

AGREED

The 46th NHSBT Governance and Audit Committee Meeting
Held on Friday 27 February 2015
In the President Room, King's Fund, No. 11 Cavendish Square, London

Present:	Andrew Blakeman (AB) - Chairman Roy Griffins (RG) Keith Rigg (KR) Shaun Williams (SW)	
Apologies:	Sally Johnson (SJ)	NHSBT
In Attendance:	Ian Bateman (IB)	NHSBT
	Rob Bradburn (RBr)	NHSBT
	Mick Burton (MB)	NHSBT (Observing)
	Anthony Clarkson (AC)	NHSBT (Deputising)
	Nicki Cook (NC)	Deloitte
	Denise Dourado (DD)	NHSBT
	Kay Ellis (KE)	DH
	David Evans (DE)	NHSBT
	Karen Finlayson (KF)	PwC
	Linda Haigh	NHSBT
	Rachel Johnson (RJ)	NHSBT
	Kate Mathers (KM)	NAO
	John Pattullo (JP)	NHSBT
	Aaron Powell (AP)	NHSBT
	Richard Rackham (RR)	NHSBT
	Clive Ronaldson (CR)	NHSBT
	Ann Smith (AS)	NHSBT (Minutes)
	Paul Thomson (PT)	Deloitte
	Huw Williams (HW)	NHSBT
	Lorna Williamson (LW)	NHSBT

Action

Declarations of Conflict of Interest

Members confirmed that they had no conflicts of interest.

Chairman's Introduction

AB welcomed all to the meeting, including John Pattullo, Anthony Clarkson, Denise Dourado, Mick Burton and Richard Rackham. AB noted there would be no risk presentation but a Transformation Programme governance presentation would be presented to the GAC in item 4.

15-01 **Minutes of the 45th Meeting Held 28 November 2014**

The minutes were accepted as a true and accurate record of the meeting subject to one minor change on page 7 re whistleblowing report (removal of 'if necessary').

15-02 **Matters Arising**

The matters arising table was reviewed.

Pandemic flu

RR noted that the paper outlined NHSBT's plans with regard to pandemic influenza, to give reassurance. It is intended to review fully in 2015/16 and work has already started in relation to this. RR assured GAC that a working plan would be in place by September/October 2015. It was agreed that this was necessary for the winter season. RR also confirmed that plans could be accelerated as required.

1 Clinical Governance Report**15-03 Clinical Governance Report**

The report was presented to the Board in January 2015. LW reported there was nothing additional to note following Board review. It was noted that the September and November 2015 GAC meetings will be re-arranged to fall in line with the Clinical Audit, Risk and Effectiveness (CARE) and Board meetings. AS to re-schedule.

AS

15-04 Serious Incident report

NHSBT's International Blood Group Reference Laboratory (IBGRL) undertakes reference tests using the tiny amount of fetal DNA circulating in maternal blood. NHSBT erroneously reported four samples in three pregnancies as negative for the K blood group when "no result" should have been reported. Letters of apology have been sent and a copy of the final report will also be sent to the clinical teams caring for the affected families. The incident has been reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) and the Serious Hazards of Transfusion (SHOT) haemovigilance scheme.

The poor performance of the assay was investigated. It was thought likely this was due to one or more of the reagents functioning below optimum, which may be due to their age. The shelf life of reagents in such assays varies depending on the size and structure of the reagent. They were in date within the 5 year expiry that had been defined for these reagents but as a precaution this was shortened to 2 years. Immediate remedial actions had been taken and further actions will be monitored through CARE.

A joint Quality and Clinical audit of IBGRL had been performed and no major or critical non-compliances were identified. LW explained that the IBGRL will move into DTS in April, which will allow more rotation of staff and tasks. This would mitigate against the 'human factor' issue of skilled staff carrying out important but repetitive tasks. KR suggested that there could be more scope for training with regard to behavioural factors. JP queried whether there was enough routine validation and testing in place. LW confirmed that human elements had been taken out of all processes as far as possible. Assay performance was assured by participation in external Quality Assurance schemes with blinded panels of samples. We do not routinely have results verified by an independent laboratory. HW confirmed that human factors work is planned in DTS. AB asked whether systematic learning was happening. It had been agreed by the Executive Team that there was more to do in this area in the context of accident reduction, and that an action plan needed to be developed. AB suggested a presentation at the April 2015 meeting regarding how we address human factor risks. IB, DE and LW to develop this.

IB/DE/LW

AB commented on the good team work and thorough review and was happy to close the incident.

- 15-05 Serious incident process document for information
 The process for managing serious incidents and the associated Management Process Description (MPD) have been updated to reflect changes requested by GAC and the Board. Further changes recommended by CARE have also been incorporated in addition to some changes in line with NHS best practice guidance. The result is a simplified process and a clear MPD with a flowchart highlighting the key stages and actions in the process. Both CARE and the Executive Team have approved this new process and MPD. GAC were supportive of the changes. RG noted that 'SIRIs' should be replaced with 'SIRI' as the appropriate plural term. The new process will then be trained out and implemented.

2 Integrated Governance report

- 15-06 Board performance report – governance issues arising
 RBr reviewed the report and asked the GAC whether they felt there were areas requiring a more detailed review of assurances. He identified key areas of ODT (on the agenda) and cord blood. He confirmed there would be a strategic review of stem cells in March.
 The key strategic issues that are red in status were discussed, with particular reference to issues that are habitually red versus those that we are not routinely aware of, and need particular attention. RG noted the importance of regularly reviewing the red status items. SW asked about use of agency staff and was assured that this is well controlled with numbers reported in the Board performance report.
 AB asked whether there were any issues that the Executive Team (ET) were aware of that could have material effect and had not been raised with GAC or the Board. ET members confirmed they were not aware of anything.

ODT – performance gap to strategic targets - verbal

To date this year, the number of deceased organ donors has dropped, despite recent increases. AC confirmed there were fewer audited deaths in quarters 1 and 2 although reasons for this were not clear. There were 1320 donors last year and we are predicting 1298 this year. The consent rate remains static. The number of audited deaths has increased and AC confirmed that next year's target figure of 1365 donors and 62% consent rate will remain. We are still on the trend line for the 2020 target which remains in place.

KR suggested that a clinical review of relevant data could be beneficial. LW noted that the optimal process for feeding back guidance to clinicians was being examined as a research project in transfusion, so this approach could be used with regard to clinicians' decisions to accept organs. A new clinical fellow post has been approved to look at non-cancer donor risks and help resolve some of the inconsistency in clinical decision-making.

- 15-07 Alignment with DH Guidance Principles for Assurance and NHSBT Assurance Map
 The Department of Health have produced a guidance document entitled 'Guidance Principles for Assurance – DH, ALBs and the Wider System' (March 2014). This was discussed at the DH and National Partners Audit Committee Chairs and Non-Executives conference in October 2014, following which it was agreed that NHSBT's assurance processes should be mapped to the principles specified and any gaps identified for the GAC. RJ had produced a summary paper and RBr had remodelled the Assurance Map to be more in line with the guidance, noting that the guidance had not included regulatory compliance. RBr identified the 'enablers' quadrant re leadership and culture as the main areas where it was generally difficult

to provide assurance. It was agreed that assurance is difficult in this area but that the issues had been considered (eg in response to the staff survey) and that there were action plans in place. The GAC were sufficiently assured and no additional actions were identified.

Governance Transition Arrangements – verbal

The newly appointed Assistant Director, Governance and Clinical Effectiveness, Louise Cheung, will start the role at the beginning of April 2015. Rachel Johnson's interim role as Assistant Director, Governance and Clinical Effectiveness, will end in early March. Reporting lines have been agreed for the Governance and Clinical Effectiveness team for the remainder of March 2015.

LW noted that maternity cover will be required for the role of Clinical Claims Manager, as Hannah Wardle will be taking leave. LW also noted that the Clinical Claims Manager role had considerably expanded over the last two years and ongoing support to the role was being considered.

3 Quality Assurance

15-08A&B Management Quality Review report

NHSBT has had a very good quarter three in terms of performance in regulatory compliance and accreditation inspections, of which there were four. There were no Major non-compliances raised in any of these inspections. IB noted that the Medicines and Healthcare Products Regulatory Agency (MHRA) are currently behind schedule with three inspections overdue. This has resulted in six regulatory inspections being scheduled in March 2015, three HTA and three MHRA.

The project to bring the Manchester and Bristol Corneal Transplant Service (CTS) Eye Banks into NHSBT Tissue Services continues. The Manchester Eye Bank will remain in its current location, but the Bristol Eye Bank will eventually be relocated into NHSBT, Filton. Works are being planned and licence variations submitted to bring the Eye Banks in house.

The overall number of overdue events continues to increase with a total of 330 events overdue. This increase could cause issues with inspections and all Directorate SMTs have been asked to ensure that their staff are actively reviewing and addressing any overdue actions.

An action plan is in place to ensure all audits scheduled in 2014/15 are completed before the end of the year. However, there are resource challenges, with dates for self inspections often being rearranged due to competing priorities. IB noted that NHSBT do not intend to transfer the Bristol Heart Valve Bank; this will therefore remain the responsibility of the University of Bristol. This project is now closed.

It was noted that it remains very difficult to get full, consistent and timely submission of data from other services for benchmarking purposes. LW noted that she will be attending the UK Forum in March and will raise the issue there. QA will then lead and map out a consistent approach with regard to benchmarking and report back to the GAC.

LW

IB

15-09 SABRE reporting

The report was taken as read, with nothing to note.

4

Transformation Programme GovernanceTransformation programme governance arrangements – Presentation

DD as Assistant Director Business Transformation Services (BTS) (Interim) presented an overview of BTS and the programme board framework as this was the first report to the GAC. The report and issues arising were then also discussed.

BTS co-ordinate and manage the overall Transformation Portfolio, provide specialist programme and project management resource, manage dependencies and ensure effective governance and provide assurance on the realisation of committed benefits. The NHSBT transformation portfolio is managed as one entity, informed by business strategies and mandatory external initiatives. The portfolio is self-sustaining based on financial benefits generated. The Executive Team set priorities and overall investment funding is £12-18m.

Since the BTS function was centrally established in 2007, 121 projects have been delivered and closed, making a significant contribution towards reducing blood price and delivering many non financial benefits within an agreed budgetary envelope. Currently there are 39 active projects and 20 pipeline projects.

Immediate priorities are to improve the effectiveness of the Transformation Programme Board (TPB), to establish an effective prioritisation process, to ensure appropriate resourcing and to develop the internal team. An improved reporting process will help, including better governance arrangements including a reporting structure to the GAC and Board.

There are 20 prioritised pipeline projects under the TPB and a review of key skills required in BTS has been undertaken resulting in recruitment to reduce reliance on contractors. There will be a focus on agile delivery where that approach is appropriate. It is recognised that the new portfolio is particularly complex and challenging, with significant cross-functional process and IT change.

Going forward, the programme aims to achieve greater transparency and to regularly engage with the GAC and Board.

15-10A&B

Transformation Programme Board report

The report template has been developed in collaboration with members of the GAC. 40% of projects were in red or amber status and KR asked about this high rate. DD replied that there was a need to drill down to resolve some issues but that given the complexity of many projects it would not be expected that they would all be green. It was noted that projects were in red for a number of varying reasons eg timescales, benefits. RR noted that risks to project and risks to the organisation were different things. The GAC discussed the nature of the Red status and the impact of Red issues. RG suggested that a cover note could be added to the report outlining what is of concern and what the GAC need to consider. DD to provide for future reports. JP noted the importance of benefits realisation. Assurance is needed that wise investments are being made and at the close of projects, a review of benefits delivered should be sent to the GAC. Change capacity and capability were also noted as key and DD to consider appropriate indicators. AB thanked DD and DE for their report and advised GAC that individuals should feed back any further comments directly to DE and DD.

DD

DD

5

Standing Orders

15-11A&b

Fraud Report

This was an interim report, considering the NHS Protect review.

Five cases have been referred to the Local Counter Fraud specialist for NHSBT in 2014-15. One is subject to ongoing prosecution and another relates to fraud outside of NHSBT which bears reputational risk for NHSBT. Details will be shared with an NHS Protect Specialist.

Of note, additional sample checks will be implemented with regard to agency staff

		Action
(contractors and volunteers). Also, it was noted that with regard to petrol theft of about £60k, controls were in place but had not been applied. Overall, however, it was concluded that NHSBT arrangements to protect against fraud are reasonable and that reasonable actions are taken in response to incidents.		
6	Internal Audit	
15-12	<p><u>Internal Progress Report</u></p> <p>The plan for 2015/16 is being developed and will be discussed with the Executive Team. A draft will be brought to the GAC in April.</p> <p>KF noted that eight audits have been completed to date against the Internal Audit Plan which was approved by the Governance and Audit Committee (GAC) in June 2014. There were two low risks reported regarding the Data Centre Hosting project, although the scope had been narrowed to focus on procurement aspects (with substantial assurance reported). It was noted that the Terms of Reference for internal audits should be developed with an executive lead and signed off appropriately with Executive Team agreement.</p> <p>An audit of ODT Information Services identified two risks, one of which was high. The reliance on manual processes is a key area of risk. There are documented processes but they are complex and manual rather than automated and streamlined. AB noted that this related to work needed as discussed earlier around human behaviours and risks associated with manual processes. The report also noted that 'business as usual' ODT IT activity was limited as there was a project focus and the intention to replace the National Transplant Database (NTxD) meant lack of investment in enhancements to the current, complex NTxD. There were questions raised as to the safety of fundamental processes as defect levels indicated underlying problems.</p> <p>AB asked that:</p> <ol style="list-style-type: none"> 1) the ODT Information Services audit should be brought back in full to the GAC and that SJ and AP should attend to respond. 2) RBr to look at processes for Internal Audit and give assurance (eg agreed scope) 3) errors related to human factors be considered as discussed earlier 4) consideration be given as to how to link to Performance Management work. <p>KF noted recent involvement in work concerning culture and behaviours and offered to make a presentation to the Executive Team. KF and RBr to discuss.</p> <p>A number of areas for audits to be considered in the next report include risks in reliance on key staff and succession planning/knowledge transfer. There is also interest in auditing NHSBT's horizon scanning, which is felt not to be clearly documented although is working effectively in practice.</p>	<p>KF</p> <p>SJ/AP</p> <p>RBr</p> <p>RBr</p> <p>KF/RBr</p>
7	External Audit	
	<p><u>External Audit Progress Report – verbal update</u></p> <p>NC reported to the GAC that the external audit plan was on track and that she was not expecting any setbacks to arise. NC noted that this would be her last GAC meeting and that going forward, Paul Hewitson (PH) would be attending the GAC meetings. AB thanked NC for her contribution to the GAC over the last five years.</p>	
8	Risk Management	
15-13	<p><u>Risk Management update</u></p> <p>The Risk Management workshop held in August 2014, reviewed the current risk management processes, as they are operated at NHSBT. The Risk Management</p>	

Assessment Framework management process description (MPD) was drafted and approved in December 2014 and a risk management MPD has now been drafted. The Risk Register will be modified to capture a target risk scoring. The project to harmonise incident reporting, complaints, audits etc would be considered further by the Transformation Board in May. Louise Cheung, as new Assistant Director for Governance and Clinical Effectiveness, will take the reporting system project forward.

9

IT Governance

Data Centre Hosting – verbal

- AP noted that options are being considered for the way forward with this project. Cabinet Office approval was gained in January for this contract. SCC, the likely contractor, are requesting changes to the contract and clarity is required about essential changes by early March. Crown hosting is another option and may require further investigation.

Plans for new desktop – verbal

This work is progressing well and a report was presented to the January 2015 Board. AP noted that NHSBT staff will receive communications in due course.

Capacity and capability – verbal

AP noted progress with regard to capacity and capability, in support of the new strategic framework.

- Change and incident management processes are being made more robust.
- Changes are being made to the Senior Management Team.
- New staff are being recruited within the current budget. 19 posts are being advertised including replacements for contractors. This will give greater day to day resilience.
- A review of capabilities required going forwards will underpin the IT strategy and may lead to some retraining

AB summarised that there were no new risks or concerns in respect of capacity and that capacity and capability were being strengthened.

10

Business Continuity

15-14

A Business Continuity Annual Report was provided to the GAC. Business Continuity objectives were met in 2013-14 and are on track for 2014-15, with the exception of a crisis management exercise which is due in March 2015. Such an exercise is required every 3 years and involves a full day rehearsal for crisis management. The Executive Team are committed to achieving this and a day has been planned in October after being delayed. AB advised that this must take place and that it will be monitored by the GAC. The date is to be advised to the April 2015 GAC meeting.

RR

11

Freedom to Speak up

Freedom to Speak up Review – verbal

DE reported that following on from the Francis report, a report on whistleblowing has recently been published. The implications for NHSBT are being considered. A Whistleblowing report will be presented to the GAC in June 2015, adopting appropriate recommendations. GAC were content with this plan.

12 Chair's Actions (for discussion only as required)

- 15-15
- **Chair's action report**
The GAC approved the Chair's action report section of the meeting and agreed that this new process was working well.
- 15-16
- **Review GAC Terms of Reference**
The GAC ToR were approved.
- 15-17, 15-18A,B,C
- **Approval of revised standing orders, standing financial instructions and scheme of delegation**
Discussed briefly and accepted. RBr noted that there may be some minor changes before these are presented to the Board.
- 15-19
- **Outstanding and Overdue Audit Actions**
Nothing to note.

13 Any Other Business

The September and November 2015 GAC meetings to be aligned with the CARE Committee and Board meetings. The September meeting will now take place on Friday 18 September and the November meeting will take place on Friday 20 November 2015.

14 Review the effectiveness of the meeting

AB asked the Committee for their opinion regarding the length of the Committee meeting and whether it should remain a 3 hour meeting or change to a 3.5 or 4 hour meeting. The Committee agreed that the length of the GAC meeting should increase to a three and a half hour meeting. All future meetings will commence at 09.30 hrs and finish at 13.00.

AS

Date of next Meeting

Friday 24 April 2015

Please note: The next meeting will be held in the **Intavent Suite at the Association of Anaesthetists, 21 Portland Place, London , from 09.30 – 13.00 hrs**