



**One Hundred and Eighty-Third Meeting of the NIBTS Agency Board
Thursday 3rd July 2025 at 10am
Venue: Lecture Room, NIBTS HQ**

Present: Mr Brendan Garland – Non-Executive Chair
Mr Michael Graham – Non-Executive Member
Mr Noel Brady – Non-Executive Member
Ms Bernie Lunney – Non-Executive Member
Mrs Karin Jackson – Chief Executive

In Attendance: Dr Allameddine Allameddine – Medical Director
Mr Eamon McCann – Head of Finance & IMT
Ms Angela Macauley – Quality & Regulatory Compliance Manager
Mrs Barbara Mullin – Head of Blood & Component Supply Chain
Mr Matt Gillespie – Head of Testing Services
Mrs Verity Cochrane – Head of HR & Corporate Services
Mrs Hannah Wilson – Minutes

1. Apologies

There were no apologies.

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

There were no declarations of interest.

3. Minutes of One Hundred and Eighty-Second Meeting of the NIBTS Agency Board held on 15th May 2025 and action list

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

Action List:

N/A

4. Matters arising from minutes of meeting held on 15th May 2025

There were no matters arising.

5. Chair's Business

- Mr Garland advised that a meeting of the Remuneration & Terms of Service Committee had taken place on 23rd May 2025.
- Mr Garland confirmed that the Non-Executive Members appraisals had been completed and that his appraisal with the Department of Health (DOH) is to follow.

6. Chief Executive's Report

Mrs Jackson referred to her report and advised that there were no significant updates since it had been circulated.

Industrial Action

Mrs Jackson referred to media speculation regarding pay awards for 2025/26, however, there has been no indication of further industrial action at this stage.

Plasma for Fractionation (PFF) (Plasma for Medicines)

Mrs Jackson outlined progress on the Plasma for Medicines Business Case. It was highlighted that the market prices of Immunoglobulins had reduced, which will have a material effect on the financial benefits of the business case.

Mrs Jackson also highlighted that, due to current limited staffing capacity within NIBTS as a consequence of activity associated with the delivery of the BPAT project, it would be sensible to pause work on delivering Plasma for Medicines once the business case has been completed. To progress this workstream, significant work will be required to complete the 'plasma master file' by October 2025. This would be difficult to achieve whilst work on BPAT is ongoing. In the meantime, NIBTS will continue to be able to benefit from income derived from surplus plasma.

Infected Blood Inquiry

This item will be covered in the Medical Director's report.

Infrastructure Upgrade

Mr McCann advised there has been no confirmation of capital funding and the proposal for a new building is still included in the 10-15 year plan. Whilst availability of space is increasingly challenging (for example, the only available space for a much-needed walk in freezer is outside), this risk is being managed.

While NIBTS has the income to recruit much needed additional staff, there is very limited office accommodation available.

Currently, the primary risk identified is the ongoing maintenance of the plant servicing the building. The building was commissioned in 1994/95 and certain components are no longer manufactured, resulting in delays while replacements are sourced. Issues exist with heating, ventilation, and climate control systems as well as lift mechanisms, which is typical of a 30-year-old building.

Irradiator

Plans are underway to decommission the existing irradiator by October 2025. X-ray technology has been implemented into routine use and successful audits by CTSA, DEARA, HSE England and HSE NI.

EU SoHO Regulations

NIBTS is still waiting for approval of 2026-2030 funding under the Windsor Framework. Job descriptions have been developed/are in development to recruit staff using 2025/26 funding. A gap analysis and document updates are still pending and will be completed when new staff are in post.

Organisational Culture Programme

The Head of HR & Corporate Services is proactively reviewing how NIBTS' current organisational culture aligns with our strategic goals and HSC values. Feedback from service user and staff complaints, trade union meetings, staff surveys and informal discussions will be analysed to form a baseline assessment of our current culture. Mrs Cochrane will engage across HSC regarding cultural assessment tools in use.

While there have been no formal concerns, NIBTS wants to remain pro-active in its approach and ensure consistent messaging across the organisation.

7. Blueprint Programme – Update

Mrs Jackson referred to her report and updated on the following:

1. The Blueprint team met with DOH Economists on 1st July 2025 to discuss comments on the OBC, which was submitted in December 2024.
2. The DOH has secured the support of the Permanent Secretary for next steps, and is briefing the Minister for Health. Feedback will be provided to the Programme Board on 9th July 2025. An update to the NIBTS Board will be provided thereafter.
3. Formal communication to staff and the HSC system will begin 8th August 2025, followed by written communication to Trust Chief Executives, staff and other key stakeholders.

4. PA Consulting is also helping with reprofiling the business case.
5. A NHS England Commissioning Support Unit (CSU) is assisting the Programme team to identify cash and non-cash benefits. This is similar to work they have previously done with Cheshire and Merseyside
6. The Northern Ireland Pathology Network is working with the Blueprint team in engaging with GP Liaison Services to review the process and logistics of tests from primary care in order to further strengthen financial elements of the business case.
7. Currently the plan is for the Business Case to be shared with the Blueprint Board in October 2025 and NIBTS Board in the same month.
8. NIBTS has been approached by the Institute of Biomedical Science (IBMS). Lord Carter – who completed an initial review of pathology services in England in 2016 – is conducting an update on the recommendations from then and wishes to include data from the Devolved Administration as well as England for this project.
9. The Blueprint Programme budget of £220k is recurring with no indication of it being withdrawn.

8. Blood Production & Tracking (BPAT) – Update

Mr Gillespie referred to his report and updated the Board on the following project activities:

BPAT Production Workstreams

BPAT production workstream timelines are within projections, with a focus on build and configuration. The first phase of testing will begin on 22nd July 2025.

Mr Brady queried the workstream timeline chart, as the darker line showing the level of completion looks like it is behind schedule in some cases. Mr Gillespie assured the Board that they are on schedule and undertook to review the timeline chart to represent progress using percentage figures instead.

Testing System Functionality

Mr Gillespie explained that the main focus has been on system refinement and writing test scripts for the first phase of testing. The first phase of testing will test all areas of functionality, but not end to end including interfacing. All bug fixes and configuration changes are to be delivered by the vendor by 21st July 2025 so that testing can begin on 22nd July 2025.

Interfacing

Interfacing will receive more of a focus over the next three months. All equipment has been agreed, except for two items; therefore, most interfaces will be in place for phase 2 testing by 24th September 2025. Two pieces of equipment required replacement due to unavoidable circumstances and will not be delivered until December 2025.

Recruitment and Staffing

Recruitment and staffing levels have increased and recruitment is ongoing for Donor Services area.

Data Migration

Mr Gillespie explained the data is likely to require several rounds of extraction, upload and checking before the process is correct. It is anticipated that the data migration process will be perfected by the third round, however, there is capacity for five rounds if needed, before phase 2 testing begins on 24th September 2025. The process used for the final successful round of data migration will be applied to the entire live data just prior to go live. There will be no delta migration during the project.

Risks and Issues

The main project risks and issues are attached, filtered for risks that remain high post-mitigation. There are five critical risks logged, out of 120 evaluated risks. These five are ones that pose a critical risk to moving on to the next phase of the project and therefore have the potential to cause delays. They will remain as critical until they are resolved and tested. MAK have committed to resolving all the current critical and high issues by 21st July 2025 and therefore they do not pose a risk to current project delivery.

Mr Brady queried the format of the risk log, specifically the colours chosen. Mr Gillespie agreed to review. There was also some discussion about the ratings pre- and post-mitigation and Mr Gillespie clarified that, while mitigations will reduce likelihood, the impact remains the same. Mr Garland asked for assurance that our mitigations were sufficient and Mr Gillespie assured the Board that they were.

Mr Graham asked about security and access. Mr Gillespie explained that security and access levels are being tested and that an external company has been engaged for penetration and security testing.

9. Finance Report 31st May 2025 and Financial Plan 2025/26

Financial Report 31st May 2025

Mr McCann presented the report for the 2-month period ended 31st May 2025, forecasting a breakeven position for 2025/26.

Financial Position 2025/26

NIBTS have historically achieved a breakeven position every year and 2024/25 was no exception. There are, however, very significant pressures and challenges facing HSC organisations going into 2025/26.

Financial Plan 2025/26 – Assumptions

Strategic Planning & Performance Group (SPPG) figures have been submitted.

Funding Adjustments

1. The pay awards for 2024/25 have been funded by SPPG and included in 2025/26 budgets.
2. Employers' National Insurance contribution has increased by 1%. This additional cost is estimated at £143K; it is anticipated that this will be funded and included in LA's
3. Plasma product cost and volume in Trust SLA's has been amended to reflect Trusts' requirements. Associated income and expenditure budgets have been adjusted to reflect this change.
4. 220K Blueprint funding has been included in our budgets.
5. Additional funding from SPPG of £200k has been allocated for the Blood Group Reference Laboratory.
6. Non-Pay Inflation is currently estimated to be approx. 2.5% (£109K).
7. DOH has indicated that inflation costs will need to be addressed from within NIBTS baseline funding. A number of large adjustments would be required to fund these pressures, including; cost reduction arising from staff turnover; phenotype labelling; reduced advertising costs; review of platelet production methods; and release of apheresis consumable budget.

Cost Pressures and Other Revenue Funding Considerations

1. Blood Group Reference Laboratory – a business case for additional funding has been prepared and sent to SPPG for consideration due to the increase in volume

and complexity of samples referred to the Blood Group Reference Laboratory. Recurring funding of £200K was allocated, however, the estimated funding requirement to meet continued demand in 2025/26 is £271K.

2. Energy costs have increased by £57K during 2024/25, additional funding has not been provided to meet these increases.

The Board approved the Financial Plan for 2025/26.

10. Update from Audit Committee – 12th June 2025

Mr Brady stated that the Audit Committee meeting on 12th June 2025 had been very positive and commended NIBTS on their response to last year's report and on completing the 2024/2025 audit programme to a satisfactory standard. Mr Graham agreed and congratulated NIBTS on a significantly positive shift.

11. Annual Report

This was approved by the Board.

12. Charitable Trust Fund Annual Report

This was approved by the Board.

13. Quality Management System Report

Documents

At 7%, the SOPS target (<4%) is currently not being achieved. Laboratories and IM&T are within the KPI, however, all other departments failed to achieve this target in April, with figures ranging from 7-20%. Similarly, at 11%, the Policy target (<4%) has also not been achieved. Donor Services, Finance and IM&T are within KPI, however, all other departments failed to achieve this target, with figures ranging from 8-25%. It was noted that staffing resources is currently limited within Document Control due to one member of staff being absent due to illness. Additionally, a high number of documents have been issued as a priority due to ongoing work on projects such as HbS testing, the irradiator audit and changes to packing configurations for frozen products.

NIBTS currently have a large amount of staff absence due to personal issues, but this is particularly felt in the Quality and HR&CS departments, making it difficult to achieve these KPIs. The number of staff in all departments that are being required to focus on preparations of test scripts for the BPAT project has also led to a rise in the number of documents outside of review.

It may be necessary to extend the review period on those documents which are non-GxP related to allow staff to focus on those documents which are GxP related.

Incident Investigations and CAPA's

Compliance with target dates for incident investigations and CAPA's remain a challenge. Conformance with targets for CAPA show a decreasing performance level. Four CAPA's were associated with major incidents during April and May, all of which are currently passed their due date and remain open. These actions are across three departments. The staff member who manages incidents is currently absent due to illness, resulting in a backlog of submitted incident investigations which are currently being worked through by the Q&RC Manager.

Change Controls

The quality metrics produced for the QIR meeting held in June indicated that the number of open changes remained relatively consistent during March/April/May, with a decrease in those overdue during April, followed by an increase again in May.

As of 24 June 2025, the number of changes past target date was 61. Of these, 5 were at review stage, 6 were at implementation, 13 had a status of 'new' and 8 are currently assigned under 'suspended' status, with the remaining 29 at action plan stage. 40/61 changes are overdue by a period of 6 weeks or more. Of these 40, none were classified as red, 13 as amber and the remainder are yellow/green.

Mr Brady queried how much of the issue of meeting targets was down to other departments. Mrs Macauley confirmed that there was a resourcing issue across all departments, with a high number of staff on long-term, non work-related sick leave. This has highlighted a vulnerability in resourcing during periods of absenteeism.

The risk is currently a combined risk, as targets are not being met across the board. There is currently a large number of projects requiring staff focus. Departments will be asked to risk assess and postpone or withdraw changes that are not deemed essential.

NIBTS are struggling to maintain appropriate levels of compliance within the QMS due to resource constraints. Finance is available to allow the organisation to boost staffing resource, however, difficulty has been experienced in identifying personnel with the required expertise. Companies that could assist do not have the expertise needed in relation to blood safety and quality, quality management systems and blood transfusion, however, we may be able to subcontract a staff member from NHSBT's Quality Department.

Mrs Macauley assured the Board that while we consider re-setting timelines, these will be appropriately risk assessed, and that while we are currently approaching a level of concern, the quality system is functioning

Audits

Mrs Macauley reported that 33 audits are scheduled within 2025 to be carried out by NIBTS staff. To date 2 have been completed with findings raised and a further 2 completed with findings yet to be agreed and raised. A former member of the quality department has engaged to assist in completing some audits to help bring us up to date.

MHRA Inspection

The 2022 Audit action plan has closed. The next inspection was due in the latter part of 2024, however, a date has not yet to be notified. Mrs Macauley noted that MHRA have recently been giving 3 weeks' notice of audits, therefore, it is essential NIBTS are in an audit ready state.

UKAS Inspection

UKAS has closed all findings relating to the 2025 reassessment. The next surveillance visit is due in January 2026.

14. Medical Director Report

Dr Allameddine referred to his report and provided updates on the following:

Blood Stock Management

Dr Allameddine advised that, while there has been no blood importation since May 2023, O-negative blood stocks have recently been low, around 3-4 days. This has been communicated out to the hospitals as a pre-amber alert and Dr Allameddine has arranged a meeting with stakeholders later in the afternoon. During pre-amber we can restrict the use of O-negative red cells. The reduction in supply has been due to predicted lower donor engagement over summer months and an aging donor population, as well as continued over requesting and wastage on Trust sites.

Hospital wastage remains significantly high, wastage of red cells has increased from 3.5% last year to 4.4% this year. O-negative blood wastage has increased from 5.6% to 7.3%; but as O-negative is universal, wastage should be close to zero; the majority of hospital wastage is avoidable, as they could use an alternative.

Data from 2023 has shown that more units were wasted than were imported, meaning that NIBTS carries the burden of unnecessary waste. The Medical Team continues to engage with hospital blood bank managers and clinical colleagues from NITC to discuss wastage and identify practical solutions, including issuing monthly reports each Trust.

Mr Garland commended NIBTS on their focus on O-negative blood.

SoHO (Substances of Human Origin) Regulations.

The SoHO Regulations (equivalent to BQSR in the UK) came into force in the European Union in August 2024. Under the Windsor Framework, these regulations apply to Northern Ireland, but not Great Britain. The regulations aim to ensure high standards of quality and safety for substances of human origin, such as blood, tissues and cells, intended for human application. The regulations will take full effect from August 2027, following a three-year transition period. Northern Ireland must designate competent authorities responsible for monitoring SoHO activities and additional medical resources will be needed.

Bone Marrow Registry

Dr Allameddine advised that progress on recruitment and charitable fund utilisation continues to be monitored.

Donor (DAEDs) and Patient Adverse Events

An interim solution to ensure recording of donor adverse events (DAEDs), pending implementation of eProgesa, is in place. A database to record patient adverse events due to blood issued has been live since February.

Donor Deferrals

There has been a significant rise in donor deferrals this year, especially due to low Hb and travel. It is expected that eProgesa will help reduce unnecessary deferrals, however, resilience is more difficult due to travel restrictions constantly being updated.

Haemochromatosis

NIBTS continues to engage Belfast Trust's Hepatology Team to facilitate transfer of active, eligible haemochromatosis patients to NIBTS to become blood donors and that this trial will be reviewed over 3 months to assess risks and benefits. NIBTS is also working on using this pilot to identify O-negative donors to help stabilise supply issues.

Infected Blood Inquiry

Work is continuing to implement the IBI recommended actions and the transfusion related standards produced by SHOT.

Occult Blood Infection

Work on OBI is slowly progressing but is slightly behind schedule. 12 donors have been identified requiring lookback, 3 of these were apheresis donors. Initial data returned from hospitals is currently being reviewed, however, some have not supplied all necessary information and communication is ongoing to address this.

Fetal DNA (antenatal screening for D-Negative pregnant women)

Dr Allameddine confirmed that discussions with PHA are progressing, with the aim of reducing unnecessary exposure for women during pregnancy to blood products and mitigating against the risk of anti-D shortage.

15. KPI's

Mrs Cochrane presented the KPI figures for April and May 2025/2026, referring specifically to those areas which were amber/red. Mrs Mullin explained that the target for red cell stock holding should mirror the daily stock figures, where the aim is to remain in green with 5-7 days red cells stock. Therefore, the minimum KPI target will be changed to 5 days stock, rather than 7. This target maintains sufficient availability, while also managing any potential wastage.

Mrs Cochrane noted that complaints figures were exceeding target, however, it was agreed that the target was potentially unrealistic and required review. Mrs Cochrane also noted that appraisal completion rates were below target and this was reflective of current resourcing challenges across departments. It was noted that prompt payment targets had not been reached in April, however, this had been rectified in May and was most likely due to the Easter holiday period in April.

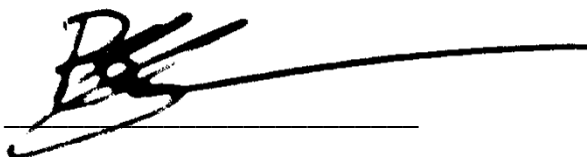
16. Any Other Business

There was no other business.

Mr Garland thanked everyone for their continued hard work and participation in today's meeting.

Date of next Meeting:
Thursday, 18th September 2025 at 10:00am
Venue: NIBTS HQ

Signed:

A handwritten signature in black ink, appearing to be 'D. S.', written over a horizontal line.

Dated:

18 September 2025