NHS
Blood and Transplant

The 50th NHSBT Governance and Audit Committee Meeting
Held on Friday 20 November 2015
In the Portex Room, at the Association of Anaesthetists,
21 Portland Place, London, W1B 1PY

Present:	Roy Griffins (**RG**) - **Chairman**	
	Andrew Blakeman (**AB**)	
	Keith Rigg (**KR**)	
	Shaun Williams (**SW**)	
Apologies:	Karen Finlayson (**KF**)	PwC
	Aaron Powell (**AP**)	NHSBT
	Sally Johnson (**SJ**)	NHSBT
	Huw Williams (**HW**)	NHSBT
In Attendance:	Ian Bateman (**IB**)	NHSBT
	Rob Bradburn (**RBr**)	NHSBT
	Tom Bullock (**TB**)	NHSBT (Observing)
	Louise Cheung (**LC**)	NHSBT
	Alan Daley (**AD**)	NHSBT
	Denise Dourado (**DD**)	NHSBT
	Kay Ellis (**KE**)	DH
	David Evans (**DE**)	NHSBT
	Linda Haigh (**LH**)	NHSBT
	Ben Hume (**BH**)	NHSBT
	John Lawson (**JL**)	NHSBT
	Peter Lidstone (**PL**)	NHSBT
	Edwin Massey (**EM**)	NHSBT
	Richard Rackham (**RR**)	NHSBT
	Nick Rayner (**NR**)	Deloitte
	Ann Smith (**AS**)	NHSBT (Minutes)
	Peter Stephenson (**PS**)	PwC
	Mike Stredder (**MS**)	NHSBT
	Paul Thomson (**PT**)	Deloitte
	Nick Todd (**NT**)	NAO
	Lorna Williamson (**LW**)	NHSBT
	Felicia Wright (**FW)**	NAO

Risk Presentation – Mitigating the risks associated with the scale and complexity of NHSBT's emerging change portfolio

The purpose of the presentation was to update the Governance and Audit Committee (GAC) on the steps taken to manage the risks associated with NHSBT's transformation programme. A copy of the presentation to be circulated with the minutes of the meeting.

It was acknowledged that this was NHSBT's most complex and challenging programme of change to date. The GAC having queried whether it was possible to stagger the proposed changes across the programme, noted that priorities would be reviewed continually and the programme adjusted if necessary and where possible.

While drawing some assurance that the key delivery risks had been identified, and measures put into place to manage them, the GAC in the meeting proper (see item 5) asked for regular updates on the Transformation Programme for its next meeting onwards.

Action

Declarations of Conflict of Interest
Members confirmed that they had no conflicts of interest.

Chairman's Introduction
RG welcomed all to the meeting, including Felicia Wright, Peter Lidstone, Tom Bullock, Alan Daley, John Lawson, Edwin Massey, Nick Rayner and Ben Hume.

15-112 **Minutes of the 49th Meeting Held 18 September 2015**
With one amendment, the minutes were accepted as a true and accurate record of the meeting.

15-113 **Matters Arising**
The matters arising table was reviewed. Three outstanding items from paper 15-12 at the February 2015 were closed and one item was updated to clarify a report would be prepared for the Executive Team (ET) in early 2016.

1	**Clinical Governance Report**

15-114 Clinical Governance report
LW brought to the committee's attention that this was the first report written in the new board report template and welcomed any comments. In early November 2015, the Clinical Audit, Risk and Effectiveness Committee (CARE) received a presentation from Aaron Powell, Chief Digital Officer, on Information Technology (IT), which covered risks associated with the current IT systems, risks posed during the replacement of core systems and included some examples of how IT can help mitigate current clinical risks. It was noted at CARE that many governance discussions, including Serious Incidents Requiring Investigation (SIRI) meetings, would benefit from IT input.

The Hepatitis E (HEV) testing implementation project continues with clinical guidelines for appropriate use being developed with internal and external expertise. A detailed update paper will be provided to the November Board.

Discussions with the Medicines and Health Products Regulatory Agency (MHRA) regarding the European Union (EU) amendment requiring West Nile Virus (WNV) testing to be performed on individual samples continues. Discussions regarding the EU amendment are ongoing with the MHRA following the continuation of WNV testing rather than the deferral of returning travelers, was supported by the Therapeutic Products Safety Group (TPSG).

The GAC discussed imports of Fresh Frozen Plasma (FFP) from Austria for transfusion for patients born after 1 January 1996. The supplier has indicated that they are no longer able to supply all the plasma from male donors, a strategy which reduces the risk of Transfusion Related Acute Lung Injury (TRALI), associated with anti-white cell antibodies. The risks will be assessed by the Serious Adverse Blood Reactions and Events (SaBTO) in December 2015 and will be taken to the Executive Team (ET) in January 2016.

A proposal outlining changes to CARE following the governance review will be submitted to the January CARE prior to submission to the Executive Team for approval, and submitted to the GAC and Board in March 2016.

15-115   <u>Serious Incident (SI) report</u>
- INC63390 - Histocompatibility and Immunogenetics (H&I)
  The report was summarised to the GAC for closure. **Closed to the GAC**.

- INC62979 - British Bone Marrow Registry (BBMR)
  The report was summarised to the GAC for closure. **Closed to the GAC**.

It was noted that both reports have open items and it was questioned whether the reports should return to the GAC. The GAC agreed to close both reports and the final actions would be taken to the Transformation Project Board, if appropriate, for closure.

AB questioned who decides whether an incident should be titled an Serious Untoward Incident (SUI) or a Serious Incident Requiring Investigation (SIRI). LC confirmed the SIRI MPD will be reviewed and involvement of the Board in the final classification of serious incidents will form part of the review.
Action: Proposal regarding involvement of the Board in final classification of serious incidents to be submitted to March GAC.   **LC**

<u>Items for the GAC attention</u>

- <u>SIRI - Organ Donation and Transplantation Directorate – INC1471</u>
  During a routine review of the organ offering process it was identified that both kidneys had been offered and allocated to separate multi-organ recipients. This contradicts the offering policy which states that if one kidney has been accepted for a recipient with intestinal failure, as in this case, then the remaining kidney will *not* be held for liver offering and should be offered as per the normal kidney matching run. On this occasion the second kidney was incorrectly offered and transplanted into a combined liver and kidney recipient.
  The recipient is now prioritised for receipt of further kidney offers. A root cause analysis (RCA) will be undertaken.
  Three new incidents (two in ODR, the third in Blood M & L)
- **Incident one** - The paper outlines the details of the first serious incidents identified with the Organ Donor Register (ODR). BH summarised the paper noting that the incident was identified by a member of the ODR team in September 2015, whereby an opt-out decision may be overwritten with an opt-in decision under certain circumstances.
- **Incident two** - During the action to correct the seventy one registrations identified in issue one, a second issue was discovered, which affects transactions coming in via the web service only (ODT, Scotland, Northern Ireland, Wales web pages). Initial analysis shows very small numbers of affected records due to the nature of how the issue is created.

SW questioned future confidence in the ODR. BH assured the GAC that a hot-fix to mitigate both issues is required; the software partner is providing a proposal and specification for this. AB noted he was assured by the response. BH also assured the GAC that the Communications team have been fully briefed and are ready to respond. An RCA will be arranged for both incidents.

- **Incident three** – LW informed the GAC of an incident which was reported shortly before the 50th GAC meeting. An infant received an incorrect product during transfusion. The incident is considered an SUI and an RCA will be carried out. An update to be provided to the November Board.

15-116 <u>Risk based decision framework for blood safety</u>
The report was taken as read and will be presented to the Board. If the framework is approved by the Board, the next steps would be the removal of the current framework from the quality system and replacement by the new framework.

2	**Quality Assurance**

15-117 <u>Management Quality Review (MQR) report Q2 July – October 2015</u>
There were seven regulatory and accreditation inspections in Q2 2015/16. One Major non-compliance was raised during the MHRA inspection at Filton. Elements of the Quality Management System (QMS) were cited as requiring improvement. None of the issues were safety related; they were all good manufacturing compliance improvements. A key element of this non-compliance focused on what the MHRA saw as a lack of action and escalation of overdue actions.
The percentage of overdue documents has remained more or less static and was raised as part of a Major non-conformance at a recent MHRA inspection.   KR commented on the high number of change controls open beyond their target date. IB assured the GAC that a number of Quality Assurance (QA) led initiatives, working with all departments were taking place to reduce them. RG noted that a Non Executive Director (NED) visit would be of benefit, post inspection.

3	**Business Continuity**

15-118 <u>Update business continuity risks and plans</u>
The paper outlined to the GAC, the progress against objectives set for the Business Continuity Team in April 2015.
One of the objectives was to develop a mass casualty response plan with relevant external partners by Q4. This objective was reported as being unlikely to be achieved by March 2016, due to difficulties engaging with NHS England, who lead on the exercise. In the light of the very recent terrorist attacks in Paris, concern was expressed about an inter-agency mass casualty response plan in the UK. RR gave assurance that provisions were in place, noting that the blood service did not always appeal for blood in mass casualty events. Donor offers in these situations were managed by taking donor details and recruiting the donors at a later stage. SW questioned NHSBT's stock level of skin. RR assured the GAC that currently the stock levels of skin were at a satisfactory level and most requests for skin were requested forty eight hours after a mass casualty event. The GAC approved the proposed 2016-17 objectives. While assured regarding NHSBT's internal mass casualty response plans, the GAC expected the November Board to want to know the latest multi-agency response plans.

4	**Information Technology (IT)**

15-119 <u>Results of Failover Exercises</u>
The first-stage data centre failover exercise took place on 25 and 26 September 2015. The work was planned to validate the failover procedures, provide some accurate timings for a controlled failover and provide useful lessons for an even more substantial failover test planned for the end of November 2015. Only one unexpected event occurred. Connection to Oracle Financials was lost as a result of a missing route on one of the firewalls. This was remediated and no loss of service occurred. All of the lessons learned will inform a more substantial failover exercise being planned by the Infrastructure Hosting (IH) project at the end of November

2015 (know as the dark-site failover).

AD provided assurance to the GAC that appropriate processes and tools exist to allow a controlled failover between the two NHSBT data centres.

| 15-120 | Risk mitigation plans for Colindale |

The Infrastructure Hosting (IH) project will move the IT services from the data centres in Colindale and Elstree to commercial data centres provided by Specialist Computer Centres (SCC). The approach is to move one location at a time, beginning with Elstree, and this means that for a short period of time the majority of IT services will be delivered from Colindale alone.

| **5** | **Transformation programme** |

15-121
A&B

TPB report

DD reported on the project status report. The Stock Management project has improved from Red to Amber status and will 'go live' in eight hospitals. The overall programme status remains Amber. RG questioned who decides on the RAG status of each project. DD clarified that the report is submitted to the Transformation Programme Board (TPB) for the individual discussion of status and action, for informing each accountable Executive. The GAC expected at its next meeting, and regularly and after that, to review the programme's scope, structure, timing and risk mitigation.

DD/DE

| **6** | **Internal Audit** |

15-122

Review Internal Audit Progress report

There were no problems to report to the GAC. PS notified that the ten days that had been allocated for the Diagnostic Review were now merged into the Mapping High Risk Systems review, to be undertaken in the Stem Cell and Diagnostic Services Operating Units, giving a total budget of thirty days for this review.

NHSBT management requested a review to the controls relating to fuel. This covers the controls in place to monitor the use of fuel across the fleet including specific controls over mileage cost per vehicle, fuel cards and on-site fuel pumps.

Progress against the plan was noted with the draft report for the procurement of service, for the networks and telephony audit.

15-123

Review outstanding and overdue internal audit actions

There are eight medium/high points overdue at the end of October 2015, with two further extensions requested, relating to the approval of the Acceptable use policy. LH to inform action holders that dates must be set and that these dates must be met on time.

| **7** | **Risk Management** |

15-124

Risk Management update

The Risk Management action plan and organisational rollout, which will further support the organisation's risk agenda and enhance the awareness and management of risk across the organisation, will be rolled-out from January 2016. A paper was discussed at ET in early October 2015, which made recommendations on improvements to the organisations risk "software". The ET agreed to the paper's proposals, which will now be implemented. RG noted the three elements of change in the report which will re-focus risk management. The GAC raised concerns that further work is needed to ensure risk management processes are fit for purpose in

	NHSBT and the right level of risk discussion occurs at Board. **Action**: detailed implementation plans to be submitted to March GAC following the current work planned.	**LC**

8	**Integrated Governance – other governance matters / assurance streams**	
15-125	Board performance report RBr reported on the September 2015 status and trends in the Board report. It was noted that additional time should be allocated at Board to consider those sections documented as Red in the RAG status. **Action:** RG to request Board Performance Report be moved higher up the Board agenda.	**RG**
15-126	Assurance map RBr reiterated to the GAC that the assurance map is an aide-memoire and that there were no changes to report. PS commented the assurance map is a very useful document which could be further enhanced by priority rating the areas requiring assurance and RAG rating the types of defence. The GAC confirmed they have previously discussed RAG rating and felt at this stage to remain without it, but consider on next review along with priority rating. **Actions**: PS to send examples of assurance maps in other organisations to RBr for circulation.	**PS**
15-127	Integrated Governance Framework - review The GAC's annual review was to see that the framework continues to capture the processes through which the Board gains assurance of the delivery of NHSBT's statutory and strategic objectives. RBr confirmed amendments had been made mainly to changes in titles and responsible roles. RG pointed out the need for some small textual corrections. It was agreed at the next review to consider the flow and layout of the document and consider addition of index.	

9	**External Audit**	
15-128 A&B	External Audit plan/fees/payment schedule and final accounts timetable and plan – To be agreed PT addressed the key issues, including red blood cell decline, financial pressures, efficiency implementation and the Triennial Review of NHSBT, which commenced in June 2015 and is expected to conclude by the end of December 2015. A number of other areas of audit focus have been identified, but are not considered to represent a significant risk of material misstatement in the financial statements. The areas of audit will continue to be monitored and responded to as appropriate throughout the audit It has been requested that the June GAC occurs on or before the 17 June 2016 to enable NHSBT to meet the Treasury target of laying accounts prior to the end of June 2015. The GAC agreed to ensure the date of the June 2016 meeting will fall on or before the 17 June 2016.	

10	**Chair's Action (for discussion only as required)**	
	No actions were discussed.	

11	**Papers for information**

15-132   <u>Equality and Diversity</u>
The paper is due to be discussed at the NHSBT Board meeting in November 2015.

15-135   <u>Mandatory Training</u>
The Shine Academy is the new Learning Management System, which was launched in July 2015. There have been system errors in the implementation of the new Shine Academy. DE assured the GAC that the system is now working effectively and he would expect compliance with mandatory training to have increased when next reported.

12	**Any Other Business**

There were no further items to note.

13	**Review the effectiveness of the meeting**

Overall, the meeting was considered to have been chaired effectively, providing for informative and challenging discussion throughout. Although there was a large number attending the meeting it was commented that all attendees contributed to the exchanges. Time keeping proved a challenge earlier in the meeting, as three SIRI were a late addition to the agenda.
An appropriate amount of challenge was noted for the Risk section of the meeting. The high quality of the papers for both content and presentation was noted.

Date of next Meeting

Post meeting: The first GAC meeting of 2016 will be held in the Portex Room, at the Association of Anaesthetists, 21 Portland Place, London, W1B 1PY, on **Tuesday 19 January 2016**, 09.30 – 13.00 hrs.