UK TRANSFUSION LABORATORY COLLABORATIVE

Minimum standards for staff qualifications, training, competency and the use of information technology in hospital transfusion laboratories 2023

Purpose

The UKTLC standards have been revised for 2023, replacing the previous version (Chaffe *et al.*, 2014) and a full report will be published in Transfusion Medicine. An abridged version of the standards is provided here for laboratories to begin the compliance and gap analysis process. To support this process a gap analysis template is also provided, along with other resources that can be used to aid compliance.

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UKTLC collaborators

The UK Transfusion Laboratory Collaborative membership is: Institute of Biomedical Science (IBMS), British Blood Transfusion Society (BBTS), the Medicines and Healthcare products Regulatory Agency (MHRA), the Ministry of Defence (MoD), the Royal College of Pathologists (RCPath), Serous Hazards of Transfusion (SHOT), United Kingdom Accreditation Service (UKAS), United Kingdom National External Quality Assessment Service (UKNEQAS) and the NHS England National Blood Transfusion Committee (NHSE NBTC) and their equivalents in Scotland, Wales and Northern Ireland. The standards have been revised, agreed and approved by these professional bodies.

The Standards

Standard 1: Staffing

Standard: **1.1 Staffing levels**

Appropriate laboratory staffing levels must be in place to ensure the safe and effective delivery of all transfusion service activities and be subject to regular review, risk assessment and agreement through local governance structures. Staffing level assessment should include consideration of the laboratory practical workload, training requirements and QMS activities.

Standard 1.2 Capacity plan

A regularly reviewed capacity plan must be in place covering the numbers and skill mix required to provide a safe service. The capacity plan must include all aspects of the service, including supervision, training and the QMS.

Standard 1.3 Quality management system
It is expected that all of the requirements of a quality management system (BSQR SI50/2005) and ISO15189 are included in capacity planning as part of the workload and service delivery.

Standard 1.4 Transfusion advanced specialist staff
There must be an adequate number of staff (as defined within the laboratories capacity plan) with specialist transfusion knowledge (see standard 2.1) and skills to provide supervision over the transfusion service. These specialists must have protected time agreed enabling them to provide the quality management system elements of the workload, service improvement projects and to maintain specialist knowledge, competence and CPD.

Quality measures:

All transfusion laboratories must have in place:

- Capacity plan and evidence of regular review
- Risk assessment that includes impact of staffing levels and contingency plan if staffing levels drop below minimum
- Evidence that staffing levels and risk assessment are agreed and reviewed at governance level

Standard 2: Qualifications, knowledge and skills

Standard 2.1 Advanced Biomedical Scientist or Clinical Scientist Band 7 and above
2.1.1 It is expected that all registered members of staff working at Agenda for Change (AfC) band 7 or above who either train staff, supervise and/or take responsibility for work at any time within a blood transfusion laboratory will hold at least one of the qualifications listed in Appendix A.

2.1.2 Within hospitals where AfC band 7 staff are currently in post who do not hold one of the qualifications listed in Appendix A, the hospital should risk assess the post and evidence that the staff at band 7 meet the hospitals requirements for the clinical specialisms and the job description for the role. The guidance for equivalency could be benchmarked against the learning outcomes of the IBMS HSD.

2.1.3 Advanced staff members (Band 7 and above) who would be expected to carry out routine laboratory practical tasks should complete a minimum of 10 working days per annum performing these activities in a blood transfusion laboratory.

2.1.4 To help facilitate compliance with the BSQR SI50/2005 advanced specialist staff are required to participate in the following:

- a programme of practical and knowledge-based competency

- regular education, training and CPD for scientific, managerial, leadership and QMS activities

2.1.5 It is expected that access is available to advanced specialist staff at all times for transfusion specific advice. Organisations should devise a strategy to enable advice to be available to specialist/non-specialist staff. Examples include pathology networking, on call, back up rosters.

2.1.6 To help facilitate compliance with the BSQR SI50/2005 and 2.1.5 it is expected that advanced specialist staff will be enabled to fulfil their specialist role. Organisations should not routinely roster advanced specialist staff for:

- the staff establishment required for practical service provision
- the rota for non-core hours service provision if there is any impact on core hours availability

Standard 2.2 AfC Band 6 and 5

2.2.1 It is expected that all registered members of staff working at AfC band 6 or above who work alone *unsupervised* at any time within a blood transfusion laboratory will hold at least one of the qualifications listed in Appendix B.

2.2.2 Within hospitals where AfC band 6 staff are currently in post who do not hold one of the qualifications listed in Appendix A, the hospital should risk assess the post and evidence that the staff at band 6 meet the hospitals requirements within the job description for the role. The guidance for equivalency could be benchmarked against the learning outcomes of the IBMS Specialist Portfolio or another qualification within appendix B.

2.2.3 Multi-disciplinary scientific staff (Band 6 and 5) who would be expected to work within blood transfusion should complete a minimum of 10 practical working days per annum in a hospital blood transfusion laboratory.

2.2.4 It is expected that all staff including locums working at AfC band 6 or above will be assessed and documented as competent in all relevant local work practices prior to any unsupervised lone-working.

2.2.5 It is expected that staff working at AfC band 5 in a Blood Transfusion laboratory who wish to progress to band 6 should be working towards the qualifications identified in Appendix B.

Standard 2.3 Scientists in training and support staff

2.3.1 It is expected that all registered members of staff working at AfC band 5 within a blood transfusion laboratory, who require supervision (e.g. a BMS who has changed discipline, or newly registered professional), will hold or be working towards obtaining one of the qualifications listed in Appendix B.

2.3.2 It is expected that all non-registered members of staff working towards registration will always be supervised by a HCPC registered staff member who also holds a qualification, appropriate to their AfC banding, from those listed in Appendices A and B.

2.3.3 Support staff (AfC band 2-4) working in blood transfusion must have a locally defined scope of practice that sets the appropriate limits on their activities. These staff must have access to registered HCPC scientists for support and escalations.

Standard 2.4 Staff supporting the Blood Transfusion service

2.4.1 It is expected that individuals who manage transfusion services or act as a quality manager for transfusion services, but who do not hold one of the qualifications listed in Appendix A, will seek appropriate specialist advice from a member of staff as defined in standard 2.1, when matters arise that have the potential to impact on the provision of transfusion services and/or patient safety.

2.4.2 It is expected that staff providing quality management expertise, including laboratory haemovigilance activities, will have relevant qualifications, knowledge and skills for this role. It is expected that CPD activities include regulatory aspects of transfusion and haemovigilance.

Standard 2.5 Training and competency assessment

2.5.1 It is expected that all staff including locums working in transfusion will have completed induction and initial training relevant to their role and their grade. There must be provision for planned, regular on-going training and re-training where appropriate. Training programmes must include the quality management system and non-technical skills, as well as the technical skills and knowledge for the role.

2.5.2 It is expected that there will be a locally defined, periodic, risk assessed programme of practical and knowledge-based competency assessment with regular review. All members of staff working at any time within a blood transfusion laboratory must participate in this programme. The programme must cover all aspects and levels of competency relevant to the individual's role and include but not be limited to appropriate scientific, methodological, scenario, high-pressure situations and case-based activities (NHSE, 2014).

2.5.3 Training and competency assessment for staff in advanced specialist roles must include equipment, IT, quality management activities (including change control, validation & incident investigation) supervising and mentoring and personnel management.

2.5.4 The training plan links integrally with the capacity plan to ensure sufficient supervisory capacity. The training plan should include a trigger at which the risks should be escalated (for example trainees to qualified exceeding a 1:1 ratio).

Standard 2.6 Resources

2.6.1 There should be provision within the budget for staff to access external training courses, conferences and meetings relevant to their role. Time requirements for attendance should be included in the capacity plan.

2.6.2 There must be protected time as detailed in the capacity plan, for staff training and competency assessment, that does not impact on service provision or safety.

2.6.3 There must be access to appropriate tools for providing the training and competency assessment.

Quality standards:
Laboratory management must have evidence that all staff working in, or for, the transfusion laboratory have:

- The appropriate qualifications for their role
- The appropriate training for their role
- Regular competency assessment for their role
- Recorded participation in CPD activities, if appropriate

Standard 3: Information Technology

Standard 3.1 Analysers

3.1.1 It is expected that all laboratories will have complete walk-away automation which is in use 24 hours, 7 days a week, interfaced to the laboratory information management system (LIMS). In the absence of full automation, documented measures must be taken in order to mitigate procedural laboratory errors (Jones et al 2014).

Standard 3.2 LIMS

3.2.1 It is expected that the LIMS will be compliant with the BSH guidelines for IT (Jones *et al*., 2014)

3.2.2 It is expected that electronic issue of red cells will be introduced where a laboratory's infrastructure is both robust and supports this procedure as described in both the British Society for Haematology (BSH) guidelines on the specification, implementation and management of information technology systems in hospital transfusion laboratories (Jones *et al.,* 2014) and MHRA electronic issue guidance (MHRA 2010).

3.2.3 Where remote issue of components is in place, or being considered as part of service delivery, guidelines must be followed and full validation performed.

3.2.4 It is expected that the transfusion LIMS has the functionality to prevent the issue of ABO incompatible components, including occasions where units are issued for emergency use or where the patient's blood group is unknown (Narayan, 2021).

3.2.5 Transfusion laboratories must have a documented contingency plan for IT downtimes, planned or unplanned. The plan must be accessible and easy to implement and be included in staff training and competency assessments.

3.2.6 Merging of patient records must be controlled as per the current BSH IT guidelines. If the records merged have different ABO/D groups, different antibody or antigen profiles or different special requirements, the system must alert the user. Differences should be resolved by an individual with transfusion laboratory training/knowledge.

Standard 3.3 Electronic transfusion systems

3.3.1 All available information technology (IT) systems to support transfusion practice must be considered and these systems implemented to their full functionality. Electronic blood management systems (EBMS) should be considered in all clinical settings where transfusion takes place (Narayan *et al*., 2018). This includes safe sample labelling (Robinson *et al*., 2017), collection of blood components from storage and administration to patients.

3.3.2 Temperature monitoring systems should be utilised for safe storage of blood components and products. Systems must be robust with escalation processes that ensure rapid action where temperature excursions have occurred.

3.3.3 Transfusion IT systems must be interfaced wherever possible to reduce the risk of transcription errors. This includes the use of interface systems for transfer of results from external reference laboratories, blood component information from electronic delivery notes from UK Blood Services, test request and component orders from electronic patient record systems and order communication systems. Test results and relevant information must be transferred electronically from the LIMS to other hospital systems wherever possible to avoid errors.

Quality standards:

Systems for electronic transfer of patient results between IT systems must be implemented wherever possible. Risk assessments must include details of mitigating actions where interfaces are not in place.

Standard 4: A Just Culture

4.1 Laboratory management should support a just and learning culture where staff are encouraged to report errors, near miss events, suggestions for improvements and potential risks that may affect patient safety.

4.2 There should be a process for reporting, and learning from, excellence.

4.3 Incident investigation processes must include consideration of human factors and systems thinking, avoiding application of blame on individuals.

APPENDICES.

The qualifications below in Appendices A and B are current at the time of publication of these standards but may be subject to revision in the future. Interested individuals are encouraged to check with the provider listed.

APPENDIX A - Advanced Biomedical Scientist or Clinical Scientist Band 7 and above

In addition to HCPC professional registration:

- IBMS Higher Specialist Diploma in Transfusion Science
- IBMS accredited MSc with a Transfusion/Transplantation specialism of at least 45 Level 7 CATS points
- MSc in another Biomedical Science discipline in conjunction with an IBMS Higher Specialist Diploma in Transfusion Science or a Transfusion Science education course equivalent to 45 Level 7 CATS points
- Evidence of Masters level learning equivalent to 180 Level 7 CATS points with at least 45 CATS points in Transfusion Science
- Fellowship of the Institute of Biomedical Science (FIBMS) by examination (Special Exam, 2-part Fellowship) in blood transfusion or transfusion science

APPENDIX B - AfC Band 6 and 5

In addition to HCPC professional registration:

- BBTS Specialist Certificate in Transfusion Science Practice
- IBMS Specialist Diploma in Haematology with Hospital Transfusion Practice
- IBMS Specialist Diploma in Transfusion Science

References

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