United Kingdom Transfusion Laboratory Collaborative (UKTLC)
Minutes of a meeting held on 14 November 2019
at MHRA, 10 South Colonnade, Canary Wharf, London, E14 4PU

Present:
Rashmi Rook (RR) (Chair)
Anna Capps-Jenner (AC) (CCMO’s NBTC)
Sinead Carty (SC) (NHS Northern Ireland – via phone)
Chris Robbie (CR) (MHRA)
Julie Staves (JS) (BBTS/ CMO NBTC – via phone)
Caroline Subramaniam (CS) (UKAS)
Tracy Tomlison (TT) (NHSBT – RCI)
Vicky Tuckley (VT) (SHOT)
Claire Whitham (CWh) (UKNEQAS)
Lee Wong (LW) (NHS Wales)
Chris Ward (CW) (IBMS, Head of Examinations)

Guests
Kerry Dowling (KD) Southampton NHS FT
David Johnson Imperial College NHS Trust
Zoe Sammut Western Sussex Hospitals

1. Introductions/ Apologies
RR welcomed everyone to the meeting. Apologies were received from:
Debbie Asher (Eastern Pathology Alliance/ TLM)
Paula Bolton-Maggs (RCPath)
Malcolm Needs (IBMS - Transfusion Science Chief Examiner)
Dr Shruthi Narayan (SHOT)
Courtney Spinks (CSp) (SHOT)
Anne Thomson (AT) (NHS National Services Scotland)
Tracy Tomlinson (TT) (NHBST (RCI))
Dan Willis (DW) (Centre of Defence Pathology)

RR noted that Malcolm Needs had written to CW and herself to inform that he was stepping down from the UKTLC with immediate effect. CW informed that Malcolm had also stood down from his role as Chief Examiner on the IBMS Transfusion Science advisory panel.

LW informed that this would be her last meeting representing Wales on the group but that a replacement representative for Wales had been identified.

All members of the group wanted to put on record their thanks to Malcolm and Lee for their work whilst they have been members of this group.

2. Actions from last meeting held on 15 May 2019

Capacity Planning
RR thanked those who following the last meeting had sent her examples of their capacity plans. The draft Capacity Planning Guidance document had been circulated with the papers for the meeting. Group members were asked to review the draft document and to send RR any comments by Friday 29 November.

ALL/RR
Once the document has been finalised it was agreed that it should be disseminated as widely as possible. It will be published on the TLM forum, sent to the National Blood Transfusion Committee so that they can send it on to Laboratory Managers and LW stated she would be able to send it to an appropriate group in Wales. The finalised version will include the logos of the organisations responsible for the document.

3. **UKTLC Survey 2019 Findings**

The draft document that summarised the findings of the UKTLC 2019 Survey had been circulated with the papers for the meeting. Panel members were asked to send any comments they have on this to VT by Friday 29th November.

The finalised version will be available on the SHOT website and will be added to the Blood Forum. It was agreed that it will be cascaded through the TLM group.

UKTLC members felt that it should be a maximum of three years before the survey was undertaken again and agreed that the questions should be reviewed ahead of the next survey and that consideration should be given on other ways of collecting the data. It was agreed that this would be an agenda item for a future meeting of this group.

4. **Culture Survey Report**

The draft 2019 UKTLC Culture Survey Report had been circulated with the papers. The report is based on a survey of the culture prevalent in transfusion laboratories across the UK. It was undertaken as a joint venture by the MHRA, UKTLC, SHOT and the Transfusion Laboratory Managers working group of the National Blood Transfusion Committee. It was noted that CSp (SHOT) is drafting a covering letter to be issued with the publication of this report and therefore it was important to agree its contents and the logos that would go on the front cover of the report.

RR asked whether the IBMS logo could be added to this report and whether an article could appear on it in the IBMS Biomedical Scientist. CW agreed to liaise with the Deputy Chief Executive (Sarah May) on this matter.

SC stated she would enquire as to what logo could be placed on the report to show that laboratories in Northern Ireland had been involved.

CS agreed to confirm whether the UKAS logo could be included.

As they were absent from the meeting today RR agreed to liaise with AT regarding an appropriate Scottish logo; DW regarding and Defence logo and with TT regarding any NHSBT logo going on the front cover of this Culture Survey Report along with the BBTS logo.

5. **Non-medical authorisation/recommendations for stand-alone work practice**

LW indicated that she had attended a workshop in March to discuss this issue. She explained that in Wales there is a ten-day course aimed at pharmacy staff, ambulance service, physicians and other emergency staff that leads to a qualification (tied with Swansea University) for non-medical prescribers. Members of the group that in England that there was no such national course but that instead there were local internal intensive courses that were aimed at a similar individuals with the same outcomes.
It was felt that the new UKTLC standards should include something on the formal training of people in such prescribing roles.

6. Feedback by Organisations

NEQAS Feedback
CWh provided an update on the NEQAS exercises that had been undertaken recently. For 19E1 CW commented that there remained issues with one manufacturer and that a ‘Yellow Card’ report had been produced for this.

UKAS Feedback
CS provided on behalf of UKAS the following response around the Measurement of Uncertainty for the Blood Grouping Test.

CWh indicated that she will be presenting at a future NEQAS meeting on the confidence of the test as a whole and will report back at the next UKTLC meeting.

RCPath Feedback
PBM provided the following update for the inclusion in the minutes:

MHRA Feedback
CR indicated that there had been no great variations in the number of incidents that were being reported. He stated that it was encouraging that the quality of the reports was improving and from these reports it was clear that the root causes of many of the incidents remained the same.

IBMS Feedback
CW indicated that the 2019 HSD exam results were to be issued on the 15th November and that disappointingly in Transfusion Science only three out of nine candidates has passed (overall across all disciplines 23 out of 41 had passed).

He informed the group that the HSD is an ‘M-Level’ qualification and that it required a significant depth and breadth of knowledge. He added that it appeared in many cases, despite the IBMS providing guidance and support on the issue, that candidates had difficulty in writing at the appropriate level and were failing to discuss things critically. LW indicated that this is an also issue that she had come across in her dealing with qualifications offered by Swansea University. CW suggested that some candidates may be undertaking the HSD before they had sufficient experience because they required it to gain a more senior role.

CW provided the group with information on the on-going HSD review and how it was hoped that the outcomes of that work might improve the performance of candidates in the exam. Finally, he provided the group an outline of the Certificate of Expert Practice (CEP) Distance Learning qualifications that the IBMS offers in Leadership and Management, Quality Management and
Training. It was agreed that these might be suitable for inclusion in the UKTLC Standards and CW was requested to send RR details on these qualifications.

7. TLMs Feedback

IT Issues
There was a discussion around the issues of IT/LIMS systems and how they coped with the specific requirements of Transfusion.

Several members commented that their systems were not coping and that remote/electronic issuing could not take place without building in a ‘manual work-around’ which added to the complexity of process. It was felt in some cases that Trusts were purchasing pan-pathology systems that were not fit for purpose with insufficient User Acceptance Testing (UAT) taking place and non-conformities not being properly addressed. It was recognised that whilst pan-pathology systems had some merit it was queried whether they were always appropriate.

Other members present suggested that it was essential at the start of the tender/procurement process the precise requirements of all disciplines including Transfusion were documented accurately. If this is done properly it is much easier to reject proposed systems from suppliers if they fail to meet the specified requirements.

LW highlighted the issues that NHS Wales had experienced in their Data Migration process with Transfusion remaining outside the pan-pathology and pan-hospital system because of the specific needs of this discipline.

8. Focus for SHOT Report Chapter

VT indicated that the chapters in the new report will be shorter than in previous reports and that it will be available principally on-line rather than as a printed report. She added that the report will include clear definitions and that the report will include sections on the IT issues that laboratories faced. RR indicated that she was drafting a chapter for the report. The group also discussed the Capacity Plan and questioned as to whether laboratories will use it and adhere to its suggestions and the impact that such a Plan might have.

9. UKTLC Standards: Chapters

The group discussed the template for the UKTLC Quality Standards for Transfusion Laboratories: Assuring Safety of Patients and Staff. This template had the proposed headings for the chapters of the next version of the standards. Following the discussions that took place the template for the chapters within the Standards was agreed and certain members of the group agreed to take on work in drafting specific sections.

Purpose
It was felt essential that the purpose of the Standards is described and that this section clearly explains who the Standards were aimed at. It was felt that the Standards are aimed at Directors of Pathology and Executive Teams with Laboratory Managers being aware of the Standards. It was agreed that the Standards themselves should be seen as good practice and mechanism for developing a quality system and ultimately improve patient safety in Transfusion.

AC to work with Donna Wiles on developing a clear purpose statement.
**Vision**
The vision statement should make clear that the Standards are aiming for maintaining and improving standards within Blood Transfusion with the aim of creating a safe environment.
KD indicated that she will attempt the first draft of this vision statement.

**Background**
This section will include references to the recent SHOT and SABRE reports. It was agreed that the summary produced by SN (SHOT) should be included in this section.

**UKTLC Collaborators**
This section will include details on all the organisations involved in the development of the Standards.

**Culture**
This section should include references to the Francis, Butler, SHOT and Culture Survey Reports all of which have helped to shape the Standards. This section should also include details on the culture that is being aspired to – with a focus on openness, transparency and enabling.

**Risks**
It was felt as risks are the basis of UKTLC that some must be referred to. There are risks to the organisations, reputational risk and those to patients. It was suggested that some of the recent blood scandals should also be referred to in this section.

**Legislation and Regulation**
There are various pieces of legislation and regulation (rather than accreditation as initially suggested) including ISO 15189, Health and Social Care Act, Medical Devices Regulation, Medicines Act, General Data Protection Regulation (GDPR), RCPath ‘Choose Wisely’ Guidance, NICE Guidelines, British Society for Haematology (BSH) Guidelines, NHS ‘Never Events’, National Institute for Health and Care Excellence (NICE) Guidance, Human Tissue Act, and Council for Europe – Good Practice for Blood Establishments. All of these, and possibly others, influence the work of Blood Transfusion Laboratories and will impact on what is included in the Standards themselves.

**Transfusion Community Interactions**
This will include the laboratory and transfusion teams and other individuals such as the ‘Responsible Officer’ (equivalent to the CEO), Blood Bank Manager, Training and Quality Manager(s), Pathology IT Manager, Consultant Clinical Scientists, Pathology Management Team, Consultant Haematologists and UK Blood Services.

**Networks**

**THE STANDARDS:**

**A: Staffing**
This will include reference to the Capacity Planning documentation and the importance of appropriate staffing levels and skills mix.

**B: Qualifications and Knowledge**
Qualifications for staff at different levels, including support staff, should be referred to and staff need to be directed to appropriate qualifications and to recognise the importance of CPD. Qualifications
can include the Higher Specialist Diploma (HSD), potentially the IBMS Certificate of Expert Practice (CEP) Distance Learning qualifications and relevant MSc’s.

**C: Training**
This includes training on issues such as competences, supervision, mentoring, good practice, leadership, major events, LIMS downtime etc.

**D: Resources**
This section will refer to funding/budgets for courses, attendance at meeting and training, protected time and QMS maintenance.

**E: Equipment**
This will include Laboratory Information Management Systems (LIMS), Tracking Systems, Electronic Identification, Temperature Monitoring, Analysers and Quality Management Systems.

**Monitoring Adherence to the UKTLC Standards**

**Acknowledgements**

**References**

**Publication of Standards**
RR indicated that she would like the finalised version of the Standards to be published by February/March 2020 and that once completed they will need to be publicised widely.

10. **Succession Plans / Key Posts for 2020**

It was agreed that UKTLC needs to review its membership to ensure that it continues to have clear representation from the relevant groups/interested parties from across the four nations. RR indicated that she would be willing to stay as Chair but would also welcome anyone else taking on that role as she has been in that position for three years.

RR will work with CW in early 2020 to review the membership of the group.

11. **AOB / Dates for Next Meeting**
The next meeting of the UKTLC will take place in spring 2020.