1 Status – Official

2 Executive Summary
This paper summarises the work of the NHSBT Governance and Audit Committee (GAC) for 2018/19. The GAC has complied with its existing Terms of Reference (ToR) in 2018/19 during which it has:
- reviewed and approved the financial statements for 2018/19;
- reviewed the Governance Statement for 2018/19 and confirmed that it is consistent with the GAC assessment of control;
- reviewed reports prepared by Internal and External Auditors along with the ensuing management actions, where appropriate.

This year was marked by several unexpected challenges as follows:

i) Blood stock levels falling below target levels on 13 occasions,

ii) The CSM programme being halted which resulted in a constructive loss of £26.2m, subsequently approved by the Department of Health and Social Care (DHSC), notified to HM Treasury and referred to in a report by the C&AG in his opinion on the Annual Report and Accounts. An advisory Internal Audit report following CSM which contained 31 recommendations.

iii) A limited assurance Internal Audit Opinion for the year due to; CSM, two limited assurance reviews in the Blood Donation area, one Limited Assurance Review in Quality Assurance and a lack of progress in addressing the GDPR audit recommendations.

Overall the Head of Internal Audit reported that there were significant weaknesses in the framework of governance, risk management and control such that it could be or could become inadequate and ineffective. Whilst our systems of internal control do not indicate any reduction in the safety of our products and do confirm that our key financial controls remain robust, improvement is clearly required. We fully support the Chief Executive’s fundamental review of governance and risk management to address the weaknesses identified in 2018/19.

As the new GAC Chair I will review the workings of the Committee to ensure changes are put into effect to reflect the lessons learned. The Committee looks forward to applying its wider experience of other organisations to ensure governance, risk management and control change to reflect best practice.

3 Action Requested
The GAC is asked to;
- comment on and offer improvements to the content of this report.

4 Purpose of the report
The GAC has prepared this report for the NHSBT Board. It sets out how the GAC has delivered against its ToR during 2018/19 and seeks to provide evidence relevant to its responsibilities for the Governance Statement.

5. **Background**

- An independent GAC is the central means by which a Board ensures effective control arrangements are in place. Including an independent check upon the executive arm of the Board.

- The GAC independently reviews, monitors and reports to the Board on the attainment of effective control systems and financial reporting processes. In particular, the Committee’s work focuses on the framework of risk, control, and related assurances that underpin the delivery of the organisation’s objectives.

- The GAC receives and considers reports from the Executive, Internal and External Auditors including the Annual Report and Accounts.

- The CSM project and the limited assurance audit opinion highlighted some gaps in governance, risk management and control for which the GAC is responsible on behalf of the Board. As the incoming GAC Chair I will consider what lessons GAC needs to learn to ensure the Board has effective control in place.

6. **Membership**

The GAC membership in respect of the financial year 2018/19 comprises of four non-executive directors:

- Roy Griffins Non-Executive Director and Chair of the GAC (June, September and November meetings).
- Piers White Non-Executive Director and Chair of the GAC (March 2019 meeting)
- Keith Rigg Non-Executive Director Interim Chair for the January 2019 meeting.
- Charles St John Non-Executive Director – June, September and November meetings.
- Lord Jonny Oates Non-Executive Director

Rob Bradburn (Finance Director) and Gail Miflin (Medical and Research Director) support the GAC as lead Executive Directors.

7. **Compliance with Terms of reference**

All meetings during 2018/19 have been quorate. Two have had 100% attendance, and three had 75% attendance of members (3).

The Committee has ensured that its ToR are in line with those recommended in the NHS Audit Committee Handbook. Its ToR have been approved by the Board and are reviewed a minimum of every two years by the GAC. The ToR were last reviewed in November 2018.

The GAC has regular attendees, including:

- Ian Bateman Director of Quality
- Rob Bradburn Finance Director
- Louise Cheung Assistant Director Governance and Clinical Effectiveness
- Anthony Clarkson Director Organ Donation and Transplantation (or deputy)
- Linda Haigh  Assistant Finance Director
- Brian Henry  Interim Technology Director
- Greg Methven  Director of Manufacturing & Logistics (or deputy)
- Dr Gail Miflin  Medical and Research Director
- Richard Rackham  Assistant Director Governance & Resilience
- Katherine Robinson  People Director
- Mark Rodgers  Assistant Director, Business Transformation Services
- Ann Smith  Secretariat to the GAC and Senior PA (Minutes)
- Mike Stredder  Director of Blood Donation (or deputy)
- Huw Williams  Director of Diagnostic and Therapeutic Services (or deputy)

The GAC is regularly attended by representatives from both Internal and External Audit. Members meet separately with Internal and External Auditors during the year.

8. Meetings

Five meetings were held during the financial year: -

18 June 2018  
23 November 2018  
15 January 2019  
17 September 2018  
27 March 2019

9. Audit Provision

Internal Audit was provided by Price Waterhouse Coopers (PWC) and External Audit by the National Audit Office in partnership with Mazars.

Internal and External Auditors submitted annual audit plans, which were agreed and monitored by the GAC. In addition, due to early delivery challenges on the CSM programme, GAC also commissioned Internal Audit to provide real time advisory reports on CSM until it was halted in October 2018.

The GAC also received reports on the overdue high and medium priority recommendations from previous Internal audits.

10. Governance and Audit Committee Opinion

The Board and the GAC recognise that assurance given can never be absolute. The highest level of assurance that could be provided to the Board is a reasonable assurance that there are no major weaknesses in the Authority’s risk management, control, and governance processes.

Following the CSM programme, the Blood Stock minimum levels breaches and the resulting Limited Assurance opinion from Internal Audit in the year, the GAC can give reasonable assurance that product safety and financial controls are operating effectively. However, weaknesses have been identified in governance, programme management, risk management and controls in Blood Donation, Quality reporting, and GDPR. A fundamental review of governance, including how the GAC operates, will be undertaken to ensure reasonable assurance can be provided in all areas in 2019/20 and beyond.

11. Duties and Findings
The GAC Terms of Reference comprise five main areas of responsibility:

- Governance, Risk Management and Internal Control
- Internal Audit
- External Audit
- Other Assurance Functions
- Financial Reporting

The agenda is arranged under the following headings:

- Clinical Governance
- Quality Assurance
- Business Continuity
- Transformation Programme/ Transformation Project Board (TPB)
- Audit (Internal and External)
- Risk Management
- Information Technology (IT) Governance
- Integrated Governance – other governance matters/ assurance streams
- Committee Business
- Chair’s Actions (for discussion only as required)

11.1 Governance, Risk Management and Internal Control

The Committee received and can give reasonable assurance that products and services are safe based on robust Clinical Governance and Quality Assurance in the year. There were some weaknesses identified in Quality Assurance reporting which suggested all trends and wider learning may not be identified but we still consider the assurance levels from all the external reviews and internal inspection findings good.

The Committee received and can give assurance that the financial controls are operating effectively based on the outcomes of Internal and External Audits undertaken in 2018/19.

The Committee has received assurance that the business continuity planning and preparation is adequate.

The Committee is aware that further work in needed to enhance controls in the following areas:

- Programme and wider organisational Governance
- Blood Donation management
- GDPR
- Cyber Security and broader ICT risks
- Risk Management
- Quality trend reporting

The Committee will oversee the planning and implementation of plans to enhance these controls in the coming year.
11.2 Internal Audit

The GAC receives all unsatisfactory or limited opinion audit reports and receives any advisory reports it has commissioned. The reports are provided to GAC at the meeting following agreement by management. The GAC also receives a report on all the outstanding Medium and High internal audit recommendations at each meeting and GAC approval is required to extend any timescales for delivery. The Committee has overseen and supported the work of Internal Audit through:

- Agreeing an audit plan
- Reviewing the reports with a less than moderate assurance
- Reviewing all medium and high audit points not completed on time
- Reviewing and agreeing the Head of Internal Audit Opinion

As above, the Head of Internal Audit concluded that there were significant weaknesses in the framework of governance, risk management and control such that it could be or could become inadequate and ineffective. They identified weaknesses that lead to the CSM project failure; in governance, risk management and controls in Blood Donation; Quality reporting and GDPR. GAC will oversee all recommendations being addressed in these areas in the coming year.

11.3 External Audit

The GAC has overseen the delivery of the external audit plan for 2018/19. The risks identified included CSM which has materialised with a constructive loss of £26.2m being reported and the C&AG referring to this with a report in his opinion on the Annual Report and Accounts in 2018/19. The National Audit Office (NAO) and Mazars were content with the level of self-disclosure and the approval for the constructive loss which avoided any qualification of the opinion and hopefully there will be no need for further review of the matter.

11.4 Financial Reporting

The GAC has reviewed the Annual Report and Accounts for 2018/19 and is assured that the accounts comply with legal requirements, which was subsequently confirmed at the Meeting with the auditors on the 6th June and the Meeting of the GAC on the 11 June 2019.

11.5 Other Assurance Functions

Business Continuity – The GAC continued to review the Business Continuity function at each meeting. The GAC sought assurance on NHSBT’s response and management of mass-casualty incidents and Information Security (including Ransomware cyber-attacks).

The areas of responsibility of the TPB were presented to the GAC as standing agenda items at each meeting. In addition, the GAC had real-time advisory assurance from PWC regarding the CSM programme until that halted in October 2018. This ensured the GAC was aware of progress (or lack there-of) and the risk factors within the Transformation Programme. The Board were in-turn informed of the CSM progress. Despite being informed the risks materialised and the governance review will determine whether lessons need to be learned in how GAC oversaw this during 2019/20.
Information Technology – The GAC and Board have received reports on the IT environment, the cyber readiness, understands the need to update core systems and is aware of the failure to deliver a major programme to update our core blood systems pulse. GAC will continue to focus on the ICT risks and ensure they are sufficiently governed controlled and managed as a priority in 2019/20.

12. Integrated Governance

The GAC have reviewed, updated and approved the Integrated Governance Framework during 2018/19.

The GAC Committee workplans were reviewed and amended during 2018/19 to reflect emerging risks and consequently the GAC has examined governance arrangements for:

- Board Assurance Framework
- Board Committee self assessments and annual reports
- Board Performance Report
- Clinical Audit
- Clinical Governance issues
- Committee workplan
- Commercial Insurance
- Core System Modernisation Real-time advisory report from Internal Audit
- Information Governance
- DH Group Assurance
- Directorate risk overviews by Specialist Services, Tissue Services, Organ Donation & Transplantation
- Draft and final accounts
- Equality and Diversity Annual Report
- External Audit
- Financial Governance - losses and special payments, waivers
- Focus of the GAC in respect of Blood Supply/ODT
- Fraud
- Information Governance Reports including regular General Data Protection Regulations (GDPR) updates
- Integrated Governance Framework
- Health and Safety Reports
- Infected Blood Inquiry (IBI)
- Infection Control
- Information Technology (IT) risks
- Intellectual Property Annual Report
- Internal Audit
- IT Governance
- Losses and Special Payments
- Mandatory Training Annual Report
- Organ Donation Register (ODR)
- Quality Management
- Risk Management
- Security Management Report
- Site Resilience
- Serious Incidents (SIs)
- Sustainability Annual Report
The Committee has received risk presentations related to:
- Business Continuity (BC)
- Therapeutic Apheresis Services (TAS)
- Organ Donation and Transplantation (ODT)
- Blood Donation (BD)

The GAC reviewed its second Serious Incident (SI) deep dive on a Diagnostic and Therapeutic Services (DTS) Composite SI, January 2019. The GAC agreed to continue undertake one SI deep dive per year.

Following the unexpected events in 2018/19 the ToR will be reviewed following completion of the governance and risk review to ensure governance, risk management and control at NHSBT is in place and reasonable assurance can be given in all areas in 2019/20.

13. Conclusion

The GAC has:
- reviewed and approved the financial statements for 2018/19;
- reviewed the Governance Statement for 2018/19 and confirmed that it is consistent with the GAC assessment of control;
- reviewed the Integrated Governance Framework;
- reviewed reports prepared by Internal and External Auditors along with the ensuing management actions, where appropriate; and has
- reviewed NHSBT plans to achieve financial stability

However, despite this, major risks have materialised and significant weaknesses in the framework of governance, risk management and control were identified by Internal Audit. As the new GAC Chair I will, with my colleagues, review the workings of the Committee to ensure changes are put into effect to reflect the lessons learned. The Committee looks forward to applying its wider experience of other organisations to ensure governance, risk management and control change to reflect best practice.

Piers White
Chair of Governance and Audit Committee, NHSBT

July 2019