

**United Kingdom Transfusion Laboratory Collaborative (UKTLC)
Minutes of a meeting held on 15 November 2017
at 12 Coldbath Square, London, EC1R 5HL**

Present:

Rashmi Rook (RR)	(Chair)
Debbie Asher (DA)	(Eastern Pathology Alliance/ TLM)
Paula Bolton-Maggs (PBM)	(SHOT)
Anna Capps-Jenner (AC)	(CCMO's NBTC)
Hema Mistry (HM)	(SHOT)
Malcolm Needs (MN)	(IBMS - Transfusion Science Chief Examiner)
Claire Witham (CWh)	(UKNEQAS)
Lee Wong (LW)	(NHS Wales)
Chris Robbie (CR)	(MHRA)
Megan Rowley (MR)	(RCPath - via phone)
Caroline Subramaniam (CS)	(UKAS)
Chris Ward (CW)	(IBMS, Head of Examinations)

1. Introductions/ Apologies

RR welcomed everyone to the meeting. Apologies were received from Alison Geddis (AG) (NHS Northern Ireland), Marie McQuade (MM) (NHS Scotland), Julie Staves (BBTS/ CMO NBTC) and Alison Watt (AW) (SHOT)>

2. Actions from last meeting

Terms of Reference (ToR)

The revised ToR document was briefly discussed and it was suggested that someone from a Red Cell Immunohaematology (RCI) laboratory should be invited to join the UKTLC. RR requested that if anyone thought of any other changes that were required to the document to let her know and she would also seek to find a representative from an RCI laboratory to join the UKTLC.

ACTION: RR/ALL

Staff capacity planning guidance

RR had circulated with the papers for this meeting a draft version of a potential staffing capacity plan. It was suggested that turnaround times could be used as part of the evidence for the final classification as this was a commonly used quality indicator. RR requested that any additional comments on the capacity plan be sent to her before this was finalised.

ACTION: RR/ALL

TLC Survey

PBM stated that she was writing an article for Transfusion Medicine on the outcomes of the survey and agreed to circulate this once it has been drafted.

ACTION: PBM

RR suggested that it would also be useful to include something in the Health Services Journal on the matter. The group felt that this should happen after the article appears in Transfusion Medicine.

Technical Lead

It was noted that it needs to be considered that restructuring within laboratories will inevitably mean that different individuals will complete and therefore the action relating to defining the term technical lead which has not been completed will need to be done ahead of any future survey.

ACTION RR

Blood Compliance Report

RR noted that one additional question had been included in the latest Blood Compliance Survey but it was felt that the UKTLC would like to have greater involvement next time. RR agreed to write to the Blood Consultative Committee (cc'ing CR) to request greater UKTLC input in the future.

ACTION RR

3. Feedback: Scotland/ Wales/ Northern Ireland/ Private sector/ BT committees

Scotland and Northern Ireland

In the absence of Marie McQuade and Alison Geddis there were no updates from either Scotland or Northern Ireland.

Wales

LW explained that there remains a general shortage of Biomedical Scientists across the 19 laboratories in Wales. She also informed the group there were 21 Welsh Government sponsored places for Healthcare Scientists in 2018. This degree programme was undertaken through Cardiff Metropolitan University and those who took sponsor place were required to stay in Wales for a period of time at the completion of their degree. LW also explained the Welsh Government sees life sciences (of which Biomedical Science is part) as a critical area and therefore funding is also going into Level 4 apprenticeships.

LW also outlined the fact that Welsh health service is moving towards all using the same LIMS system however there are some complications caused by the way legacy data has been recorded across different institutions which has slowed progress.

TLMs

DA stated that there are on-going staffing issues at Bands 5 and 6 in her region and that they growing their own in attempt to at least partly resolve these problems. She explained that there are 13 people currently undergoing training (at Specialist Portfolio level) in Norwich alone but a problem they have experienced is people leaving for jobs in Cambridge and London once they have completed their training. DA also commented that locums are being used to fill the gaps but that these were not always of the best quality.

Private Sector

AC reported that her company are investing in training and that individuals are being put through both BBTS and IBMS qualifications as well as through in-house training programmes.

AC queried as to how the new pathology networks proposed in the recent NHSI document would actually work and whether any GAP analysis would be undertaken to ascertain the training and qualifications that are needed in each area.

4. SHOT Update

PBM highlighted the publication of the SHOT report which had shown similar patterns to previous reports. The report summary can be found here:

<https://www.shotuk.org/wp-content/uploads/SHOT-Report-2016-Summary.pdf>

It had resulted in two recommendations (the use of a bedside checklist as standard of care and the use of a Transfusion-associated circulatory overload (TACO) checklist). PBM explained that as a result of this the Department of Health had issued to all organisations that provide NHS funded care

which involves the provision of blood transfusions an immediate CAS alert on Safe Transfusion Practice: Use of a bedside checklist. This alert can be accessed here:

https://www.shotuk.org/wp-content/uploads/DoH-CAS-Alert-Safe-Transfusion-Practice_Use-a-bedside-checklist.pdf

It was agreed that it should be noted that the UKTLC fully endorse the outcomes of the report and its key recommendations.

Fresh Frozen Plasma (FFP) Compatibility Rules

MR expressed some concerns about the rules around FFP which are held within some LIMS systems and the need to balance risk against unnecessary blood delay. MN commented that response received from some laboratory staff was not always helpful and therefore the provision of mismatch tables to staff could help to resolve this issue.

SHOT Bite

MR explained she is writing a SHOT bite on IT and there were plans to undertake a survey on the knowledge and experience of LIMS. It was suggested that this could be included in the next Compliance Report. It was also explained that the SHOT Symposium will take place on 12 July.

General Data Protection Regulation (GDPR)

PBM explained with the introduction in May 2018 of GDPR (it replaces the Data Protection Act) that SHOT has undertaken an information governance review and will be amending its privacy statement. The Information Commissioner Office had provided guidance of the pseudo-anonymisation of data in reports so that ages but not date of birth would be used in reports. SHOT will also be ensuring that secure email addresses for the exchange of data.

Irradiation Labelling

There was discussion on the proposed new labelling for irradiated blood components and concerns were raised over the possibility of confusion with the new labels and the lack of consultation in the decision-making process. It was recognised that there would be commercial implications for any changes at this stage but the group thought unanimously agreed that its concerns should be raised as a matter of urgency. PBM agreed to contact Gail Mifflin, Medical and Scientific Director (NHSBT) on this matter

ACTION PBM

5. UK NEQAS Report

CWh provided an update on the UK NEQAS Blood Transfusion Laboratory Practice (BTLP) pre-transfusion testing exercise codes 17E7 (Antibody screen/identification) and 17R8 (ABD/D antibody screen/identification, cross-match and red cell phenotype).

CWh also explained that there were plans to review the structure of the scheme and that early planning was underway to undertake a practical exercise with HEI's and asked whether the Institute of Biomedical Science (IBMS) could support this. CW agreed to send CWh a list and contact details for all IBMS accredited Biomedical Science degree programmes but did point out that there are other institutions that offer Biomedical Science but which are not accredited by the Institute. CWh stated that the first part of the process would to ascertain the willingness of the HEIs to be involved and the equipment, consumables and costs to the institutes.

CW

6. BBTS Report

In the absence of Julie Staves there was no update on this item.

7. UKAS Report

Caroline explained that there are changes in the latest version of the ISO standard for sample tubes. Originally this was ISO 6710:1995, with BS EN 14820:2004 as a stop-gap standard. ISO 6710:2017 has been in the works for some time, and has now been formally released. It is the standard used by manufacturers for venous blood collection tubes.

Caroline stated that previously, there were differences in the tube cap colours between manufacturers and this caused, and still causes, problems with wrong sample tube types being sent to the lab, especially where hospital catchment areas overlap, share phlebotomy services, and with rotating clinical staff. The ISO committee took the view that this potential for patient harm should be removed, and have coalesced around a set of 'standard' tube colours, denoted in Annex F of the 2017 standard.

The problem has arisen because there are only a finite range of colours that we can use for tube caps. Each must be chromatically distinct, such that humans and pre-analytics can recognise the different specimen types. Most of the world doesn't denote crossmatch samples with a pink cap and stripe, leaving that colour without a harmonised application. Therefore, pink has now been assigned to the citrated fluoride tube ('rapid glucose') for glucose analysis.

Caroline informed the group that Annex F that this is detailed in is an Informative Annex. The standard itself has an 18-month transition period in Europe. During and after that time, the colour coding is not mandatory. Increasingly rapid glucose tubes will coexist in healthcare facilities alongside crossmatch samples and there is a clear patient safety and compliance issue if a crossmatch sample is bled into a rapid glucose tube. A serum crossmatch tube will show a clear difference, but it is unclear what the effects are of using a citrated sodium fluoride tube instead of EDTA. Conversely, EDTA will be utterly unsuitable for glucose preservation.

Any changes needs to be on the terms of what is best for patients, and in the context of widespread agreement and it will take time for companies time to create new tube variants, so a national consensus, and driving the change in a proactive manner seems to be the best path.

Caroline also explained that UKAS have produced a Position Paper relating to the Assessment of a Medical Laboratory's approach to the assurance of clinical staff competence and the use of EQA. That Technical Bulletin can be found here:

<https://www.ukas.com/download/technical-bulletins/2017.11.28-Technical-Bulletin-UKAS-Position-Paper-Clinical-Staff-Competence.pdf>

In summary this bulletin states that the assessment of the laboratory's approach to evaluating clinical staff competence may include assessment of, but not necessarily be limited to, the following:

- Qualification records, experience, knowledge, appointment process, induction, training sign off
- Records of EQA participation
- Mechanisms to monitor on-going competency internally and associated records
 - Any competency assessment programme would have defined acceptance criteria, including for clinical staff. It would be expected that such an on-going programme is suitably robust to cover all of the staff member's scope of activity, at sufficient frequency.
- Records of knowledge sharing, for example MDT involvement, case review discussions, case handovers, on call involvement
- Suitability of competency programme acceptance criteria
- CPD (e.g. College CPD, external meetings, course evaluations, iEQA)
- Review of test reports

- Coverage of all areas by internal audit
- Minutes of meetings aimed at service improvement

8. MHRA Report

CR explained the new guidance for the SHOT/SABRE systems is live and that registered reporters would have to sign-up to participate in the forums. He also informed those present that the inspection programme is currently underway but could not go into any more details on the outcomes of any inspections.

The group discussed SABRE reporting arrangements and how a judgement can be made on whether a particular laboratory was under-reporting. It was reported that there appeared to be little correlation between those that were 'high risk' and the amount of reporting that they did and it was suggested that inspectors need to look at the incidents reported locally as those reported to SABRE.

9. RCPATH Report

MR indicated that the Transfusion Medicine Specialty Advisory Committee had not met in recent months but the SHOT report had been discussed with the President of the College (Dr Suzy Lishman) and it was hoped that at least the summary report could be placed on the RCPATH website. Megan reported that she was meant to be stepping down from the role as Chair of this particular SAC but that she would be keen to remain part of that Committee. It was noted that PBM will be the new Chair of this particular SAC.

MR also discussed the proposals around the harmonisation of IT and that there was a recent meeting of the writing group of the previous IT guidelines to discuss the issues that need to be considered. It was suggested that should be a survey of IT suppliers to how these work and where responsibilities lie but it was noted that LIMS systems are not medical devices and therefore are not CE marked and that this posed a challenge for the harmonisation work.

10. IBMS Report

CW highlighted the fact that the Institute is currently revising the content of the Haematology with Transfusion Science Practice Specialist Portfolio and that members of both the haematology and transfusion science advisory panels are contributing to this work. He also commented that the IBMS are working with universities to accredited Level 6 apprenticeship programmes.

CW stated that the results of the Higher Specialist Diploma (HSD) exam were scheduled to be released on Friday 17 November and that five of the nine transfusion science candidates has passed. He also commented that the numbers scheduled to undertake the HSD in 2018 were significantly higher across all the disciplines including transfusion science with currently 17 candidates due to submit for this subject. MN need explained that in relation to the responses given by the HSD candidates that the examiners were disappointed in the nomenclature used and that some candidates did not answer the question set but rather the question they hoped would be asked!

CW also explained that an external examiner has recently reviewed the HSD and following comments from the IBMS advisory panel members the IBMS Education and Professional Standards Committee had agreed to review aspects of the HSD including the syllabus content and this work would take place in 2018. RR commented whether the IBMS could work with the BBTS on this so that the qualifications that both organisations offered complimented each other.

MN stated the second edition of the OUP book on Transfusion and Transplantation Science is due out in 2018.

11. Group Discussion: Way forward - Actions and Plans

UKTLC Standards

The group discussed what qualifications and experience should be acceptable for different grades and it was decided that this was an opportune moment to review and where appropriate revise the UKTLC standards and that this could include an addendum to cover IT systems.

It was thought that this could take place during 2018 and that the SHOT symposium in July would be a good place to highlight the planned work. RR agreed to put together a proposed timeline for this work which would be circulated to the group for discussion.

ACTION RR

Centralised Support

It was discussed whether the UKTLC would benefit from having central forum where pertinent issues could be raised and debate. Concerns were expressed about who would control this and how it would be monitored and that there are dangers associated with Social Media.

CWh indicated that she was the Chair of the Quality Forum for the appropriate UKNEQAS scheme and that they had felt that individuals would be more likely to engage and be responsive to an application rather than using a centralised email forum.

RR and CWh agreed to work together on appropriate support system for the UKTLC.

ACTION RR CWh

NHSI Pathology Networks

The recent NHSI Future Pathology Networks document was mentioned. It was noted that the document did not specifically refer to Transfusion Science and its possible implications for the system. It was queried as to whether anyone was aware of any changes that were already happening as a result of this document. No one at present had any knowledge of any changes that were being planned as a result of this document but it was agreed that UKTLC members would keep each other informed as and when any changes took place in their area.

ACTION ALL

12. Succession Planning

CW highlighted the fact that AG is due to become the new President of the IBMS at the start of 2018 and therefore he was unsure whether she would remain on the UKTLC. He agreed to liaise with her to ascertain her intentions regarding her membership.

ACTION CW

It was also noted that MM is on a phased retirement and therefore is likely to be leaving the group shortly. RR agreed to liaise with MM on the timescales for this and to find an appropriate replacement.

ACTION RR

13. AOB

Academy of Healthcare Science (AHCS)

It was queried as to whether the UKTLC should become a member of the AHCS Professional Council. CW explained that the Institute does have links with the Academy and was unsure as to whether the

UKTLC would be able to join the Academy. The group felt for the time being it would not pursue either full or observer member of the AHCS Professional Council.

Post-Meeting Note

For more information the Academy was set up explicitly to deliver the Certificate of Attainment and the Certificate of Equivalence for the Scientist Training Programme (STP), Equivalence and voluntary registers for those outside statutory regulation. More recently it has evolved to deliver the Practitioner Training Programme (PTP) and the Higher Specialist Scientist Training (HSST). More information on the Academy can be found here: <https://www.ahcs.ac.uk/>

14. Dates for next meeting

CW would circulate potential dates for the next meeting of the group.

ACTION: CW