

One Hundred and Fifteenth Meeting of the NIBTS Agency Board

Tuesday 22 September 2015

Venue: Lecture Room, Northern Ireland Blood Transfusion Service

Present: Mr Jim Lennon, Chairman
Mr Philip Cathcart
Mr Ian Henderson
Mrs Lorraine Lindsay
Mr Paul Simpson

In Attendance: Mr Glenn Bell
Mr Charles Kinney
Ms Angela Macauley
Mr Patrick Madden
Dr Kieran Morris
Mr Ivan Ritchie

1. Apologies

There were no apologies received.

2. Declaration of potential conflicts of interests with any business item on the agenda

There were no declarations of interests received.

3. Chairman's Business

Mr Lennon welcomed Mr Paul Simpson to his first Agency Board meeting as interim Chief Executive.

Mr Lennon formally noted the appreciation of the Agency Board to Mr Mervyn Barkley who left the Service on Thursday 03 September 2015. An evening will be scheduled with Mr Barkley to thank him for his work.

Mr Lennon has been in touch with the Department in relation to the review of ALBs. The Department are currently considering a number of papers at their Board meeting and no further information has been received. NIBTS should operate business as usual.

4. Minutes of One Hundred and Fourteenth meeting held on 01 July 2015 and action list

These minutes were agreed as correct and signed off by the Chairman.

Action	Responsible Person	Update
Follow up CEO recruitment with Deborah McNeilly	Mr Ritchie	Complete
Communication position re CEO to Board	Mr Lennon	Complete
Complete appraisals by 09 July 2015	Non-Executive Directors	Complete
Inform Chair of Agency Board of any regulatory concerns	Ms Macauley	Complete

5. Matters arising from minutes of meeting held on 01 July 2015

Accountability Review

The Department of Health were broadly content following this meeting. Nothing to report.

Platelet Project

The anticipated increase in platelet demand has not taken place, the likely reason being that referrals to the independent sector are no longer made and there has been no funding for new initiatives.

The demand for red blood cells has decreased, and the Ulster Hospital, Dundonald has now moved to single unit transfusions where historically 2-4 units may have been transfused.

Mr Lennon requested that an updated, financially costed business plan is prepared to enable movement on this issue. Dr Morris agreed to provide an updated paper to the next Agency Board meeting.

Gold Award Function

Mr Henderson congratulated Mr Kinney and his team on a super evening. Mr Kinney confirmed this event was covered by three local newspapers.

6. Audit Committee update

Internal audit reported on a review carried out on the management of assurances on quality management. No priority one findings were identified. A number of priorities two findings were identified and all recommendations have been accepted.

Internal audit reported their mid-year follow up on outstanding audit recommendations 2015/16. It was noted some work is required to take these actions forward and Mr Cathcart would like to see an improvement when Internal Audit returns to audit these areas in 6 months' time.

The 2014-15 Report to Those Charged with Governance from NAI0 was tabled at the meeting. This document was unchanged from the draft which the Audit Committee had received and discussed at a previous meeting.

7. Governance and Risk Management Committee update

The Governance and Risk Management meeting took place on 09 September 2015. There were no new risks added to the corporate risk register this quarter and the audit calendar was reviewed without any issues.

Mrs Lindsay noted she would like to see more accuracy in reports with more information and explanation to ensure full understanding. Full attendance at this meeting was requested where possible. There were no issues for the Board's attention.

8. Report from interim Chief Executive

Appointment of new Interim Chief Executive

Mr Simpson commenced the post of interim Chief Executive on 08 September 2015 with a review scheduled 31 December 2015. Mr Simpson has written to the Permanent Secretary to confirm his acceptance of Accounting Officer responsibilities and will attend an Accounting Officer refreshment course on 24 November 2015.

Review of ALBs

Mr Simpson has requested from the Permanent Secretary, an update on the scope, membership and timescale of this review. As yet no response has been received.

UK Blood Forum

NIBTS hosted the latest meeting of the UK Forum on 11 September 2015.

European Blood Alliance

Mr Simpson decided against attending the EBA Board meeting in Berne, feeling it would not be sufficiently beneficial to justify the cost and time involved.

BloodMobile

BSO solicitor consultant Colm Johnston has confirmed that the contractual dispute resolution process had expired in early September 2015. As of Friday 11 September 2015, BSO have confirmed with the supplier Lynton that they must have their independent inspection carried out within two weeks. We are, however, also expecting a letter of response to related matters going back to June – which is unrelated to the inspection. Mr Kinney noted Lynton have confirmed due to family illness, an independent inspection will not be carried out within this time frame. Litigation will proceed.

It was agreed Sponsor Branch should be informed of this course of action and Mr Kinney will take forward a new business case for a replacement BloodMobile.

9. Report from Medical Director

Medical aspects of the blood donor programme

At its mid-year review point the medical team noted completion of the following items:

- Deployment of electronic tablets on blood donor clinics
- Structured adverse event reporting in donors
- Completion of screening of female plateletpheresis donors for anti-HLA and anti-neutrophil antibodies.

Patient blood management initiatives

The National Confidential Enquiry into Perioperative Deaths (NCEPOD) in its 2014 report has highlighted management of acute upper gastrointestinal haemorrhage including blood transfusion support as a top priority. The NIBTS medical team are collaborating with the Gastroenterology Team, BHSC to design a clinical pathway for acute upper gastrointestinal haemorrhage which will be implemented and then audited for compliance.

Regulatory affairs and compliance

SaBTO agreed at an extraordinary meeting held on 07 July 2015 to introduce HEV screening for selected patient groups. It was decided to provide HEV RNA negative labelled blood components for two selected patient groups:

- Recipients of allogeneic haemopoietic stem cell transplants
- Recipients of solid organ transplants

NHSBT and WBS have decided to provide additional HEV RNA negative labelled blood components for the neonatal patient group. This exceeds the SaBTO minimum requirement.

A business case to support this development was reviewed and approved by the Board. It was noted due to installation of necessary instruments in January 2016 this testing would not be available before 01 April 2016. NHSBT will proceed to offer this test January 2016 as their equipment is available. SNBTS will not proceed before 01 April 2016.

Clinical audit and haemovigilance

It is now ten years since the introduction of routine antenatal anti-D immunoglobulin prophylaxis (RAADP) in pregnancy which is a measure to reduce the rate of sensitisation of antenatal patients to anti-D antibody which can prejudice their pregnancy outcome.

New cases of sensitisation of anti-D for the period 2010-2015 were audited giving an overall residual alloimmunisation rate of 0.2%. This compares favourably with reports from the best programmes internationally such as the Netherlands which gives a residual alloimmunisation rate of 0.3%.

Media and public interest

We were notified of a potential public interest story by colleagues in NHSBT on 09 September 2015. The current edition of the scientific journal *Nature*, 10 September 2015 has published a report on *Evidence for human transmission of amyloid- β pathology and cerebral amyloid angiopathy* (doi:10.1038/nature15369) and a review commentary *Amyloid- β pathology induced in humans*.

This is a small case series of eight autopsies of patients who died of CJD at between 36 and 51 years of age. They were recipients of cadaver derived human growth hormone with which they were treated serially for constitutional smallness. In addition to the neurodegenerative changes typical of CJD four of the subjects showed extensive A β deposition in the brain and these features are pathognomonic of Alzheimer's disease which would not have been expected at this relatively young age. It is speculated that the pituitary gland preparations prepared from human cadaver brains and homogenised and repeatedly infused to these patients from early childhood were contaminated with prions and also transmitted Alzheimer's disease. Previously it had not been considered that Alzheimer's was potentially a contagious phenomenon. The circumstances are very specific in that there was a contaminated source, there was high dose exposure for recipients and case report lacks a control group.

It was wrongly *lost in translation* in the national newspapers and other media that blood transfusion might be implicated. This is not the substance of the report at all. There has never been a documented case of peripheral transmission of CJD through blood transfusion despite extensive surveillance and vigilance. This is not an issue for NIBTS and did not attract any media enquiries or donor traffic.

10. Finance and IM&T report for the period 01/04/2015-31/08/2015

The cumulative revenue position for the five months ended 31 August 2015 shows a net surplus of £368k. Excluding haemophilia a surplus of £273k is noted. In accordance with funding arrangements for haemophilia products, a refund of any surplus on haemophilia products will be made to HSCB if necessary at year end.

Current projections indicate that a breakeven position can be achieved by year end. This may require the agreement of a non-recurrent refund of any in year underspend to HSCB. A projected surplus of £50k has been reported to DHSSPS.

All projected capital expenditure is planned between December 2015 – February 2016. Mr Bell has requested an assurance from senior managers by 30 September 2015 that all capital schemes will be completed by 31 March 2015.

Compliance with prompt payment policy has been achieved and working well with Shared Services.

The notional value of blood components issued to hospitals is 3.3% below the service level agreement value at the end of August 2015. The South Eastern Trust (114.9%) is currently outside the SLA tolerance limit. This is monitored and managed on a monthly basis.

NIBTS payment, income and payroll services are all provided by BSO Shared Services Centre . A quarterly assurance report has been received from BSO on these services and this has stated that services are being delivered in accordance with the SLA.

11. Bank mandate approval

The bank signatory mandate requires updating. Mr Bell proposed the following five people as signatories – Mr Glenn Bell, Mr Ivan Ritchie, Dr Kieran Morris, Dr Kathryn Maguire and Mr David Moore. The Agency Board agreed and Mr Lennon signed as Chairman.

12. Business case for replacement of Ford Connect

The Agency Board approved this business case.

13. Capacity Plan

This item was briefly discussed at the SMT meeting, 15 September 2015.

Mr Simpson noted he was unimpressed with the report document indicating lack of financial information and costings.

Generally support is for option 1, which is the least risky option.

Mr Simpson agreed to bring this item back to the next Board meeting, 22 October 2015 with a collective view.

14. Report from Responsible Person/MHRA

The situation in relation to incidents remains static with no incidents currently open over 90 days. Problems continue in relation to staff failing to request an extension when their investigation/actions will be overdue. Senior managers were requested to reiterate the importance of timely actions and requesting extensions where necessary.

Ms Macauley noted the intention to make changes to the change control process however she is having difficulty in identifying how to make the system more user friendly while ensuring the requirements are being met.

A mock MHRA audit will take place in November 2015; a date for this has not been scheduled as yet.

Ms Macauley identified data integrity as a high priority in preparation for the MHRA inspection. This will involve carrying out a gap analysis of NIBTS systems initially against the relevant standards and guidance after which an appropriate action plan to address the gaps can be formulated. To facilitate this piece of work the contract for a temporary BMS staff member has been extended by 6 months to allow this individual to act as project lead.

MHRA have indicated that Mr Kevin Page will be conducting an abbreviated inspection in January 2016 however it has not been confirmed whether a second inspector will also be visiting.

15. Complaints Q1

Only five complaints were received during the first quarter of 2015/16. No concerns at this time.

16. Corporate Risk Register

The Corporate Risk Register currently contains 8 risks. No risks have been added or deleted this quarter.

Risk 1 – Remains as was at last quarter.

Risk 2 – This risk has been reduced to a score of 10 by the Medical Director. The narrative has been updated to explain the reduction in score. The reasons given are that there has been no activation of the platelet shortage plan since July 2014 and the conformance of buffy coat derived platelet pools is now meeting “red book” specification. Also activity reports for four months of this year to date evidence no increase in demand which had been projected.

Risk 3 – The risk score remains the same as a decision has not been made on the laboratory capacity plan. Review date amended to December 2015.

Risk 4 – This risk remains as was at last quarter and is likely to remain until December 2015.

Risk 5 – This risk remains although Pulse Project Board has met. Review 31 December 2015.

Risk 6 – Public consultation closure date 22 May 2015. Outcome awaited. Review 30 September 2015.

Risk 7 – This risk remains the same as at last quarter, further update from the manufacturer due. Review 30 September 2015.

Risk 8 – This risk remains the same and will be reviewed again in December 2015.

17. Mandatory training schedule

This schedule was approved by the Agency Board.

18. Voluntary Exit Scheme

This document was produced regionally had has been agreed with staff side regionally. The process takes 8-10 weeks and expressions of interest will be sought from staff. All staff on payroll must be advised of the scheme, including those on career breaks and maternity leave.

It was noted this scheme is likely to have a limited impact on NIBTS as staff must meet a number of eligibility rules to be considered.

The Agency Board approved this scheme.

19. Any other business

NIBTS draft meeting dates 2016

The draft meeting dates were agreed and will be circulated to senior managers.

20. Action list from meeting 24 September 2015

Action	Responsible Person
Provide an update in relation to the platelet project to the next Agency Board meeting	Dr Morris
Update Sponsor Branch in relation to BloodMobile litigation	Mr Simpson
Provide collective view in relation to laboratory capacity plan to the next Agency Board meeting	Mr Simpson

20 Date of Next Meetings

20 October 2015, 11am, Library

03 December 2015, 1pm Lecture Room

Signed: _____

Dated: _____