

Blood and Transplant

Minutes of the Audit, Risk and Governance Meeting

Microsoft Teams Meeting Monday 18th November 2021 13:15 – 16:15

Present	Piers White (PW) Prof. Deirdre Kelly (DK) Phil Huggon (PH)	Gail Miflin (GMi) Ian Bateman (IB) Rob Bradburn (RB) Wendy Clark (WC)
In attendance	Richard Rackham (RR) Katrina Smith (KS) Rachel Meeke (RM – Item 3.2 only) Dave Roberts (DR- Item 4.1 only) Lucy Nutley (LN – Mazars) Graham Smith (GS – GIAA)	Linda Haigh (LH) Helen Gillan (HG) Dan Jeffery (DJ – Item 5.4 only) Michael Gallagher (MG – From item 3) David Hakin (DH – NAO) Peter Morland (PM – NAO) Alice Williams (Minutes) (AW)

		Action
1	Welcome and apologies	
	No apologies were received for the meeting.	
2	Minutes of the last meeting and actions arising	
	<p>The minutes were agreed as an accurate record of the previous meeting.</p> <p>The following updates were provided on the outstanding actions:</p> <ul style="list-style-type: none"> ARGC30 – It was agreed that the current operational/management committee map would be shared with Committee members offline, ahead of the next ARGC meeting ARGC44 – PW confirmed that he would circulate a note to Committee members offline on the impact of the Board Effectiveness work for ARGC, and the specific recommendations for ARGC. ARGC43&48 – actions to be combined. IB updated Committee members on the progress of the CQC Well Led preparations including the external support from GGI and the internal Programme led by KS and H Gillan which builds on the prior Deloitte work. ET are due to consider an update in December, and further detail will be shared with ARGC in January 2022. IB also highlighted that HG continues to build relationships with the NHSBT's CQC account management team which is yielding useful intelligence about CQC's changing approach to inspections. ARGC47 – R Rackham provided an update on the approach to the Loss of Key Facility risk, noting that 'Disruption' will likely remain a strategic risk, but further work is underway between the Risk Team and Operational leads at Centres to understand the Business Continuity plans and how these will feed into the overall 'disruption' Strategic risk. 	KS

	<ul style="list-style-type: none"> ARGC48 – H Gillian advised there are regular discussions with the CQC to get intelligence on the changing approach to inspections, formal engagement meeting scheduled for 16th December, paper to be shared with ET, ARGC and Board in January 2022 	
2	Strategic Risk Deep Dive	
	NHSBT-05 Functionality of Critical ICT Systems and Technology	
	<p>WC introduced and advised the risk was last reviewed by ARGC September 2020 where the score was 4x4 following quarterly reviews and investment in critical systems this has now reduced to 4x3.</p> <p>WC advised the sustainability of the supply chain has been reassessed and likelihood reduced, which may seem odd considering the national supply chain issues being experienced by all industries, however the impact of this on the risk of functionality of critical systems is reduced. The ability to recruit is also considered but not increased at this time.</p> <p>PW queried supplier risks and mitigations, WC advised largest risk is with Savant but not their ability to maintain or deliver, more their capacity and capability to implement change at pace, a longer-term approach to the working relationship is being considered.</p> <p>Committee acknowledged the wider pressures on the organisation and the importance of ARGCs role to ensure the blood tech modernisation remains a corporate priority and other critical investment to national infrastructure such as Hematos remain on the Board's radar as a core element of improving patient safety. The NEDs agreed this would be raised to the Board in the Committee's report back.</p> <p>WC confirmed business continuity testing is planned for the summer 2022.</p>	
3	Regulatory & Legislative Compliance Risk	
	<p>IB introduced the new risk which has been reviewed at Quality SMT and the Risk Management Committee (RMC)</p> <p>RM highlighted key areas including the quality management system, PW queried whether NHSBT were able to go to open tender for a new Quality Management system. IB confirmed this and that the team are engaging with other ALBs to review their systems and considering tying in health and safety and business continuity.</p> <p>Committee sort clarity on IPMA, RM confirmed this is the International Plasma Manufacture Association, a membership organisation not a regulator.</p> <p>PH queried which was the most significant child risk as scoring was fairly similar across all 3, RM advised it was most likely QMS given our reliance on the system.</p> <p>On the issue of regulatory divergence, PW asked whether commercially, this could mean products and services in other parts of EU could no longer be sold and what this would mean financially. IB agreed to investigate and provide an update at the next meeting.</p>	IB
4	SI Deep Dive	
	D Roberts was welcomed to the Committee to present the Deep Dive analysis of the Serious Incident QI21561, <i>Transcription error in a stem cell search</i> . Committee members were asked to consider the presentation and to comment	

	<p>on the level of assurance provided that the correct operational processes were followed, that action was taken to address the identified root causes and that learning occurred as a result of the SI investigation.</p> <p>Committee members thanked DR for the helpful and comprehensive review of the incident and for clearly explaining a very complex process. DR confirmed that previous searches were checked and the errors referenced in the deep dive had not occurred previously at NHSBT, and there had been no report of these occurring at Anthony Nolan.</p> <p>There was further discussion on the potential for electronic transfers to remove the likelihood of future incidents of internal transcription errors and also, the potential for this project to be rolled out across the rest of the organisation to replace potentially other manual but critical processes. The first of which is underway, and the business case for the latter is being developed. Whilst internally these issues are being addressed and overcome, it was noted that there are some challenges with the external transfer of data as current NHS systems are incompatible. NHS England are aware of this issue and are developing a new system specification to resolve it, and it is also a live issue under consideration within the DDTS team.</p> <p>PW reaffirmed the Committee's thanks for the analysis undertaken and confirmed that the exercise had checked operational procedures had been followed during the incident, and that the appropriate learning had been shared across the organisation.</p>	
5	Clinical Governance Report	
	<p>GMi summarised the clinical governance issues discussed at the last NHSBT CARE meeting and highlighted whilst there were no other new open SIs recorded within NHSBT during the reporting period, a Serious Incident was raised outside of the period and would be circulated to the Board in the next 48 hours. Two previously reported SIs remain under investigation and remain open whilst further analysis is undertaken.</p> <p>Members were briefed that reviews of both the Cumberlege and Paterson reports are underway to understand whether there are further non-legal, non-regulatory recommendations which could be applied within NHSBT to mitigate risks towards patient safety, and that these would be shared with ARGC following ET consideration.</p> <p>GMi also confirmed that a new Patient Safety Incident Response Framework is currently being piloted by NHS England/Improvement, which will replace the Serious Incident Framework in England to be finalised and published in April 2022. An informal working group has started preparing for the implementation of this in NHSBT. Committee members encouraged GMi and team to retrospectively compare previous incidents under the new framework to help aid understanding of the application of the new process.</p>	
6	Infected Blood Inquiry Update	
	<p>GMi provided a verbal update on the progress of the Infected Blood Inquiry and noted that the written statement from NHSBT had been published in the public domain which the inquiry team have complemented for being comprehensive. Calls with key stakeholders had also been taken place in advance of the publication of the statement. Whilst hearings have been cancelled due to sickness, GMi noted that otherwise there is nothing further to escalate to the Committee.</p>	

	Committee members thanked the team for their continued professional and sensitive handling of the inquiry.	
7	Update from Risk Committee	
	<p>IB briefed Committee members on the highlights from the recent Risk Management Committee meeting including constructive feedback from GGI on their observation of the meeting, and the decision to review the Committee Terms of Reference.</p> <p>IB also highlighted that Deb McKenzie would be presenting an update on the current risks and concerns around recruitment at the December RMC meeting.</p>	
8	BAF & Assurance Mapping	
	<p>ARGC members were invited to review and comment on the first draft of the revised Board Assurance Framework (BAF) and on any immediate changes required in format/content and any reflections on the strategic risks identified ahead of its presentation to the NHSBT Board in January. It was reiterated that the document will remain as a live document throughout its life cycle and will be subject to further iterations.</p> <p>Committee members welcomed the updated BAF and recommended the inclusion of a heat map and/or summary page, and to include simpler strategic risk definitions within the document. D Kelly also offered to speak to RR offline to provide further contribution.</p> <p>Members discussed whether there is a strategic risk missing from the BAF to more specifically describe the risk that there is no/limited innovation to improve patient outcomes and requested that this be taken away for consideration. Building on this point, members linked 'innovation' to risk appetite and noted that the risk appetite for each strategic risk should be defined in future iterations as risk tolerance will be greater in some areas, and less in others. It was confirmed that the consideration of risk appetite is included in the Board Effectiveness review action plan.</p> <p>Both L Nutley and G Smith offered to share best practice documents used with other clients and to send these to RR to benefit the NHSBT BAF.</p> <p>PW encouraged RR and team to arrange 121 conversations to discuss the BAF with Non-Executive Board members.</p> <p>Committee members also reviewed the revised assurance mapping undertaken by the Risk Team and agreed to revert to a three lines of assurance approach to the mapping. Members also encouraged RR to ensure that all aspects of the organisation are covered by the mapping, and that this exercise aligns with the BAF.</p>	RR/LN/GS
9	3-5 Year Audit Schedule	
	<p>The 3-5 year plan of scheduled audit activity was introduced to the Committee, with the aim to give a high-level view of the planned audit activity across NHSBT from 2021-2026; and the assurance that this activity provides.</p> <p>Committee members were supportive of the approach to review the plan at each March ARGC to ensure it aligns with the new financial year and business plans. Members advocated that the schedule should reflect a balance of audit activity across the organisation at it's next presentation to the Committee, noting that whilst Clinical Audits are well documented, there are fewer references to</p>	

	<p>HR & Donor Experience related audit activity. This was noted and KS highlighted that this was a finding during the work, and that there may be more work to do on understanding the levels and breadth of audit activity in these areas which may not be formally recognised.</p> <p>It was also suggested that the frequency and repetition of audits be aligned to the risk profile of certain 'business areas'.</p>	
10	Cyber Metrics Update	
	<p>D Jeffery briefed Committee members on the Q3 Board level Cyber Security KPIs, noting that the overarching risk score has dropped in part due to a lull in the cyber-crime environment, and due to NHSBT's enhanced security as a result of efforts from the team to continue to correct legacy debt & patching, achieve better control of ports, and strengthened security of email standards.</p> <p>Members acknowledged the progress made to date and the need for the team to keep up the pace on improvements to continue to reduce vulnerabilities. There was also further discussion on NHSBT's target cyber risk score position compared to other Arms-Length Bodies and NHS organisations, and reflection on the need for the organisation to discuss and define its risk appetite(s) within this broader topic both internally and with the DHSC.</p> <p>PW mentioned the importance of rehearsing a Cyber Ransom scenario and encouraged the team to think about this as a topic for the Board. It was noted that to be effective, any simulation exercise should involve our Departmental sponsor.</p>	
11	Regulatory Radar	
	<p>Committee members were updated on the current regulations which impact NHSBT activities and efforts by the organisation to continue to meet its regulatory responsibilities by making necessary changes as required.</p> <p>HG highlighted that whilst a response from JACIE in relation to (ICCBBA) ISBT 128 is still outstanding, Oxford SCI was inspected by JACIE on the 5th and 6th October 2021 but did not receive the same finding.</p> <p>HG also confirmed that the aforementioned revised Patient Safety Incident Response Framework has been included within the Regulatory Radar.</p> <p>Committee members thanked the team for the report and continued efforts.</p>	
12	Management Quality Report (MQR) & Overdues Report – taken together	
	<p>HG provided highlights from both the quarterly MQR and Overdues report, confirming that NHSBT has continued to perform well in external accreditation inspections.</p> <p>HG updated members on monthly performance relating to overdue Quality Management System activities and on recent ET endorsement of the proposal to improve the management and monitoring of overdue items across NHSBT. A zero-tolerance approach has been adopted for overdue majors alongside new KPIs and the identification of directorate quality champions.</p> <p>IB also highlighted that work is underway to ensure that robust data and reporting is provided to Directorate representatives to support the review of overdue, and to consider the removal of documents that do not need formal control from the Quality Management systems.</p>	

	<p>Members acknowledged that prior ARGC advice had been considered and adopted in the most current report, also including best practice from the Association of Blood Operators Network, and that by January, members can expect considerable progress on the reduction of overdue events.</p> <p>PW remarked that the overdue situation drew parallels with the number of outstanding recommendations from the internal audit progress report, in that a number are repeatedly missing their targets. It was highlighted that the Executive should consider both the application of resource in these situations, but to also assess whether management accountability is also being applied appropriately – and whether the appraisal system might be best placed to challenge some of the potential detrimental behaviours.</p>	
13	Update on External Audit 2022/23	
	<p>P Morland introduced the Committee to the new team from the National Audit Office. L Nutley and R Woodley were also confirmed as the lead contacts from Mazars for the 2021/22 audit.</p> <p>Both NAO and Mazars expressed a keen interest to visit NHSBT sites and meet with teams in person ahead of the start of the audit, to familiarise the new staff with the organisation. PW endorsed this suggestion and encouraged the Executive to support this initiative.</p> <p>LN confirmed that a more detailed timetable for the 2021/22 audit would be circulated to Committee members in January.</p> <p>Committee members thanked DH for his contribution and guidance during his NAO audit tenure with NHSBT.</p>	
14	Internal Audit Progress Report	
	<p>G Smith updated members on the progress of the 2021/22 internal audit programme and highlighted that there have been no findings to date to alter the proposed moderate audit opinion for the period. Two thirds of historic recommendations have been closed, and GS highlighted that other health organisations have had to request extensions too as a consequence of focusing on bigger priorities during the pandemic.</p> <p>Committee members were content that there had been sufficient engagement across the Executive and supported the proposed amendments to the 2021-22 Internal Audit Programme detailed within the paper.</p> <p>GS also confirmed that sufficient resourcing had been put in place at GIAA to support the NHSBT Internal Audit programme and that this was sufficient to deliver the current programme on time. Members also recommended that the 2022/23 audit programme is more evenly distributed throughout the year to avoid the resourcing challenges experienced in the current year.</p> <p>PW requested a verbal update on requirement for compliance against the functional standards at the next meeting.</p>	RB/GS
15	DHSC Delegations Update	
	<p>LH provided a verbal update on the progress of the implementation of revised delegations from DHSC and highlighted that they would not be finalised until mid to late 2022.</p> <p>LH confirmed that as NHSBT is a Public Corporation, it is outside of the Cabinet Office approvals mechanism, but is continuing to work with DHSC and the</p>	

	<p>Cabinet Office to agree the appropriate delegation levels. In turn this will determine NHSBT's internal financial delegations covered under Section 10 of the Scheme of Delegations.</p> <p>Under the new delegations, business cases will be required for professional service spending over £200k – whilst one has been produced so far as part of the Plasma Programme, the finance team have forecasted that there would have been three other business cases required YTD under the proposed revised spending limits. An internal review is also underway to consider whether the current level of Board oversight of revenue expenditure projects is appropriate.</p> <p>LH confirmed that ARGC would be presented with the final draft of the delegations for comment and consideration.</p> <p>PW requested that any delegations agreed which are contrary to the Cabinet Office approvals limit, under NHSBT's status as a Public Corporation, need to be clearly documented and agreed with the Sponsor.</p>	
16	Review of Insurance Arrangements/Cover	
	<p>RB highlighted that there has been no significant change to NHSBT's risk profile, and that some clinical risk is not covered by NHS Resolution, but there is no identified need as of yet to procure top-up Commercial insurance.</p> <p>GMi and RB confirmed that the relationship with NHS Resolution continues to work well.</p>	
17	For information	
	<p><i>Fixed Asset Register</i> LH agreed to propose revisions to the NHSBT Standing Financial Instructions to reflect the revised process detailed in the circulated paper.</p> <p><i>IFRS16 Update</i> The report was noted.</p> <p><i>Losses & Special Payments</i> LH confirmed that no fraudulent activity has been identified during the prior reporting period and that the Annual Fraud Report would be shared with Committee members in March 2022.</p> <p><i>Waivers</i> RB informed the Committee that there were no further waivers to declare, and that the number had been reducing in recent periods. RB highlighted to the Committee that there was a present risk arising from the extension of contracts (agreed with suppliers and the marketplace) during the Covid pandemic. It was reiterated that this had placed a resource strain on the commercial team internally, but that also there had been signs that these effects were also impacting suppliers as they face a similar number of responses to tenders and extensions. Committee members noted this risk and acknowledged that whilst this may have positive benefits in terms of greater supplier flexibility, this may also pose future challenges.</p>	LH