

MINUTES

**The 62nd Meeting of the NHSBT Governance and Audit Committee Meeting
Held on Monday 19 March 2018
West End Donor Centre, Board Room, 26 Margaret Street, London, W1W 8NB**

Present: Roy Griffins (**RG**) NED Chairman
Jonny Oates (**JO**) NED
Keith Rigg (**KR**) NED
Charles St John (**CSJ**) NED

Apologies:

In Attendance: Ian Bateman (**IB**) NHSBT
Rob Bradburn (**RB**) NHSBT
Ele Brown (**EB**) NAO (*via telecom*)
Louise Cheung (**LC**) NHSBT
Ruth Clarke (**RC**) NHSBT (*Observing*)
Kay Ellis (**KE**) DH
Karen Finlayson (**KF**) PwC
Gail Miflin (**GM**) NHSBT
Helen Gillan (**HG**) NHSBT
Linda Haigh (**LH**) NHSBT
Jeremy Monroe (**JM**) NED
Lucy Nutley (**LN**) Mazars
Aaron Powell (**AP**) NHSBT
Richard Rackham (**RR**) NHSBT
Katherine Robinson (**KRo**) NHSBT
Jonathan Sawyer (**JS**) PwC
Ann Smith (**AS**) NHSBT (*Minutes*)
Katrina Smith (**KS**) NHSBT (*Observing*)
Huw Williams (**HW**) NHSBT

Action

Declarations of Conflict of Interest

Members confirmed that they had no conflicts of interest.

Risk Presentation – Tissue Eye Services (TES)

Based in Liverpool and supported by retrieval teams in Leeds, Bristol and London and Eye Banks in Bristol and Manchester, TES treated 13,800 patients in 2017 with tissue products or serum eye drops, with approximately 3000 eye donors per year. TES is a largely independent operation managing the entire supply chain (donor consent, retrieval, processing and distribution, sales).

TES operates in a highly regulated environment, requiring the following compliance; Internal audits, external audits and quality assessment schemes, along with regular management quality reviews, service resilience and recovery plans. HG noted the risks within TES and recent Serious Incidents (SI) including the challenges regarding the provision of human skin. Hospitals are now choosing alternatives to human skin because of cost and so the sale of skin has continued to decline, with a reduction of £1m sales over 2 years. Discussions are ongoing with the DHSC regarding the request to hold emergency stock.

The GAC were generally assured by the TES risk presentation noting the business concerns regarding future skin provision.

Action: AS to circulate the Tissue and Eye Services presentation with the draft minutes. **AS**

Chairman's Introduction

RG welcomed all to the meeting.

18-19 Minutes of the 61st Meeting Held on Tuesday 16 January 2018

The minutes were signed as a true and accurate record.

18-20 Matters Arising

The outstanding actions were updated and closed to the GAC. It was agreed the next Deep Dive would be at the November meeting. AS to update the workplan. The actions regarding the surgical de-brief and NHSBT's lawyered position regarding liability for communications action were discussed and a current position given. **Action:** AS to blend the two actions together and GM to invite JF to the June 2018 GAC meeting for discussion. AS to add to the June 2018 agenda.

**GM/
AS**

1 Clinical Governance

18-21 & 18-22 Clinical Governance Report

Serious Incident (SI) update

The recent extreme weather conditions (outside the reporting period) were noted to the GAC. NHSBT did not fail to deliver blood to any hospital. During the worst of the weather, (Red weather alert) ODT operations in Scotland were stood down, but recovered quickly. Diagnostic and Therapeutic Services (DTS) (including Therapeutic Apheresis Services (TAS) were maintained throughout. The week following the snow an Amber alert for platelets and red cell stocks was called due to collection difficulties during the weather. This was despite platelet stock being healthy before the snow started.

The following SI are now closed

- ODT INC 2306: Removal of two kidney grafts following histology results in donor indicating lymphoma.
- DTS QI4492, the removal of ocular tissue in error without consent.

In addition

- ODT INC 2273: Disseminated Herpes Simplex Virus (HSV) infection. It has been agreed that this report can now be closed and the final draft is in preparation.

NHSBT will provide information for three upcoming inquests; two relating to incidents QI1697 and QI6552 in DTS. In both cases the patients died despite interventions and blood components from NHSBT, rather than as a result of them. QI1697 concerns the death of a patient following a thyroid operation. The death is associated with low blood pressure during the operation, significant bleeding, and multiple organ failure post operatively. QI6552 concerns the death of a patient with Thrombotic Thrombocytopenic Purpura (TTP). The third is a Coroner's inquest concerning the recent patient death, which is reviewing the possibility of the transmission of Hepatitis C via a blood transfusion from transfusions received before 1997.

There was a discussion regarding the extreme weather impact. HW confirmed a full lessons learnt (snow report) review is being undertaken, and following queries from the GAC it was confirmed this will differentiate between platelets and red cells, there already being wider concerns about blood stock levels. **Action:** RR to send a copy of the reviews

RR

to GAC members ahead of the June 2018 meeting. **Action:** Lessons learnt review - HW
to differentiate between platelets and red cells.

HW

2 Quality Assurance (QA)

18-23 Management Quality Review

Regulatory oversight continued throughout quarter 3, with visits from the Medicine and Healthcare products Regulatory Agency (MHRA), the Human Tissue Authority (HTA) and the European Federation for Immunogenetics (EFI). There was one Major non-compliance raised during the MHRA inspection at Manchester.

(Items 18-23 & 18-25 reviewed successively)
Change Control Management - the number of change controls open beyond their target date at the end of quarter 3 remains high. KR asked IB what timescales were in place for completion of the facilities work required to address the bacteriology recall issue in Manchester. **Action:** IB to report the timescales to KR.

IB

18-25 Overdue Document Update

GAC members expressed concern about the number of overdue QMS items. Since the end of quarter 3 progress has slowed and a recent ET meeting all Directors were asked to address the overdues in their areas as soon as possible. The MHRA have received the required regular reports but as of this date no feedback has been given to NHSBT. IB highlighted an area of good practice in the South West Region where through robust local management they have not had overdue items in this area for some time. The roll out of this good practice across NHSBT it being reviewed and implemented. Penalties for not performing were discussed. Personal Development and Performance Reviews (PDPR's) were considered as a tool to lower the number of overdue items by building into the formal annual review process. **Action:** KRo to raise at the ET and consider the inclusion of overdue documents as an objective in staff PDPR's

KRo

18-24 Non-Executive Director Site Visit Update

NED visits are planned and good progress has been made to arrange further visits. Extra dates will be added as required. IB agreed to remove reference to KR's retirement from the document prior to further circulation.

3 Business Continuity (BC)

18-26 Business Continuity Update Report and Management Review 2017

AEF
An overview was presented of all papers submitted to the GAC, paying in depth attention to the BC update report and the Management Review 2017.

- The British Standards Institute visited NHSBT between October and December 2017 and ten minor non-conformities were found, with two issues of note. A failure to close non-conformities was noted and the second was a Business Impact Analysis (BIA) within the system, which needs improvement to cover consumables more effectively. The list of critical consumables will be completed by September 2018 and a report will be submitted to the GAC for assurance.
- The BC Team continue to support the Core Systems Modernisation (CSM) programme with a full-time secondment to the programme, covering BC issues.
- The exercise to test the Red Cell Immunohaematology (RCI) BC plan has not been completed because of staff shortages. The exercise is written and RR assured the GAC that BC would work through the processes and that BC are confident of delivery.
- Mass casualty plans need to be more intelligently considered and RR confirmed that the stock holding methodology would hopefully be reviewed by September.

The GAC asked if BC were confident of delivery of all the BC objectives noted in the Management Review report. HW assured the GAC that he was confident of delivery in 2018/19.

4 Transformation Programme

Core Systems Modernisation (CSM) Project Update

The CSM project was discussed at length in advance of its going to the full Board meeting on 29 March 2018. JM, the NED on the CSM programme board, attended the GAC meeting.

The CSM Programme is reporting a Red status and in order to address this, decisions were made at the recent CSM Programme Board meeting held on 11 March 2018. The meeting proposed an alternative approach which was discussed and approved for proposal as part of the business case for the NHSBT Board on 29 March 2018. The GAC wanted to ensure that the Board got the information needed to make considered decisions at its next meetings, notably:

- The options
- The recommended plan
- The timetable
- The milestones
- The governance arrangements
- The costs (incurred so far and forecast)
- The risks and mitigations

Many of these issues were included in ASn's presentation, asserting:

- A new Governance structure is in place
- Terms of Reference (ToR) have been finalised
- All roles have now been recruited into
- Change Control x 2 will be taken to the Board
- Completed actions
- Refine continuous improvement, going forward

ASn noted, when questioned about the structure of the programme:

- A slimmer and longer programme structure
- An Information Technology (IT) support team is aligned to IT

The GAC saw as key issues for Board decision:

- The feasibility of remediating/re-platforming Pulse and potentially relying upon it for five more years
- Reliability and management of contractors, in particular Savant
- Governance of and responsibility for the whole programme and its parts
- How to provide independent oversight and assurance in real time
- Costs incurred and forecast, and control of these

The Programme Leadership Team would review how ongoing assurance on these issues would be delivered. The GAC favoured retaining PWC to engage in a real-time audit.

5	Internal Audit	
18-28	<u>Internal Audit Progress Report</u>	
A,B	<p>Fieldwork has been completed for the Price Waterhouse Cooper (PWC) review of General Data Protection Regulation (GDPR) a draft report is to be produced shortly. PWC are proposing that the review of Change Capability and Capacity is deferred into 2018/19. The final phase of the Key Financial Controls work is in progress, with a report expected before the end of March 2018.</p> <p>Following discussions at previous GAC meetings around known issues with the Organ Donation Transplantation (ODT) Organ Donation Register (ODR) data and processes, PWC have been in discussion with ODT regarding how to assure over associated risks. The draft 2018/19 internal audit plan proposes to focus on this area.</p> <p><u>DVLA & ODR Data Discrepancies update - Oral</u> A full update will be submitted to the GAC in quarter 1.</p>	
18-29	<u>Outstanding and Overdue Internal Audit Actions</u>	
A,B	<p>There is one medium Cyber Security point outstanding as at the end of February 2018. It is proposed that the audit point is closed and the risks are left to Information Communication Technology (ICT) to manage. There will be a further cyber security review conducted by internal audit in 2018/19. This was agreed by the GAC.</p>	
18-30	<u>Internal Audit Plan 2018/19 – for Approval</u>	
	<p>The plan is set to be phased across 2018/19 by splitting the high, medium and low priority reviews. The Transformation Programme is set as high priority. Action: PWC and ASn to discuss the audit of the Transformation Programme.</p> <p>With some possible priority changes, which are driven by increases in transformation programme oversight, the GAC approved the Internal Audit Plan for 2018/19.</p>	PWC/ ASn
6	External Audit	
	<u>External Audit Progress Update</u>	
	<ul style="list-style-type: none"> All Interim Audit fieldwork has been completed. No issues were reported. The European Union (EU) Merlin Grant Audit is in its final stages of agreement before submission to the EU. Any updates will be fed back to the GAC. The GAC confirmed the timetable to complete the External Audit in June 2018. The final audit of accounts 2017/18 will take place before the June 2018 GAC meeting and before the pre-meet with the NEDs, on 12 June 2018. LN noted as an invitation will be sent to the GAC NEDs for the Governance Forum Programme. The primary aim of the Forum is to promote good governance and share current best practice. Action: AS to forward the Governance Forum programme in 2018 invitation to the NEDs. 	AS
7	Risk Management	
18-31	<u>Risk Management Update</u>	
	<p>LC confirmed the Pentana system has now been rolled out across NHSBT and is in use across all directorates and business units. The risk management manual has now gone live and the training is almost complete. There is currently a focus on improving consistency in controls and assurance, and how they are documented on Pentana and a number of changes/improvements have been made to Pentana to increase the opportunity to run reports directly from the system. In 2018/19 there will be a focus on agreeing and moving</p>	

towards target risk scores. **Action:** LC to update the GAC in June on timescales for target risk score work. **LC**

8 IT Governance

18-32 General Data Protection Regulation (GDPR) and Retention of Records
LC provided an update of GDPR and gave an overview of the risk considerations of retaining records beyond their minimum retention periods as per the request from the GAC. It was questioned if NHSBT will be ready for GDPR when the new rules come into force on 25 May 2018. The Assistant Director of Governance and Clinical Effectiveness noted that NHSBT will be ready, and at this point are not expecting any major risks to be in place, however, there will be significant on-going work post 25 May to ensure full implementation of GDPR and respond to new guidance when issued, which has currently been delayed. The Chief Digital Officer also confirmed that NHSBT will be compliant by the 25 May 2018, based on our interpretation of the legislation, guidance available and on-going residual risks which will be flagged. It was agreed that prior to the GDPR position statement to May 2018 Board, the May 2018 ET will consider and approve. If any significant concerns in compliance arise before the 24 May 2018, RG requested that the Board should be notified prior to May 2018 Board.

9 Integrated Governance

18-33 Board Performance Report – January 2018
The January 2018 report was submitted for information. The February 2018 will be released at the end of March 2018, for submission to the Board. CSJ noted the insertion of overdue debtors, and also the addition of a new row to support the RAG status, with commentary to support. The overall CSM programme will be input into the report.

18-34 Review of Standing Orders
NHSBT reviews its Standing Orders in March each year so that they may be submitted in a package with budgets and budget instructions, to all budget managers, at the start of the new financial year. There were minor changes in the documents, with the exception of changes in the Scheme of Delegation. The GAC approved the update of the Standing Orders (subject to minor textual changes). Standing Orders will be discussed at the Board.
Action: RB to forward embedded documents to the NEDs. **RB**

18-35 Period 9 Governance Statement for DH
The paper was submitted for the GAC records, regarding the Interim Month Nine Assurance Statement on Internal Control 2017-18, for information.

10 Committee Business

18-36 GAC Workplan

- The GAC agreed to add the SI Deep Dive to the workplan annually at all November meetings.
- GM noted annual reports are now submitted to the Clinical Audit Risk and Effectiveness Committee (CARE) every May. The GAC were asked if the annual reports could be submitted to June meetings, taking into consideration that the June meeting is based around financial sign off. The GAC were happy for annual reports which are submitted to CARE first to be submitted to June GAC meetings.
- GM also noted the information that was reported in the Revalidation report was now included in the Clinical Governance report and therefore could be removed from the workplan; this was agreed.
- In the Board Performance section of the workplan the Governance issues arising/follow up from Board to change to Governance issues forewarning/arising from Board, to reflect the GAC's role in forewarning the Board.

- The Assurance Framework document will be submitted as an appendix of the Governance and Assurance Framework.
- The GAC approved the workplan subject to the changes outlined above for 2018/19.
- **Action:** AS to amend the workplan as outlined above.

AS

11 Chair's Action (for discussion only as required)

- No items to note.

12 Papers for information

18-37ABC Losses and Special Payments

18-38 Waivers

18-39 Clinical Audit Programme – ***The GAC noted with approval, the Clinical Audit Plan 2018/19 (also approved by the CARE Committee 1 March 2018).***

18-40 Assurance Framework

13 Any Other Business

- No items to note.

14 Review the effectiveness of the meeting

- Documents were well presented and timelier.
- Timely finish to the meeting.

Dates of Meetings in 2018

Date/Time	Venue	GAC Papers for submission
Monday 18 June 2018 09.30 hrs – 13.00 hrs	West End Donor Centre Board Room	Tuesday 5 June 2018
Monday 17 September 2018 09.30 hrs – 13.00 hrs	West End Donor Centre Board Room	Tuesday 4 September 2018
Friday 23 November 2018 09.30 hrs – 13.00 hrs	West End Donor Centre Board Room	Monday 12 November 2018