NHS
Blood and Transplant

Minutes of the Audit, Risk and Governance Meeting

Microsoft Teams Meeting
Tuesday 14th September 2021 13:00 – 16:30

Present	Piers White	Ian Bateman
	Prof. Deirdre Kelly	Rob Bradburn
	Phil Huggon	Gail Miflin
In attendance	Katrina Smith	Joe Roberts (Good Governance Institute)
	Linda Haigh	David Hakin (NAO)
	Helen Gillan	Lucy Nutley (Mazars)
	Betty Njuguna	Ceri Victory-Rowe (Campbell Tickell)
	Graham Smith (GIAA)	Radojka Miljevic (Campbell Tickell)
	David Rose (Item 4 only)	Alice Williams (Minutes)
	Kevin Anderson (Item 4 only)	

		Action
1	Welcome and Apologies	
	P White welcomed J Roberts, R Miljevic and C Victory-Rowe and thanked the Executive for a very good set of papers.	
2	Declarations of Interest	
	No further declarations of interest were made.	
3	Minutes of the meeting & matters arising	
	The minutes of the last meeting were agreed as an accurate record subject to the clarification of Gerry Gogarty's specific attendance. PW queried whether there had been any further update on the financial risk highlighted at the previous meeting's Plasma for Medicines Deep Dive item and it was confirmed that the subject is currently due to be included within the CEO Report for the next Board meeting. RB/GMi agreed to raise the issue with the Executive to confirm whether this should form a standalone item on the private Board agenda. *Post-meeting note: Additional paper added to Private section of the Board* The following updates were provided for the action log: • ARGC23 to be closed and removed as the outstanding action is captured in ARGC42. • ARGC45 – RB agreed to follow up this action and provide an update for members offline.	RB/GMi
4	Donor Experience Risks	
	D Rose & K Anderson joined the meeting to close an open action regarding the articulation of Donor Experience risk in the Strategic and Operational Risk Register. DR introduced a paper detailing how Donor Experience is managing risk through the creation and implementation of a new robust process, in	

	accordance with MPD 1336 v2 and provided a summary of the risks in relation to the Donor Experience (DX) directorate operations and how they are managed. Members commented that there was no or limited reference to certain risks they would have expected to see included such as the effect of Opt-Out legislation and the diversity of donors. DR highlighted that the scope of the review of the risk had been kept narrow and whilst these issues were not in scope for this specific review, members were assured that these were captured elsewhere in the risk register. There was further discussion on whether the risks sufficiently reflected the impact of a fourth wave of the Covid-19 pandemic and the temporary/potentially permanent change in donor sentiment and behaviour. DR confirmed that these aspects are being considered and feature in the developing Collection Footprint work. Members also discussed how a return to 'normal' demand would be managed at within the current Covid safety constraints. DR highlighted that social distancing had been managed through larger venues and increased capacity, and if social distancing were to continue, further additional capacity would be required to return collection capacity to pre-pandemic levels. DR commented that cancellations through staff absence, donor sickness levels and HB deferrals have also increased and have been more difficult to mitigate. It was commented that the donor-based behaviours/cancellations are proving more difficult to minimise through marketing, but that the teams are putting more resource into mitigating and managing cancellations and undertaking deep-dive micro-analysis. RB also highlighted that if the additional capacity measures are not removed that this may impact future blood prices – and this risk may require further discussion.	
5	Clinical Governance Report	
	G Miflin summarised the clinical governance issues discussed at the prior NHSBT CARE meeting. GMi highlighted progress on the resolution of the two open serious incidents and the confirmation from CQC that no further information was required in relation to the "potential safety concern" which had been raised anonymously to the CQC regarding the air in line incidents during donation of plasma. GMi also highlighted that the GIAA audit to review the adequacy and effectiveness of the current NHSBT process for horizon scanning for emerging infections had concluded that the current processes are operating effectively, are supported by proportionate governance arrangements and that a substantial assurance rating is appropriate. Committee members were assured that the restart of the REMAP-CAP arm of COVID convalescent plasma, at this stage, would not have a substantial impact on resource, and that any impact on PMM would be escalated to NHS England and Improvement. GMi updated the Committee on the recent SaBTO recommendation on Anti-Hepatitis B core antibody testing, confirmed that an implementation group has been stood up and that further information will be shared at the next Board meeting, accompanied by a Hep B focused patient story. Members	

	acknowledged the pertinence of this work in relation to the Infected Blood Inquiry (IBI). GMi confirmed that NHSBT has had recent experience of the implementation of additional testing, which should assure members of the ability of the organisation to deploy Hepatitis B core Antibody (anti-HBc) testing, this will be reliant in establishing the resource to do the work. It was agreed that the additional cost pressures/reputation of donor base ramifications from the new anti-HBc testing would also be considered by the implementation team. Lastly, GMi briefed members on the ongoing preparations for the IBI and the planned update for Board members at the end of September.	
6	Serious Incidents for Deep Dive Review	
	ARGC members were asked to agree a Serious Incident (SI) for a Deep Dive review at the November 2021 meeting. Members were briefed on the SI Deep Dive approach, the SIs which met the inclusion criteria that have occurred in NHSBT since the last SI deep dive in November 2020 and were briefed on the recommendation from CARE to consider SI QI21561 *Transcription Error in Stem Cell Search* for a deep dive review. Members queried whether there are a reasonable volume of such operations/activities and therefore whether a deep dive would have learnings for more universal application. GMi confirmed that a deep dive into this particular serious incident would have useful background/context for the forthcoming work on the Automated Results Transfer Calculations project, and the review could also include an update on how errors are being mitigated in this area. ARGC agreed to the CARE recommendation to undertake a deep dive review of SI QI21561.	
7	Risk Management Committee Update	
	I Bateman briefed members on the recent discussions from Risk Management Committee and subsequent decisions and guidance from the Executive Team, in addition to the move in focus at the Committee to integrate risk into the corporate strategy discussions and to also focus on the most critical risk issues. It was highlighted that the newly revised Board Assurance Framework, developed with the Good Governance Institute will be presented to the Board in December and Board members will be asked to determine the frequency at which the BAF is reviewed and circulated. Members requested progress updates on the further consideration of the *Loss of a Key Facility* strategic risk, in particular requesting that for services that are provided from just one location that we test and report the findings on the Business Continuity plans. Committee members discussed the proposed wording for the strategic risk related to Plasma for Medicines and requested further revision to ensure this captured the strategic rather than operational elements of the risk.	IB
8	CQC update	
	H Gillan and K Smith provided an update on the CQC Well Led Inspection preparations and HG reported that in her role as the nominated individual for CQC, there had been indication in an informal call that the Well Led inspections have re-started. KS confirmed that the work undertaken by the project team and the Good Governance Institute in the preparedness work will build on the report delivered	

	by Deloitte in March 2020 to identify whether the queries and gaps previously identified are being addressed, and whether NHSBT's interpretations of the key lines of enquiry are accurate. PW queried what success criteria will be used to determine at what point the project can return to business as usual. HG agreed to raise this with the project team.	HG
9	Regulatory Radar	
	HG updated the ARGC on key variations made to NHSBT regulatory licences as a result of changing requirements since the last meeting and provided assurance that NHSBT continues to meet its regulatory responsibilities by making necessary changes as required. HG drew the Committee's attention to the two amber rated changes, commenting that actions are progressing slower than anticipated on the two pieces of legislation under the EU Medical Devices Regulation. On the ICCBBA, HG confirmed that a response is awaited from JPAC and the issues has been escalated to the appropriate SMTs.	
10	Management Quality Report and Overdue events summary	
	HG presented the regulatory performance and trends across NHSBT during the quarter and highlighted the excellent performance in external regulatory inspections particularly the visit to the new Barnsley site in which the MHRA raised no Critical or Major findings, just 3 Others. HG also reported on the number of overdue quality management system events and noted that these remain high with some improvements seen mid quarter, but with a further upward trend at the end of June. Whilst there has been some support from the leadership team, it was noted that sustained action is required to address the upward trajectory. Members discussed the causes of the high number of overdues and acknowledged that an increase in the complexity of events and the availability of resource within teams to resolve overdues are partly the cause for the high number. HG also commented that mitigations are in place for unrealistic timescales for the closure of events as this had been an issue in the past. It was also agreed that HG would investigate whether a snapshot of the overdue trend data could be included in future ARGC reports. Members were also assured that the initiation of the REMAP-CAP trial would not affect on workloads/resource within the team, and that were would be no adverse effects as a result of the PMM decommissioning. The Committee were supportive of the measures taken to address the number of overdues. PW noted that whilst the number of overdues was a concern from a regulatory perspective, there is more concern that the team are not learning from issues quickly enough, which could lead to patient harm.	
11	Annual Report timetable	
	L Haigh presented the latest proposed timetable to Audit completion for consideration. Committee members were content with the overall timetable but requested that the date of the signing of the accounts by the CEO is moved closer to the C&AG certification.	

	RB also agreed to contact Board members and brief them on the revised accounts timetable.	
12	DHSC Delegations update	
	L Haigh provided a verbal update on the forthcoming changes to delegations for Arms-Length Bodies, potentially from 1st October and how this may affect NHSBT as soon as 1st, and on the tightening of controls for Cabinet Office approvals. LH commented that a draft revised delegation schedule is available at present but that NHSBT will refresh its own internal delegations for ARGC approval when the revisions from DHSC are final. Under the potential new delegations, LH raised that there would be reduction on the permitted spend on consultancy/professional services which is likely to be £100k or 3-month contract value. WC highlighted that this could pose a potential risk to the organisation in the loss of project/programmatic support and transitional arrangements may need to be out in place to enable this capacity to be built in-house. RB raised that as NHSBT is a public corporation this may have a further effect on the delegations revision and that discussions regarding this are in train with DHSC. PW thanked LH for the update and urged the Executive to keep the Committee informed of any material changes.	
13	Internal Audit update	
	G Smith provided a progress update on the progress of internal audit work since the last ARGC in July 2021 and highlighted that the audit report focused on Blood Safety and Detecting Emerging infections had been awarded substantial assurance. Findings and recommendations associated with 2 draft reports issued to management are currently being agreed and a further 2 activities are well progressed and will report prior to the next ARGC in November. GS commented that the Cabinet Office Spending Controls audit will not start until the discussion re ALB delegations has concluded with the DHSC. It was also reported that resource has been provided by GIAA to support the Assurance mapping work currently underway. PW encouraged GS to work with Anthony Clarkson to resolve the outstanding ODT recommendation from the 2019/20 audit programme.	
14	Papers for information	
	Waivers RB reiterated that Covid-19 has had a substantial impact on NHSBT's ability to re-tender for contracts due to resourcing constraints in Blood Supply, which has led to an increased number of contract extensions. *Forward Work Plan* In relation to future risks, PW encouraged the Executive to consider whether supply chain disruption and the availability of critical components, and staffing should feature more prominently in the Strategic Risk Register. The Losses & Special Payments paper was noted.	
15	AOB	

	PW invited comments from the external observers present at the meeting and JR commented on areas of good practice such as the quality of papers and identified areas for improvement such as greater scrutiny on the outstanding internal audit recommendations.	