyping to include where and who we are engaging with and also recommend who we should be working with.

For Behavioural Research:

- The lack of behavioural research is worrying, optimisation of investments (blood / organ) is needed;
- There is a need to review our relationship with the NIHR and how behavioural research is funded in other areas;
- A "Test and Learn" approach may be preferable to substantive trials;
- We need to identify the right academic partners if we are to deliver academic research, however, the solution may be led by the new Donor Experience Directorate;
- Blood donation (donors) have evolved therefore the old approach will not work.

Action: NW/GM to work with the ET to determine where research on donor recruitment, retention and management best fit with the new organisational structure. Gap analysis to be performed and a paper presented on R&D strategy for the R&D committee to review.

In general discussion, the Committee stated that:

- There should be clarity about what activities will cease in the near future, with a focus on determining what is no longer feasible and also translating research in to service;
- A sense of priority is needed not just between the areas that the gap analysis was conducted but within them.

- As the programme becomes more aligned to business needs, the quantitative assessment of research should be accompanied with a qualitative assessment which includes impact statements and narratives around patient benefit;
- It was noted to have an appropriate balance of basic, translational and clinical research and to make sure this all aligns with the business of NHSBT

Action: NW/GM to work with each new operating division to perform a gap analysis of the R&D requirements which can be used to plan the next R&D strategy.

Action: NW/YA to retain existing reporting metrics and add 'Impact' assessment used by the Research Excellence Framework.

Committee reviewed the recommendations in the QQR report for each research theme in detail.

Action: NW to amend QQR report and Gap Analysis in line with comments received from Committee

c. NIHR BTRUs

Committee reviewed the list of priority areas for future NIHR BTRU funding previously agreed in March 2019.

They confirmed that the NIHR BTRUs are relevant to the organisational strategy and every effort should be made to secure funding for Round 2.

They also confirmed the need to review the priorities and the proposed timetable for agreeing these, noting that timing of any future competition was dependent upon approval by the Department of Health and Social Care.

Committee expressed some concern over the governance of the existing units and NHSBT's role in their oversight. They requested a review of governance as part of any future competition to ensure stronger partnerships in the future. Consideration should be given to an NHSBT Deputy Director for future Units to increase impact within their 5-year life-cycle.

Action: NW/GM to ensure that appropriate governance by NHSBT of BTRU is in place as part of any future competition

d. Extensions to existing Workpackages

NW presented the case for extending existing workpackages by 12 months to 30th September 2021 to ensure that scientists employed in Universities were not put at risk.

Committee recognised the need to provide reassurance to the affected scientists, but did not support the recommendations on the basis that:

- Insufficient information was provided to commit to what appeared to be over £1M worth of funding;
- Any decision to extend activities should be based on strategic need and whether the work was meeting its objectives;
- The size of our liabilities including redundancies if the programmes were not extended was not clear;

Outcome: The proposed workpackage extensions were not approved.

Action: NW to work with PIs to provide additional information including redundancy costs to allow the ET to decide on a case by case basis whether workpackages should be extended. Outcome to be presented to R&D Committee at June meeting.

Open Session

5. **Principal Investigators:**
    a. **QUOD 2020 – 2025 proposal**

RP presented plans for the next 5-years of the QUOD programme. It was noted that:

- The QUOD Steering Committee should ensure that duplication of studies does not occur and that researchers submitting similar studies should be encouraged to collaborate;
- There should be a rigorous scientific review of proposals as part of the approval process;
- Establishing the QUOD biobank has been a significant achievement and the team should be congratulated on their success to date;

Outcome: The RDC approved the funding, requesting that:

- **Requests for access to samples should undergo scientific review;**
- **There should be a transition to focusing on scientific quality of studies now that the biobank is firmly established;**

RP expressed concerns about the length of time it was taking to deliver the objectives of the INOAR project. This project aims to make organs available for research under NHSBT's research HTA licence. It has been delayed several times due to challenges relating to the ODT Hub and capacity to enact change.

Outcome: Committee asked that they be made aware of any further delays beyond the end of January.

Action: RP was advised to write directly to the MRC to make them aware of the delays and action being taken.

b. Transfusion and Transplantation Data Science

WA presented the scope of work which will be carried out under his PI workpackage. During discussion it was noted that:

- Efforts should be made to link to NHS Digital;
- The genotyping array should be validated on a larger number of samples from BAME donors to ensure that there are no gaps in its performance;
- The work related to frailty and organ donation, which will be funded through non-NHSBT sources, requires further refinement to ensure that the right demographic factors are considered;
- There was business support for developing a model of delivery of red cells to hospitals;

Outcome: RDC supported the proposed workplan except for the project on frailty which requires further refinement with colleagues in ODT and experts in frailty.

c. STRIDES update

EDA presented an update on the STRIDES randomised clinical trial which began recruitment in early November. Committee fully supported the work to date and congratulated Prof Di Angelantonio on the progress made.

d. RESTORE update

AT presented an update on the RESTORE clinical trial of manufactured blood cells. During discussion it was noted that:

- The currently approved project has a reduced scope compared to the original plan which included a clinical trial of red cells manufactured from cord blood CD34+ cells;
- The bulk of costs are for GMP manufacture;
- The aim of the study is to demonstrate that the cells are safe in humans;
- We are currently leading the field, but there is the potential that other trials will commence whilst we are delivering RESTORE;
- It is anticipated that the trial will stimulate further commercial interest in manufactured red cells, particularly as delivery vehicles for therapies;
- We must ensure that our investment in this project is recognised in any future commercial arrangements;
- A further update on RESTORE will be provided to NHSBT's Board early in 2020 prior to the clinical trial commencing;

Action: NW to ensure that NHSBT has the internal expertise to protect its interest in any future commercial arrangements.

6. **Women's Network**

The paper was accepted without further comment.

7. **Workplan for future RDC meetings**

The paper was accepted without further comment.

8. **AOB**
    a. **Intellectual Property Report**

It was noted that we need to provide reassurance regarding our ability to protect IP and know-how.

Action: NW/PW to discuss with IP experts to understand how investments are made in a commercial environment.

    b. **Harvey Klein**

The Committee acknowledged the significant contributions which Prof Harvey Klein has made over his 20+ years of membership. He has been a strong supporter of R&D of the quality of the current programme and cadre of scientists owes much to his guidance and insight.

Committee wholeheartedly thanked Prof Klein and wished him all the best for the future.

9. **Date of next meeting:**
    - **2nd June 2020**

Reports for Information

The committee accepted the following reports with no comments

Item	Title
10	Stem Cells: NIHR BTRU Annual Progress Reports 2018/19
10.a	Stem Cells Extension Application
11	Donor Health: NIHR BTRU Annual Progress Reports 2018/19
11.a	Donor Health Extension Application
12	Red Cell: NIHR BTRU Annual Progress Reports 2018/19
12.a	Red Cell Extension Application
13	ODT: NIHR BTRU Annual Progress Reports 2018/19
13.a	ODT Extension Application