Transfusion Advisory Discussion Group (TADG) Meeting Minutes

26th June 2025 | Face-to-Face Meeting | 9:30 - 16:00

Chair: Jey Visuvanathan
Attendance: 40 attendees

Name	Organisation	Role	Initials
Jey Visuvanathan	Synnovis	Transfusion Lab Manager / Chair of TADG	JV
Nella Pignatelli	NHSBT	London Regional Transfusion Administrator	NP
Danny Bolton	NHSBT	Customer Service Manager	DB
Michaela Rackley	NHSBT	Customer Service Manager	MR
Sally Procter	NHSBT	Scientific and Clinical Training and Education Manager	SP
Brian Robertson	Bart's Health	Blood Components and Transformation Manager	BR
Patricia Richards	Synnovis	Operational Service Manager	PR
Denroy Lindsey	Great Ormand Street Hospital	Transfusion Lab Manager	DLi
Angela Maddison	The Doctor's Laboratory	Senior Biological Scientist in Blood Transfusion	AM
Paul Wadham	Royal Marsden	Blood Sciences Lab Manager	PW
David Veniard	The London Clinic	Transfusion Lab Manager	DV
Joanne Medford	Health Services Laboratory	Blood Transfusion Compliance Manager	JMe
Peter Gregory	UKAS	Assessment Manager	PG

Sajal Patel	Epsom And St Helier University Hospitals	Blood Transfusion Lab Manager	SPa
Zaid Kazi	Cromwell Hospital/ The Doctor's Laboratory	Senior Blood Transfusion Lab Manager	ZK
Caroline Subramaniam	The Doctor's Laboratory	Group Blood Transfusion Compliance Lead – HSL & TDL	CS
Doris Lam	NHSBT	Head of RCI	DL
Matthew Hazell	NHSBT	Consultant Clinical Scientist - RCI	MH
Erin Buckley	NHSBT	RCI Biomedical Scientist	EB
Chloe Orchard	St George's Hospital	Transfusion Lab Manager	CO
Matthew Fouracre	CliniSys	Marketing Manager	MF
Craig Hayes	CliniSys	Head of Domain – Blood Transfusion	CH
Anna Capps-Jenner	The Doctor's Laboratory	Chief BMS BT and Haematology and TDL BT Technical Lead	AC
Julia Mahmood	NHSBT	Head of RCI	JM
Chris Robbie	MHRA	Haemovigilance Specialist	CR
Desma Ali	Hillingdon	Biomedical Scientist	DA
Tawe Hove	Hillingdon Hospital	Transfusion Lab Manager	TH
Nelson Jonson	Frimley park Hospital	Transfusion IT lead	NJ
Joanna Chmielowiec	Nuffield Health	Blood Transfusion Lead	JC
Luke Woodford	St Thomas' Hospital	Senior Biomedical Scientist – Blood Transfusion	LW
Donna Wiles	Cleveland Clinic London/ The Doctors Laboratory	Transfusion Lab Manager	DW

Kenneth Amenya	King's College Hospital	Transfusion Lab Manager	KA
Autumn St John	NHSBT/UKHSA Epidemiology Unit	Data Manager Blood Safety Team	AS
Angela Mateos	NHSBT	Lead Nurse	AMa
Rhian Edwards	NHSBT	Customer Benefits Lead for Universal Components & Dried Plasma projects	RE
Mel Harris	Quidel Ortho	National Sales Manager	MHa
Massimo Marino	Quidel Ortho	Senior Account Manager	MM
Melissa Robinson	Brenmoor	Sales Manager	MRo
Martin Whitcher	Haier Biomedical	Sales Manager	MW

Apologies: Marwan Nassari

Minutes Secretary: Nella Pignatelli
For any amendments, please contact nella.pignatelli@nhsbt.nhs.uk

Contents

-- Meeting starts --

1. Welcomes & Introductions

JV asked the attendees to introduce themselves.

2. NHSBT Customer Service Update

Delivered by DB and MR

The summary below captures key points from the Customer Service Team.

Blood Supply & Component Update

- Amber Alert continues for group O Red Cells
- Pre-Amber for B D negative red cells
- Triaging of O D Negative units has stopped (13th June)
- Platelet levels are currently stable, though maintaining adequate A negative platelets continues to pose a challenge.
- Red cell supplies are nearing amber status and require close monitoring.

Donor Engagement

- The Donor Experience team is promoting donations, with specific focus on group O donors.

Process & Technology Enhancements

- The Customer Service Team has been contacted nationally regarding Blood360 handhelds and blood fridge kiosks unable to scan the product barcode — suppliers are investigating and working toward resolution.
- A 24-hour advance notice is now required for all HLA orders.
- A single collection site validation is expected to begin in July 2025
- Each male donor will provide an additional plasma unit, used for clinical FFP, freeing up other plasma for fractionation.
- Apheresis Platelets in PAS will be produced as pack 1, 2 and 3 with irradiated equivalents.
- Neonatal components can be manufactured from Apheresis Platelets in PAS (along with irradiated equivalents)
- New product codes will be distributed as soon as possible to enable hospital LIMS updates

- The RCI Assist tool is now available via sp-ICE, offering improved support in patient matching and diagnostics.

Rare Blood Management Pilot

- A revised rare blood management process will be implemented to handle specialist component requests more effectively.
- When a rare unit request is received, Hospital Services will contact the on-call NHSBT Patient Consultant.
- The Consultant may discuss the clinical indication with the hospital's Transfusion Laboratory and/or the responsible clinical team to determine whether phenotype-negative units are clinically necessary.
- Following this discussion, the Consultant will either approve or decline the request.
- Once approved for a given patient, subsequent requests for the same phenotype-negative units will not require repeat Consultant authorisation.
- This process will be piloted for three months, starting 02 July 2025.

Pricing & Financials

- The prices for NHSBT blood components and transport services have now been agreed through the National Commissioning Group for Blood.

Collection & Delivery

- The Customer Service Team is currently reviewing and updating all delivery instructions for their drivers (NHS and Couriers), including the addition of W3W addresses.
- The Customer Service Team asked the group to continue to report to them about cases of deliveries being taken to the wrong location so they can follow this up with the transport team.
- The two bank holidays in May led to noticeable dips in blood collection.

3.CliniSys: A single solution for blood production and tracking across Northern Ireland

Delivered by CH

CH delivered a case study presentation on the deployment of WinPath Enterprise across Northern Ireland. This region-wide implementation spans all laboratory disciplines, including blood sciences, microbiology, transfusion, cellular pathology, and tissue typing. The deployment also includes the RCI laboratory in Belfast.

Key figures

- Covers the entirety of Northern Ireland
- £100 million operating budget
- 1,100 staff
- 40 million diagnostic tests annually
- NIBTS (Northern Ireland Blood Transfusion Service) operates two teams and conducts approximately 800 blood collection sessions per year

Key objectives and benefits

- Implementation of a vein-to-vein transfusion solution (from RCI to patient, excluding donor management)
- Standardisation of workflows and processes across all sites
- Full electronic traceability of blood products
- Real-time visibility of stock across all locations
- Improved continuity of care and reduced duplication of testing
- Integration with Haemonetics BloodTrack and the EPIC EPR system
- Enhanced communication and data sharing with RCI
- Improved auditability and traceability

Challenges

- Managing large volumes of data
- Ensuring accessibility and usability of historical test data

4. MHRA: Q&A/Discussion

Delivered by CR

CR asked the group if they have any questions relating to the new framework, workspace and reporting system.

JV asked CR whether there were any notable findings from recent inspections that could be shared with the group.

CR responded that, due to their involvement in the inspections, they were unable to disclose specific details. He noted that his colleague is currently conducting the majority of inspections.

CR added that his team are still catching up on last year's inspections and will be meeting soon to plan the current year's schedule.

CR highlighted that the issues being identified remain consistent with previous years, including:

- Lack of staffing and resources
- Inadequate incident reporting systems
- Weaknesses in recall and retrospective action processes

JV queried whether the lack of staffing was linked to the absence or outdated nature of capacity plans. CR confirmed that while many organisations have capacity plans, they are often not reviewed or updated regularly, making them less effective in the current climate.

AC added that people do not report staffing issues.

CR added that usually staff receive training when a mistake happens, which is not the issue here. CR mentioned that a solution would be to hire more Band 4 workers to do tasks that Biomedical Scientists do not need to do.

CR advised that capacity plans should be used proactively to present resourcing needs to senior management. It is important to plan resources not only for laboratory work but also for maintaining the quality system.

A key concern raised was that staffing issues are frequently underreported, with teams often continuing to operate under strain. CR emphasised that retraining existing staff is not a sufficient corrective action when the issue is lack of capacity.

Instead, organisations should consider:

- Reallocating resources
- Employing Band 4 staff to take on tasks that do not require BMS qualifications, thereby freeing up BMS time
- Adjusting workflows, such as changing sample delivery times or extending staff hours

5. UKAS: An Overview of Accreditation to ISO15189:2022

Delivered by PG

The summary below captures key points from PG, UKAS.

UKAS Assessment Overview

- PG is a UKAS assessment manager and technical assessor with transfusion lab and equipment inspection experience.
- Labs must notify UKAS of any changes to avoid surprises during assessments.

Assessment Cycle

- Years 1–3: Annual surveillance assessments
- Year 4: Full reassessment with independent review
- All technical, quality, and clinical activities are assessed at least once per cycle.

Assessment Approach

- UKAS uses a risk-based approach, informed by site feedback.
- Management reviews should include transfusion-specific data and improvement planning.

Pre-Assessment Requirements

- Assessment plans are issued via the UKAS portal ~1 month before visits.
- Labs must submit a pre-assessment declaration detailing changes or incidents.
- Assessors will verify the schedule of accreditation during visits.

Post-Assessment Process

- Labs receive a maintenance of accreditation letter once findings are resolved.

Transition to New Standard

- The 2012 standard retires on 6 December 2025.
- After this date, accreditation to ISO 15189:2012 will cease to be valid.
- The new standard is patient-focused and risk-based.

Key Requirements Under New Standard

- Review supporting documents on risk and bio-risk management.
- Staff must be formally authorised and competent for specific duties.
- CPD programmes must be in place for all staff, not just HCPC registrants.

Equipment and Consumables

- Equipment (e.g. pipettes, centrifuges) must be calibrated and verified for actual use.
- Consumables must be verified for suitability before use.

Competence and Method Verification

- Competence documentation must cover all process elements, including LIMS usage.
- Method verification must meet clinical requirements and include clinical review.
- Measurement uncertainty should be considered, especially in tests like Kleihauer.

Quality Control and EQA

- Labs should monitor trends in results and justify QC frequency based on risk.
- EQA schemes must be clinically relevant and challenge the system.
- Comparability must be done between analysers and manual methods.

Clinical Impact and Non-Conformances

- Clause 7.5 covers decisions to stop testing and assess clinical impact.
- Clinician involvement is essential in evaluating patient harm.
- Serious non-conformances should be reported to the assessment manager.

Business Continuity Planning

- Labs must test their business continuity plans and document improvements.
- Plans should cover:
    - Staff shortages
    - Equipment/LIMS failures
    - Mass casualty events
- Staff must be trained and aware of procedures.

Internal Audits

- Audits must be risk-based, with clear objectives and scope.
- Should involve transfusion staff and lead to timely corrective actions.
- Labs should regularly conduct process audits to assess stability and identify risks.
- Use audit and non-conformance findings to drive continuous improvement.

6. Sponsor talks

Each sponsor delivered a 10-minute presentation to the group:

- **Haier Biomedical -** *Delivered by* MW
- **Quidel Ortho -** *Delivered by MM*
- **Brenmoor –** *Delivered by MRo*

7. RCI Updates

Delivered by DL and JM

The summary below captures key points from the RCI Team.

Performance and Workload Challenges

- Colindale RCI has been unable to consistently meet the KPI of 95% turnaround within 5 working days.
- This is due to increased workload and a less-than-optimal skill mix following recruitment of many new staff.
- As staff progress through training and competency assessments, the skill mix is expected to improve, helping meet the 95% target.
- A review of working patterns is underway to strengthen 24/7 cover and better support staff—patience is appreciated.

Turnaround Times and Prioritisation

- Urgent samples are always prioritised to ensure results and crossmatched red cells are available when needed.
- The 5 working day turnaround applies to routine work only; urgent samples are excluded.
- Reports that miss the 5-day target are typically available on day 6.
- RCI is actively working to resolve delays—thank you for your understanding.

Recommendations for Referring Labs

- Crossmatch in-house when possible to reduce transport time and speed up investigations.
- Send good volume samples—one large sample is better than two small ones to avoid duplicate testing.
- For regular referrals, ensure clinicians collect extra samples each time.
- Provide advance notice for regularly transfused patients to allow investigation during core hours.
- Request extra units rather than adding later—this is more cost-effective and efficient.
- Use RCI Assist for guidance and support.

HGP Genotyping for Sickle/ Thalassaemia Patients

- Patients with haemoglobinopathies should ideally have an HGP genotype performed at IBGRL.
- Standard phenotyping/genotyping may misclassify variant antigens as positive.
- Patients with variant antigen expression should be considered antigen negative to avoid sensitisation.
- HGP genotyping uses primers for common variants in affected ethnic groups.
- Do not send HGP genotype requests to RCI—send directly to IBGRL or via hospital services.

RCI Colindale Services

Handles complex serological cases from 65 referring laboratories.

Services include:

- Antenatal antibody titration/quantification.
- Feto-maternal haemorrhage estimation.
- Resolution of anomalous ABO/RhD groups.
- ABO titrations for transplant patients.
- Genotyping when phenotyping isn't possible.
- Referrals to IBGRL.
- Provision of crossmatched units when on-site crossmatch isn't possible.

Routine Referrals

- Approx. 65 per day.
- Day 1 starts when RCI receives the sample; report due by Day 5.
- Many cases are first-time referrals requiring manual LIMS entry.
- Tests are based on information provided by referring labs.
- Most samples run on Grifols analyser for ABO/RhD and Rh/Kell phenotype. Exceptions include:
    - Strong cold agglutinins.
    - High titre antibodies.
    - Known anti-c antibodies.
    - FMH referrals (run post-estimation).

Urgent Referrals

- Turnaround is based on date and time required.
- "ASAP" is discouraged—please specify exact timing.
- Urgent referrals are often handled by a single individual, sometimes out of hours.

- RCI receives ~20 urgent referrals daily, occasionally up to 35.
- Good clinical planning for frequently transfused patients is highly beneficial.

How You Can Help RCI

- Only call if a result is needed in <24 hours.
- Call at 9am if investigation should start then—avoid late calls after 5:30pm.
- Consider transport time when requesting crossmatched units—some sites are up to 5 hours away.
- Crossmatch on-site if possible to eliminate transport delays.
- Always send adequate sample volume—preferably two well-filled samples.
- Remind clinicians to collect extra samples for known frequent flyers.

8. Laboratory Matters

Delivered by JV

The summary below captures key points from the Laboratory Matters discussion, focusing on sample validity post-delivery, system limitations, and clinical implications. The conversation highlighted inconsistencies in how laboratory systems apply the 3-day sample validity rule for patients who have recently delivered, and the challenges in aligning practice with national guidelines.

Sample Validity Post-Delivery

- After delivery, patients are considered to have been pregnant within the last 3 months, triggering a 3-day sample validity.
- After the 3-month post-delivery period, sample validity returns to the standard 7-day rule.
- Example: Delivery on 1 January → 3-day validity applies until 31 March → 7-day rule resumes from 1 April.
- If a patient returns within days of delivery, the system should still apply the 3-day rule, but this is not always reflected in current LIMS configurations.

System Limitations and Workflow Challenges

- Most LIMS do not automatically apply the 3-day rule post-delivery unless pregnancy status is manually flagged.
- Booking a sample as “routine” post-delivery often does not carry forward pregnancy status, leading to incorrect 7-day validity.

- Systems like WinPath may reset the 90-day clock if the patient is grouped again, causing inconsistencies.
- The process is heavily reliant on clinical teams to provide accurate pregnancy/delivery information.
- Without proper flags or updates, labs may default to the 7-day rule, risking guideline non-compliance.
- Some labs leave the pregnancy flag active for part of the post-delivery period to maintain correct sample validity.

Pregnancy Flags and Automation

- A pregnancy flag can trigger the 3-day rule but must be manually removed post-delivery.
- If not removed, the system may continue applying the 3-day rule unnecessarily.
- There is a need for rule-based automation, e.g. using EDD (Estimated Delivery Date) to calculate sample validity windows.
- Suggestions included creating a looping rule to extend 3-day validity for 90 days post-delivery.
- Better integration between maternity data and lab systems is needed to ensure accuracy and reduce manual intervention.

Clinical Implications

- Post-delivery patients may experience delayed transfusion reactions due to large feto-maternal bleeds.
- Antibodies may not be immediately detectable, making timely and appropriate sampling essential.
- Sample validity rules must reflect clinical risk, especially in the immediate post-delivery period.

Operational Considerations

- Some hospitals apply a universal 7-day validity for all patients due to operational constraints.
- Frequent sampling for outpatients (e.g. pre-op, palliative care) can be burdensome and costly, especially in larger hospitals.
- Smaller hospitals may manage stricter sampling rules more easily.
- Manual awareness of transfusion history is still required, especially if transfusion occurred at another site.
- There is interest in developing more consistent and automated workflows across different LIMS platforms.

9. Lookback Forms

Delivered by RE on Microsoft Teams

Overview of the Epidemiology Unit

- Responsible for surveillance schemes monitoring the safety of blood, tissue, and organ supplies.
- Involved in annual reporting and reviews, including infographic booklets.
- Supports evidence-based policy changes and evaluations.
- Team includes data managers, epidemiologists, and public health professionals.

Surveillance and Data Collection

- Monitors infections and transfusion/transplant-related adverse events across the UK (England, Scotland, Wales, Northern Ireland).
- Collects data from:
  - Donor registration (demographics)
  - Donation sessions
  - Routine screening
- Infection rates in donor groups remain low; UK maintains one of the safest blood supplies globally.

TTI vs. Lookback Investigations

- TTI (Transfusion-Transmitted Infection):
  - Triggered by an event in the recipient.
  - Hospital contacts the Blood Service to initiate investigation.
- Lookback Investigation:
  - Triggered by an event in the donor
  - Blood Service initiates by sending a Lookback Form to the hospital.

Transition to Microsoft Forms

- Pilot underway to replace paper forms with Microsoft Forms.
- Same data fields and process as current paper form.

- First five fields pre-filled; hospitals complete from question six onward.
- Form adapts based on responses (e.g. transfused vs. not transfused).
- Allows saving a PDF copy for hospital records.

Summary and Benefits

- Lookback investigations help maintain a safe blood supply by identifying at-risk recipients.
- Hospital engagement is crucial for timely surveillance, testing, and referral.
- Transition to electronic forms will improve accuracy, enhance efficiency and simplify hospital workflows

-- Meeting Ends --