

MINUTES

**The 67th Meeting of the NHSBT Governance and Audit Committee Meeting
Held on Tuesday 11 June 2019
West End Donor Centre, Board Room, 26 Margaret Street, London, W1W 8NB**

Present:	Piers White (PW)	NED	Chairman
	Keith Rigg (KRi)	NED	
Apologies:	Gail Miflin (GM)	NHSBT	
	Jonny Oates (JO)	NED	
In Attendance:	Betsy Bassis (BB)	NHSBT	Observing
	Ian Bateman (IB)	NHSBT	Quality Assurance
	Rob Bradburn (RB)	NHSBT	ARA, Finance & Integrated Gov
	Louise Cheung (LC)	NHSBT	IBI update, SI Annual report
	Kay Ellis (KE)	DHSC	ARA
	Karen Finlayson (KF)	PwC	ARA & Internal Audit
	Jeanette Foley (JF)	NHSBT	Observing
	Linda Haigh (LH)	NHSBT	ARA, IA Summary
	Brian Henry (BH)	NHSBT	IT & Cyber Security update
	Catherine Hepburn (CH)	NAO	ARA
	Edwin Massey (EM)	NHSBT	Clinical Governance & SI Update
	Jamie Moore (JM)	NHSBT	PwC Audit Blood Donation
	Lucy Nutley (LN)	Mazars	ARA
	Richard Rackham (RR)	NHSBT	Business Continuity & Brexit update
	Katherine Robinson (KRo)	NHSBT	Health & Safety Annual report
	Mark Rodgers (MR)	NHSBT	Transformation Programme
	Ceri Rose (CR)	NHSBT	Communications
	Ann Smith (AS)	NHSBT	Minutes
	Mike Stredder (MS)	NHSBT	PwC Audit Blood Donation
	Phil Tanner (PT)	NHSBT	Health & Safety Annual report

Action

Declarations of Conflict of Interest

Members confirmed that they had no conflicts of interest.

Chairman's Introduction

PW welcomed all to the meeting.

19-48 Minutes of the 66th Meeting Held on Wednesday 27 March 2019

The minutes were signed as a true and accurate record.

19-49 Matters Arising

- The two open actions were updated and closed to the GAC
- It was noted that our Insurance limit of £1m meant that any loss e.g. from a fire at a major property, effectively meant that we were, as with the rest of the Public Sector, self-insuring.

1 2018/19 Annual Reports and Accounts (ARA)

19-50 & 19-51 Introduction

Part of the GAC's function at the June 2019 meeting is to approve the annual report and accounts for the NHSBT Board. The Board had already commented upon and had their views reflected within the Governance Statement. Ahead of this GAC meeting, the Non-Executive Directors (NEDs), Mazars and the National Audit Office (NAO) had met and run through the proposed R&A and the audit process and findings in some considerable detail on Thursday 6 June 2019.

19-53 & 53A,B&C

The status as of 11 June 2019 is that the DHSC have approved the quantum of the Constructive Loss and informed the Treasury. The DHSC Minister will be advised of the final CSM Constructive Loss figure in due course. Having obtained DHSC approval the GAC can proceed to approve the annual report and accounts subject to agreement of the wording of the C&AGs report.

External Audit and Completion Report and Opinion

LN summarised the report, noting the key timings and clean audit. During the course of the Audit, One medium priority Internal Control - Risk was identified relating to Leavers and IT access controls. On behalf of the Exec, KRo had kindly volunteered to lead the work required to bring about improvement. KRi suggested that we follow up with an Internal Audit to ensure that once in place the new controls were working.

On behalf of the NAO, CH summarised the process of the 2018/2019 Annual Reports and Accounts, noting that the audit opinion is clean. However, she noted that there would be a short paragraph added to the CAG's report drawing attention to the quantum and disclosures surrounding the CSM Constructive Loss. *Note: Following on from the meeting on 6 June 2019 the relevant paragraph was considered by the Finance Director and NED's who felt it was fair and thus the R&A was signed by the Accounting Officer.*

KF explained to the Committee the basis for her Internal Report and Opinion on Internal Controls. It was agreed that making reference to the Substantial Assurance surrounding NHSBT's key financial controls should be included. It was also agreed to make clear to readers that the Blood Risk Management Limited Assurance Internal Audit did not cover issues to do with Blood Product safety. The adjustments to the wording of the report were confirmed immediately post meeting.

LH summarised near final draft Annual Report and Accounts (v6), which has been audited subject to final sign off. LH ran through the amendments to the document arising from the Board review of v6 and the NEDs June 6th meeting. KE advised LH of an error on page 16 of the document; this will be amended offline.

PW went on to explain that at the June 6th meeting consideration has been given to the Accounting Officer's Letter of Representation. It was noted that the only substantial change to the prior year was in respect of the CSM Constructive Loss. The GAC recommended that this Letter could be signed by the Accounting Officer.

The Chief Executive questioned whether it was possible to amend wording, around page 49 of the accounts where it implied she had been in post for much of the Financial year and able to apply and test assurance. The NAO explained that the Accounting Officers responsibilities were "standard" as written in the Financial Reporting Manual and could not be changed. The GAC noted this wording could not be changed and agreed that it should be a matter of record that the CEO only took up her responsibilities right at the

end of the Financial Year. It follows that it was only reasonable for her to rely upon the assurance of her predecessor, the Executive Team and our Internal Auditors over the course of the year.

LN expressed her thanks to the NHSBT Finance Team. LH was thanked by BB for her work.

Formal Review and Approval by GAC

On behalf of the GAC and the Board, PW recommended that the Report and Accounts be Approved (subject to agreement of the C&AG report prior to the accounts being signed). This was agreed. He thanked PwC, Mazars, and the National Audit Office (NAO). The accounts will be formally signed by Betsy Bassis, Chief Executive and Accounting Officer during June 2019.

Action: Review the process of the Annual Reports and Accounts production prior to the start of the September 2019 GAC meeting.

PW

Please note: Agenda items removed. GAC PAPER 19-52 -Review External Audit progress report (including the co-operation between Internal and External Audit) is covered in GAC PAPER 19-50.

GAC PAPER 19-54 Annual report status / timetable to laying is covered in GAC PAPER 19-53.

2

Clinical Governance (CG)

Turning to the remainder of the Agenda, PW expressed a personal view that the papers were of varying quality. He encouraged all authors and their Executive colleagues to place a greater emphasis on emerging themes and trends over time. This would help the organisation identify required action early and to see whether the actions being taken were leading to better or worse outcomes.

Additionally, PW asked for feedback offline from all GAC participants covering the content of the papers; were they too long for example. **Action: all GAC participants.**

ALL

19-55

Clinical Governance Report (01 February – 31 March)

The report was taken as read, noting one new Serious Incident (SI) in Diagnostic and Therapeutic Services (DTS) outside the current reporting period, INC 77867. PW asked how it was that one employee had been left to work on their own when it appeared that during the day, the process demanded dual control. What management discretion had been given to this person and if none, why did they not follow standard procedure? It was explained that further investigation was underway and recommendations would follow.

19-56

Serious Incident (SI)

There are currently two open SIs. The incident classified as an SI incident ODT-INC-3840, extended cold ischaemic time (CIT) beyond what was considered usable for a heart transplant. In addition, two further incidents have been categorised as SI. INC 77867 and INC 77481, samples for fetal D genotyping. These incidents occurred outside of the reporting period of this paper and are subject to an ongoing investigation as a single SI.

Action

The GAC discussed the open SIs and considered the INC 77867 - Transposition of non-invasive fetal typing samples in the International Blood Group Reference Laboratory, for an SI deep dive review at the November 2019 GAC meeting. LC confirmed the SI deep dive is scheduled for November 2019 with a paper coming to September GAC outlining the relevant SIs for selection of one for review. **Action:** LC will flag in the paper this was suggested as a possibility by KRi.

LC

19-57 During the period 1 April 2018 to 31 March 2019 there were eleven SI review meetings held. Three of these incidents were categorised as SIs and eight were managed as major Quality Incidents (QIs). Two of the confirmed SIs have been investigated and closed. The remaining SI remains open and is subject to an ongoing investigation. The two SIs which have been closed were both completed within the incident investigation standard timelines. The GAC discussed actions arising from SI's. These are recorded within NHSBT incident management system (QPulse) enabling the shared learning across divisional operating areas, within NHSBT. The question for the GAC and the ET was how would we know whether the actions – especially those of high priority had been completed on time? Where this did not happen, the escalation process was unclear. **Action:** EM to report to the ET the categorisation of the actions and subsequent reporting and tracking.. The committee would subsequently appreciate an update on how the process worked.

EM

19-58 Infected Blood Inquiry (IBI)

The report was taken as read, as a full presentation has been delivered to the Board in May 2019.

3 Quality Assurance (QA)

19-59 Management Quality Review (MQR) Annual Report

IB summarised the annual report noting, continued improvement, the Root Cause Analysis (RCA) process and timescales agreed with the Human Tissues Authority (HTA), have all worked well within the reporting period. New Medical Devices Regulations apply from 26 May 2020 and 26 May 2022 for medical devices and in vitro diagnostic medical devices. PW asked how the GAC keep sight of requested or upcoming Regulatory Licence changes. IB responded that regular reports are submitted to the Clinical Audit Risk and Effectiveness (CARE) process.

Data Integrity Guidelines – it was noted high level plans have been formulated and are being implemented to address the compliance gaps identified on review of the updated Medicines and Health Products Regulatory Agency (MHRA) guidelines. This will improve governance and integration and is to be included in the NHSBT terms of reference for the Master Data Management Council and the Information Governance Committee and will ensure closer alignment between the three teams. PW suggested that it would be very helpful to establish the extent of the gaps and the plans to close them. **Action:** Submit a report to the September/November 2019 GAC meeting, outlining data gaps, including those covering regulatory business and communications. AS to add to the forward look.

IB/LC

AS

Critical suppliers - there are a significant number of critical suppliers which have not been reviewed as required by our current documented process. An action plan is in place which prioritises the review of the outstanding suppliers and looks to improve the current process. At the time of the June 2019 meeting the assessments were not completed.

Governance management assurances over the scope of the issue; the GAC were satisfied that for the time being this was not an organisation wide problem.

Clean rooms - Training and awareness sessions have been held to improve knowledge about clean room environment design and equipment, ensuring that they are fit for purpose. QA will be leading on bringing the improvement activities into a Contamination Control Strategy which will provide greater assurance in terms of regulatory performance and ultimately patient safety. IB assured the GAC that NHSBT can use all of its clean rooms at present.

19-60 Overdue Update Report

KRi questioned the overdue document report as a small increase was reported for April. IB confirmed there was an increase due to a recent inspection in Colindale and some year-end optimism. The GAC NED's asked that pressure continues to be applied by the ET to reverse this adverse trend.

19-61 Non-Executive Director (NED) Site Visit Update

Good support from the NHSBT NEDs, was noted.

4 Risk

Pentana Blood - Manufacturing and Logistics (M&L)

- Presenting the live data on Pentana RR updated the 11 main M&L risks, noting the linked risks to the GAC.
- Performance Indicators (PI) are now in place on Pentana and work is in progress to view PIs with more transparency.
- KRi questioned M&L access to Pentana. RR assured the GAC that NHSBT now have a site licence, which is an unlimited number of users able to log into Pentana. M&L are currently expanding and identifying the right people to progress forward.
- Risk Management training was also questioned. Training is initially given to navigate the system, supported by the Risk Management Manual, although further in depth Risk Management training is required and was noted.
- Background to risk in the organisation was discussed. Pentana was acquired to move the risk culture away from cumbersome Excel spreadsheets. It's live data is being used at Senior Management Teams (SMTs) and at CARE meetings, noting that Pentana is a work in progress.

The Committee noted the progress made but that there was still some way to go to ensure the right risks were represented in the system and that plans were in place to track effective mitigation.

Verbal Risk Management Committee (RMC) Update

- New tier for the Corporate level Risk Register (CRR) to be implemented, which will improve visibility of risks against the organisation and remove the existing lists of risks
- Corporate risks to include risks scored outside of the agreed risk appetite, risks with significant gaps in controls and / or assurance and risks with external influences such as the Infected Blood Inquiry (IBI) and cyber security

- Implement new Board Assurance Framework (BAF) style reports. Prepare Therapeutic Apheresis Services (TAS) example for review at the June 2019 ET meeting.
- New risk structure to be based around four themes and include assurance. Themes to include - Provision of Core Services, Corporate Responsibilities, Risks against delivery of Business Plan and Change Management.

PW commented that going forward it would be useful for the Committee to examine some details; the plans to mitigate the organisations most significant risks.

5 Business Continuity (BC)

19-62A Business Continuity Update Report including the Annual Report

There have been a number of Vodafone ‘switch’ problems resulting in a partial loss of telephony and IT/connectivity functions. A meeting was held with the most senior Vodafone management to develop an action plan to rectify the ongoing telephony problems.

There have been a number of other incidents that have been experienced across the organisation which have included an IT failure. These were not being reported through the Business Continuity escalation process and so were not coming to the attention of the BC Team for debrief. The Head of Business Continuity has met with BH to start a more joined up way of working between the BC and IT functions.

The GAC considered the BC update report and thanked the team for their work. In response to a specific question, a report need not be submitted at every meeting. **Action:** AS to add to the forward look and amend the work plan to reflect report submission every 6 months.

AS

19-62B Management Report

Brexit has been re-prioritised and all objectives have been achieved.

19-62C BSI Final Report

For information.

19-63 Brexit Update

The European Union (EU) has offered an extension of the Article 50 notification process to 31 October 2019 and the project has been reviewed with reference to the recommendations from DHSC and NHS England (NHSE).

Actions have continued on stockpile maintenance and other preparations and the project will ensure that necessary action continues to ensure that preparations are in place and maintained. KRi questioned the expiry dates of products. The products have become part of the normal stock management process and therefore there should be no increase in write offs..

6 Transformation Programme

19-64 Transformation Programme Report

The overall Transformation Programme status remains Red with only two projects, the Filton extension and the Data Centre & Centre Infrastructure Renewal (DCCIR now reporting Red status.

- Telephony – The project is currently reporting Amber because Vodafone is currently unable to provide a revised baseline plan to support the number porting issue resolution. The project will not be able to complete by the current September end date
- Barnsley Project - schedule a further Office of Government Commerce (OGC) review ahead of the migration phase
- Session Solution - there will be another review of Session Solution in July 2019.

It was noted that the Finance Committee were also reviewing Projects for delivery against plan and for benefits realisation. PW will work with BB and the chair of the Finance Committee to reduce the possibility of duplication. The GAC should focus on Risk.

7
19-65A &
19-65B

Internal Audit
Internal Audit Progress Report 2019 / 2020
Internal Audit Summary Report

- Activities have been undertaken since the March 2019 GAC to close out the 2018/2019 internal audit plan and finalise the annual opinion
- Some Progress has been made against delivery of the agreed internal audit plan for 2019/20 (approved by the GAC in March 2019)
- Three reviews are due to take place in relation to Cyber Security and the Information Technology audits. The Cyber Security and Identity access management reviews are shortly to commence but the terms of reference have not been agreed by PwC and BH. The cloud security audit is scheduled to commence during August 2019
- Talent Management - one of the key challenges is ensuring that there are appropriate succession planning and learning & development opportunities. Succession planning is in place and is currently being refreshed
- Capital / infrastructure projects – KF summarised the findings, noting the final Opinion will be Moderate assurance
- Board Effectiveness – This audit was deferred from 2018/19. PwC are working with the NHSBT Chair, which will be delivered at the end of 2019.

Building upon the discussion around Cyber and IT Audits, the Committee made clear their wish to ensure that all Internal Audits had terms of Reference pre-agreed by the responsible Executive Director and that the timing of each audit should ensure that it adds value. For example, this means the timing should be such that PwC can test whether plans to rectify known issues are capable of solving the problem or whether, post change, the new control environment is delivering in the way envisaged. Below Substantial Assurance, each Internal Audit should be debriefed to the relevant ET member and the Management response must be produced in a prompt manner.

19-66

Outstanding and Overdue Internal Audit Actions – for review

LH advised:

- One High priority action point due at 31 March 2019, relating to information held on the Information Asset Registers from the November General Data Protection Regulations (GDPR) audit for which an extension is now required to 30 September 2019.

- The May 2018 GDPR audit findings have not been included on the audit tracker tool and therefore have not been formally reviewed by PwC as completed but would be confirmed as completed, or not, when next reported.

19-67 Price Waterhouse Cooper (PWC) – Risk Management – Blood Donation (BD)

KF gave an overview of the audit and the Opinion of Limited assurance. MS expressed his disappointment in the findings of the audit, particularly the PwC audit process. PW noted the process was not working and referenced his comments above about ET/PwC engagement on the Terms of Reference (ToR) and then subsequently when feeding back the outcomes, which he hoped represented an opportunity to improve processes in the future.

Administration processes around the use of the Pentana Risk software was questioned. It was evident that there were insufficient Licences within BD necessitating use of spreadsheets. Following the purchase of a site licence, the team are moving forward with identifying users of the software and providing them with training on the system.

JM concluded that actions and learnings from the audit are being worked through and the focus is to create streamlined culture for risk management in BD. **Action:** Map out key points for strategic risk within the blood supply chain and bring a 2 page report to the September 2019 GAC meeting. The numerous operational risks could then be attached to a strategic risk and prioritised risk reduction activities put in place. AS to add to the forward look.

MS
AS

19-68 Price Waterhouse Cooper (PWC) – Quality Systems

The findings of the audit were discussed, noting the Opinion of Limited assurance. The audit process was discussed, noting that improvements to the process, including recommendations, agreed responses and feedback following the audit could be improved. Looking forward to future year ends, PW encouraged effort to complete the Internal Audit reports no later than April and for Management to turn around their comments and actions swiftly.

8 **IT Governance**

19-69 Information Technology and Cyber Security Update

Following the March 2019 GAC meeting, the GAC agreed an approach to address the Cyber risks, agreeing the first two key steps. The first step, was to secure an external contract to ensure that the GBEST threat intelligence information is constantly refreshed. Progress to engage key suppliers has taken place, to assess the role they could play in tightening NHSBT cyber security. It is expected that a suitable supplier will be appointed shortly.

The second step to create a new post of information security manager, to add capacity to the information security team, is underway but has not progressed as quickly as hoped. Obtaining a sample Job Description (JD) from another organisation for comparison with our organisation was noted and a full procurement workshop is planned in June 2019 to agree the way forward. It was evident that responding to the resourcing needs of the IT function was taking longer than it should and more appropriate mechanisms needed to be in place.

PW advised that once the resources were in place to develop an effective Cyber Plan and the plan had been agreed by ET and GAC, then a full discussion is not required at

every GAC meeting. Rather the GAC would take a report back on progress against key milestones when they were planned to occur. For the time being however, regular reporting remained necessary.

9 Integrated Governance

19-70 Board Performance Report – April 2019

The report was taken as read, having been discussed at the main Board

Note: The Fraud report will be completed to meet the basic standard and will be published before the 16 September 2019 GAC meeting.

19-71 Health and Safety Annual Report

PT presented the highlights from his report:

- The first year of the health safety and wellbeing 5-year strategy has been completed with 39 measures green, 6 amber and 1 red. Accident performance has seen a small increase in level 1 to 3 incidents from the lowest level recorded the previous year
- The majority of lost time accidents occurred in London and South-East. In Manufacturing and Logistics (M&L) 4 of the 5 level 1s were recorded in Colindale. An audit in that area meant that no new level 1s were recorded in Colindale after September 2018 and controls are now in place
- The implementation of mental health and wellbeing champions has made good progress and there are 130 champions spread nationally across centres and teams
- Our voice employee feedback showed an increase of 7% in wellbeing scores. The implementation of mental health and wellbeing champions has been short listed for a Human Resources (HR) Excellence Award.
- Good progress has been maintained on the immunisation record regeneration project. Where NHSBT did not have information on staff hep B immunity status, the remaining individuals have had a blood test and are accounted for. Those who have not engaged in the process will see their Occupational Health (OH) records amended to reflect this.

GAC commented positively on this work and in particular the quality of the report where themes and trends were made plain.

10 Committee Business

Verbal GAC Annual Report

Action: RB, LC and LH to review the report offline and review with PW via email before the July 2019 Board meeting. There remained work to do on the initial draft in order to reflect the tone and content within the Governance section of the annual reports and accounts.

**RB/LC/
LH**

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

The GAC agreed to remove this standing agenda / section item, as the item was rarely used. **Action:** AS to remove Chair's action from future agendas.

AS

12	Papers for information
19-72A	Losses and Special Payments
19-72B	Losses and Special Payments to March 2019
19-72C	Losses and Special Payments Annex B
19-72D	Losses and Special Payments GAC Report – No comments were made for Papers 19-72ABCD
19-73	Waivers – No comment
19-74	Clinical Claims Annual Report – No comment
19-75	Information Governance Annual Report – Complete a gap analysis for the September 2019 GAC, see action item above.
19-76	Security Management Annual Report – It was noted that this report demonstrated good physical protection of our premises but that in future thought should be given to how this could be brought together with the Annual report on H&S and Wellbeing. A gap remained in that we had not reported upon how we ensure our premises remain safe for staff and patients to use. Action RB/KRo
19-77	CARE Committee Annual Report – No comment
19-78	Director Infection Prevention Control (DIPC) – No comment
19-79	Clinical Audit Annual Report – No comment
19-80	Therapeutic Product Safety Group (TPSG) Annual Report – The remit of the paper was explained to the GAC
19-81	Intellectual Property Annual Report – The reporting line of the paper can be picked up through the Research and Development Committee as it was not clear why this report should come to GAC.

RB/KRo

13 Any Other Business (AOB)

There was no AOB to note.

Dates of Meetings in 2019 / 2020

Date/Time	Venue	GAC Papers for submission
Monday 16 September 2019 13.00 – 16.30 hrs	London WEDC Board Room	Friday 6 September 2019
Monday 18 November 2019 13.00 hrs – 16.30 hrs	London WEDC Board Room	Friday 8 November 2019

Action

Monday 20 January 2020 13.00 hrs – 16.30 hrs	WEDC Board Room	Monday 13 January 2020
Thursday 19 March 2020 13.00 hrs – 16.30 hrs	Association of Anaesthetists Portex Room	Thursday 12 March 2020
Tuesday 16 June 2020 13.00 hrs – 16.30 hrs	WEDC Board Room	Tuesday 9 June 2020
Monday 14 September 2020 13.00 – 16.30 hrs	WEDC Board Room	Monday 7 September 2020
Monday 16 November 2020 13.00 hrs – 16.30 hrs	WEDC Board Room	Monday 9 November 2020