



**One Hundred and Seventy Sixth Meeting of the NIBTS Agency Board
Thursday 4 July 2024 at 11.30am
Venue: Video Conferencing**

Present: Mr Brendan Garland – Non-Executive Chair
Mr Michael Graham – Non-Executive Member
Mrs Karin Jackson – Chief Executive

In attendance: Ms Angela Macauley – Quality & Regulatory Compliance Manager
Mrs Barbara Mullin – Head of Blood & Component Supply Chain
Mr Matt Gillespie – Head of Testing Services
Mr Eamon McCann – Finance & IM&T Manager
Mr Glenn Bell – former Finance & IM&T Manager

Mrs A Carabine – Minutes

1. Apologies

Dr A Allameddine.

2. Declaration of potential conflict of interests with any business items on the agenda

Mr Garland advised that given there are currently only two NEMs and he is Chair of Board and Chair of the Governance & Risk Management Committee, the position is not entirely appropriate. However, until new appointments are made to fill the vacant non-executive posts this unsatisfactory position will continue. The risk has been included on the Corporate Risk Register and has been raised at Board previously and all scheduled Committee meetings.

3. Minutes of One Hundred and Seventy Fifth of the NIBTS Agency Board meeting held on 16 May 2024 and action list

The minutes were agreed as an accurate reflection of the meeting and signed off by the Chair.

Action List:

Mr Garland advised that Mrs McKibbin had previously issued a copy of the proposed new KPI template which had been forwarded to Board members

4. Matters arising from the minutes of meeting held on 16 May 2024

There were no matters arising.

5. Chair's Business

New SMT appointments –

- Mr Garland on behalf of Board, offered congratulations to Dr Allameddine on his appointment as permanent Medical Director.
- Mr Garland advised that Mrs McKibbin has left NIBTS to take up a position with BHSCT.
- Mr Garland welcomed Mr Eamon McCann to NIBTS as the new Finance and IM&T Manager. Mr Garland thanked Mr Bell for his work with NIBTS and wished him a very happy and healthy retirement.

6. Chief Executive's Report

Industrial Action – the junior doctor industrial action has not currently affected NIBTS. The consultant doctors' industrial action is being postponed pending discussions between the BMA and DoH. To date there has been no update on the outcome of these discussions.

Plasma for Fractionation (PFF) – Mrs Jackson advised that SMT had met with the consultant who prepared the business case. Further exploration of storage, transport costs as well as options for a phased development of plasmapheresis is underway. Mrs Jackson further advised that Mr M Gillespie is the SMT lead on PFF. The final draft of the business case will be brought to Board in the autumn for approval.

PULSE Replacement/Blood Production and Tracking (BPAT) Project – the discovery phase of the project is on-going. A number of NIBTS staff have attended workshops with the contractor which has received positive feedback from the vendor. The project is on track for delivery in late 2025. A meeting is scheduled for tomorrow (5 July 2024) where re-validation and timelines will be discussed.

CoreLIMS Project – The blood transfusion module of the Clinisys WinPath Enterprise (WPE) solution went live in NIBTS at the beginning of June 2024. Mrs Jackson congratulated all staff involved in the preparation, testing, validation and training on the system to ensuring a relatively smooth transition from DSS to WPE.

Mrs Jackson advised that Mr Gillespie took the lead with NIBTS and BHSCT and residual issues were being worked through. Mr Gillespie advised that there were good learning experiences across many departments. Mr Gillespie congratulated staff across all departments.

Mr Garland advised that he had previously asked for assurances from Mr Gillespie which were provided. Mr Garland congratulated SMT and all staff for their hard work.

UK Infected Blood Inquiry – The Inquiry Report was published on 20 May 2024. The Reflections event was attended by the Chief Executive, representatives from BHSCT and other UK Blood Services. Mrs Jackson advised that the current focus is on compensation. A meeting is scheduled with DoH on 8 July 2024 to review the Inquiry recommendations and plan for their implementation in Northern Ireland.

Mrs Jackson advised that SaBTO, the independent body that advises the government, is also reviewing the report recommendations. NIBTS will also be working with other

UK blood services through the UK Forum and in support of JPAC, the body that issues transfusion guidelines for the UK.

Mr Garland enquired when Board will receive the NIBTS action plan. Mrs Jackson advised that Dr Allameddine will develop a report which will be tabled at a future Governance & Risk Management Committee meeting.

Mr Graham enquired if there are any significant requirements. Mrs Jackson advised that one key area is how data is handled and stored to enable donations to be traced electronically. Mrs Jackson further advised that many changes have been made since 2000. However, resourcing to properly support the quality management system and to implement further changes remains a priority.

Infrastructure Upgrade – There has been no further update. NIBTS will keep this on the agenda with DoH. Mrs Jackson advised that DoH have asked for the figures to be updated. NIBTS have completed same.

Irradiator – preparation to enable validation of this equipment is on-going and the contingency arrangements remain in place. The equipment is ready to be utilised, however, new guidelines are awaited from Health & Safety.

Mr Garland enquired if there was an SLA to complete the work within a given period of time. Mrs Mullin advised that she was not aware of such.

World Blood Donor Day – took place on 14 June 2024. To celebrate this there was a well-attended event, in conjunction with the PHA Organ Donation team on, Saturday 1 June 2024 at City Hall. Mrs Mullin was in attendance and advised that Daithi Mac Gabhann (Daithi's Law) and his father were also in attendance. Mr Mac Gabhann will attend NIBTS to donate blood in the coming weeks and Daithi will be given a tour of the laboratories following the journey of his father's blood donation.

New Appointments – as previously mentioned by the Chair. Mrs Jackson advised:

- Dr Allameddine has been formally appointed as the permanent NIBTS Medical Director.
- Following Mr Glenn Bell's retirement, Mr Eamon McCann has been appointed as Finance and IM&T Manager. Mrs Jackson looks forward to working with him.

Mrs Jackson thanked Mr Bell for his commitment and service to NIBTS over the past thirty years and his support to her since her commencement in 2016. Mrs Jackson wished him a long and healthy retirement.

- Mrs Verity Cochrane has been appointed as Head of HR & Corporate Services and will take up post in September 2024.

Mrs Jackson thanked Mrs Gladys McKibbin for her support over the past year and wished her well with her new appointment with BHSCT.

7. Blueprint Programme

Mrs Jackson presented the report and advised that timelines have been extended due to a number of factors. Mrs Jackson advised that HR and the workforce are key areas that are under a lot of pressure due to other new systems coming on line such as Core LIMS, Encompass etc. The Target Operating Model (TOM) is out for consultation and currently receiving positive feedback.

Mrs Jackson advised of a meeting earlier today where the TOM and Design were considered. Funding has been confirmed for this year with the funding for Phase II being considered in the business case. The draft business case will be tabled at Board in the autumn.

There have been a number of roadshows with Trusts, Trade Unions and Critical Friends for consultation.

Mr Garland enquired about the factors influencing delivery and how Blueprint compared with other new systems. Mrs Jackson advised that there is some flexibility within the Blueprint timeline compared with other projects that have many interdependencies. The changes to the Blueprint plan should not affect the overall delivery schedule.

Mr Graham enquired about governance reviews. Mrs Jackson advised that there was a Project Assessment Review after the public consultation. In addition, there is ongoing engagement with critical friends as well as other for a to assess the progress of the project. There may also be a gateway review going into Phase 2. However, that decision will be made by the SRO. Mr Graham felt that gateway reviews are beneficial. Mrs Jackson agreed.

8. Finance Report

Revenue

Mr Bell presented the report for the second month which ended on 31 May 2024 which showed a net deficit of £274k. NIBTS, excluding haemophilia products, shows a surplus of £93k. Mr Bell advised that since the report was compiled £750k has been committed to haemophilia by SPPG. Mr Bell advised that at year-end, breakeven is project with a surplus of £1k, although did note that in coming years this would be even more challenging due to adjustments expected.

The Pay position shows a surplus of £109k. Most areas are showing an underspend with the exception of a Medical overspend of £18k due to staff in excess of funded staffing levels.

The Non-Pay position shows a deficit of £98k, primarily due to costs in Transport (£34k) and Laboratory (£48k) for which additional income is secured.

Capital

The Capital Resource Limit (CRL) for 2024/25 has yet to be confirmed. However, £636k income in respect of BPaT is anticipated. There are capital commitments of £87k and roof repairs of £80k for which funding is anticipated.

Mr Graham enquired if funding will be received for previous agreed commitments. Mr Bell advised going on past contractual obligations, funding will be received. Mr Graham further enquired when the CRL will be received. Mr Bell advised that the CRL requirements were submitted during May 2024 and expects a decision soon.

Prompt Payment Policy

Compliance with Prompt Payment Policy is meeting targets, with no issues. Mr Garland advised that he would like the targets to be included in the table.

Monitoring

The notional value of blood components issued to hospitals is 2.5% above the Service Level Agreement (SLA) value at the end of May 2024. Trusts are showing activity levels ranging from 17% above to 6.8% below SLA, with no issues to report.

9. Audit Committee Update

Mr Graham, Interim Chair of the Audit Committee advised that the last meeting was held on 19 June 2024. The minutes from 2 May 2024 were for noting. Mr Graham advised it was a positive meeting.

There were reports from; BSO Internal Audit which included the Progress Report, Head of Internal Audit Annual Report where the overall opinion from was Satisfactory. The draft Annual Report including a BSO IA letter of Assurance to the Chief Executive. The Draft Charitable Trust Fund Annual Report and finally Draft Report To Those Charged With Governance.

Mr Graham advised that there was a need to complete the Collection Strategy. Mrs Mullin advised that the Strategy has been completed and activated.

Mr Graham further advised that he would like an update on the Charitable Funds expenditure, in particular for the Bone Marrow Fund.

10. Annual Report & 11 Charitable Trust Fund Annual Report

The two reports were taken together.

The drafts of both the Annual Report & Accounts and the Charitable Trust Fund Annual Report were tabled and discussed at the Audit Committee meetings on 2 May and 19 June 2024. Following some minor changes, the reports were agreed by the Audit Committee to be tabled at Board for approval.

Board discussed the reports and approved both Annual Reports.

12. Quality Management System Report

Ms Macauley presented the Quality Management System report.

Documents – The targets for SOPs and Policies (<4%) was not achieved with SOPs at 7% and Policies at 13%.

Ms Macauley advised that documents remain problematic and reflects the focus being on CoreLIMS. There is a lot of documentation arising the CoreLIMS SOPs, which in

turn requires revision of existing document. BPaT will further impact which is reflective in the figures.

Mr Garland enquired if the advertisement for the post of Document Controller had been issued. Ms Macauley advised that the position is out for advertisement and further advised that another position to assist has been recruited and the successful candidate is currently being trained, which should relieve the pressure on documents.

Mr Garland noted that during the past year, Board have been informed of new ways of working and enquired if these had commenced. Ms Macauley that Documents have been given more focus, including reporting back to departments, which has improved and there is now a better understanding. All reporting is now both at departmental and corporate level. Ms Macauley advised of the forthcoming UKAS inspection where focus will increase.

Mr Graham enquired if the targets were reasonable, considering they have not been met during the year. Mrs Jackson advised SOPs are always a moving target. However, agreed that a target was necessary. The rationale for not meeting target is due to resourcing issues. Changes are being made and will be reviewed again. However, issues arise when the same staff members are trying to complete a number of competing role functions.

Mr Graham advised there will always be pressures, but must be demonstrated to Board that targets can be achieved. If the targets are correct, work needs to be reviewed and additional resourcing should be requested.

Mr Graham enquired if regulatory inspections note that targets are not being met. Ms Macauley advised certainly for Incidents, Inspectors will review the metrics and targets.

Incidents, Investigations and CAPAs – Ms Macauley advised for Critical/Major investigations and CAPA there has been 90% completion within the target date and 100% completion within target date with an approved extension. For Minor/Other investigations and CAPA remain within target and above the KPI of 75% and 100% completion with target date assigned with approved extension.

The 12-month cumulative figure for closure of CAPA for major/critical incidents is currently at 49.6%, similar to previously reported. The cumulative figure for minor incidents is 67.4%, which is still below target.

Changes – As of 24 June 2024, the number of changes past target was 39. Of these, two were at review stage, six at implementation stage, eight were new and not yet commenced, three have been currently suspended and the remaining 20 are in progress. 12/39 of the overdue changes are overdue by a period of six weeks. Of these 12 changes, none were classified Red, six were classified as Amber and the remainder Yellow/Green. Ms Macauley appraised the Board of the six Amber changes and advised that there are no significant risks to the organisation.

Mr Garland enquired why the change raised regarding E progresa was suspended and then re-activated. Ms Macauley advised that it was suspended while it was out to tender, after the tender was awarded the change needed to be reactivated to document progression through the next phases however the reactivation and population of the change was delayed due to resourcing issues. A project manager has now been recruited to manage the BPaT project and the change has been re-activated. Mrs Jackson advised of resourcing issues and how resourcing is used, new staff take time to get fully au fait with the systems, whilst more experienced staff move to projects such as BPaT.

Mr Garland further enquired about the change regarding the development of PULSE to allow labelling of blood based on historical phenotypes and asked why this is necessary. Ms Macauley advised that phenotyping is permissible based on historic results provided a set of conditions are met these being two phenotypes being obtained from two separate donations from the donor via an automated platform. PULSE currently cannot distinguish between manual or automated testing therefore development is required. The cost of the development work is being determined however is likely to be much less than the savings which would be made from less testing and reagent costs.

Internal Audits – The two audits scheduled for May 2024 have not been completed, due to competing priorities on the assigned auditors. The majority of GMP audits have been scheduled for the remainder of 2024 including a number of ISO 15189 audits.

Mr Garland enquired if this is a cause of concern for the organisation. Ms Macauley advised there is no organisation risk, however, there is concern as there are a lot of audits to complete before the end of 2024.

Mr Garland enquired if anything else can be done. Ms Macauley advised of some changes being made to the process for auditing which will necessitate retraining. It has been agreed that all biomedical scientists will now have to complete internal audits and will therefore be expected to attend this training. This will therefore increase the pool of auditors available.

MHRA Inspection – Action Plan – the 2022 audit action plan has been closed. The next inspection is due late 2024, dates have not yet been received.

UKAS Inspection – progress continues on the gap analysis of the new ISO 15189 standard against current practice, which will be completed for return to UKAS prior to the next surveillance visit which is scheduled for 21 and 22 August 2024. UKAS have confirmed they will also be in attendance the week beginning 26 August 2024.

Mr Garland sought assurances of the Quality Management System. Ms Macauley advised that the Quality Management System is functioning at a satisfactory level.

13. Medical Directors report to Board

On behalf of Dr Allameddine, Mr Gillespie presented his report and advised:

- Blood stock have been stable. With the exception of special blood products that NIBTS do not produce, there have been no importation in the last 12 months.
- The *Platelet Strategy* is in draft and will be an operational document to meet demand. Currently 65% of platelets are collected by NIBTS.

Mr Graham enquired if the Platelet Strategy links into the Collection Strategy. Mrs Jackson advised that they are two different strategies, however will link in with each other to achieve a balance.

Mr Graham further enquired how NIBTS reach out to platelet donors. Mrs Mullin advised that currently there are no resources to do so. However, now the strategy is coming on line it will inform.

- *Infected Blood Inquiry* – following publication of the Report, NIBTS with other blood services, SHOT and JPAC will do a full analysis of Lessons Learned and Recommendations to identify areas where UK wide collaboration is necessary and beneficial and develop relevant workstreams. NIBTS has established an internal committee to ensure these workstreams are implemented a co-ordinate with other regional and national working groups.
- *Occult Blood Inquiry* – the first stage of the donor surveillance has been completed to identify affected donors and components. 272 components were identified to be at risk from 13 donors. Those identified are in the low/medium category with none in the high category. Communications have been sent to hospital blood banks and the donors will be followed up at hospitals by the clinical teams.
- *British Bone Marrow Registry (BBMR)* – A compliance audit including relevant documentation has been completed with BBMR. Donor session training to ensure active engagement with donors is due to commence. Following this, recruitment will commence and charitable funds will be used to cover the cost of high-resolution testing.
- *European Directorate for the Quality of Medicine & Healthcare (EQDM) Blood Guide* – the 22nd edition of Blood Guide of EQDM is out for consultation. NIBTS are required to ensure compliance, as part of the Windsor Framework and is conducting an internal gap analysis.
- *Update donor website and create additional share points for professional NIBTS and NITC* – an up to date website will allow visitors to find information, guidance or resources quickly and safely at a time convenient to them. In line with other services NIBTS and NITC are working to raise their profile with a wider reach with an updated platform. A draft business case is in progress.

Mr Garland enquired if a specific log in will be required. Mrs Mullin advised that NIBTS are in consultation with other services regarding this.

- *Ethnic background monitoring and the active recruitment of ethnic donors* – accurate knowledge on donor ethnicity is relevant to ensure blood is matched accurately for recipients and those at risk from haemoglobinopathy. Active recruitment will enhance representation, reduce inequality and help meet the clinical need to treat Sickle Cell Disease.
- *Implementation of guidance on transgender and non-binary donors* – which will give an unhindered opportunity to donate. A document is being drafted and additional support will be required from the recruitment team to engage and from the donor session team and the IT dept.

Mr Garland enquired why this information would be necessary. Mr Gillespie advised if a person was born a different sex, some of the products may not be suitable.

- *Fetal DNA* – Testing D negative pregnant women as per NICE and RCOG guidelines is required. Discussions with PHA are due to re-commence to explore resources and timescales. There are concerns regarding significant pressures due to resourcing in the Reference Lab.
- *Laboratories* – there is significant pressure within the Reference Laboratory which includes a risk of impacting on-going services. Currently at risk are Sickledex, sickle free blood and molecular genotyping. A business case is currently with SPPG. If no funding becomes available the work may have to cease.

Mr Graham enquired if there was funding for these tests. Mrs Jackson advised that the monthly SMT Performance & Planning meetings looks at what can be funded, what is business critical and requires funding. Mrs Jackson further advised that if there is no funding or resources, then unfortunately testing cannot be performed.

14. Incubators Business Case

Mrs Mullin presented the business case and advised Board on the temperatures that blood and blood components should be stored and transported. The current system is not meeting the conformance requirements for transport. There are four cooled incubators, two of which are used for the validation of transport boxes which also act as a contingency for the other two. The business case is for the purchase of an additional three incubators which will facilitate the operation of system B prior to the introduction of a new system.

Mr Garland enquired if these new incubators will be able to be used for the new system. Mrs Mullin advised that the purchase of the new incubators is a pre-requisite for a long-term solution.

Board discussed and approved the business case.

15. KPIs

Mrs Jackson presented the paper. Board advised that they were content with the new template.

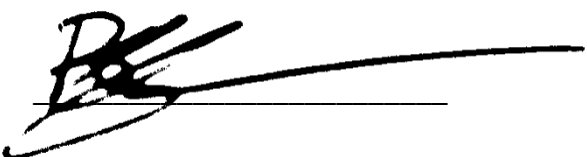
Mr Graham noted that the SDR figures had slipped from the previous month. Mrs Jackson advised the focus has been on CoreLIMS and she expected the figures to recover.

16. Any Other Business

Mr Graham appraised Board on the completion of the review of an Investigation Report from March 2022. All relevant recommendations have now been captured and will be progressed by SLT. Updates on the progress of these recommendations will be brought to the Board by the Chief Executive on a regular basis. A note detailing the approach taken in this regard has been created and agreed by all Board Members. Mr Garland thanked all for their attendance at today's meeting.

| Action | Responsible Person |
|---|---------------------------|
| Include targets in the Prompt Payment table contained within the Financial Report | Mr McCann |
| Board update re: investigation report | Mrs Jackson |

Date of next meeting:
Thursday 19 September 2024 at 9.30am
Venue: Lecture Room, NIBTS HQ

Signed: 

Dated: 19 September 2024