

UK Transfusion Laboratory Collaborative: minimum standards for staff qualifications, training, competency and the use of information technology in hospital transfusion laboratories 2014

B. Chaffe,¹ H. Glencross,² J. Jones,³ J. Staves,⁴ A. Capps-Jenner,⁵ H. Mistry,⁶ P. Bolton-Maggs,⁶ M. McQuade⁷ & D. Asher⁸

¹West Herts Hospitals NHS Trust, UK NEQAS BTLF, Watford, UK, ²Portsmouth Hospitals NHS Trust, Cytology, Portsmouth, UK, ³Welsh Blood Service, Quality Assurance, Cardiff, UK, ⁴Oxford University Hospitals NHS Trust, Blood Transfusion, Oxford, UK, ⁵TDL Pathology, Blood Transfusion, London, UK, ⁶NHSBT Manchester Blood Centre, Serious Hazards of Transfusion (SHOT) Office, Manchester, UK, ⁷Scottish National Blood Transfusion Service, Clinical Services Laboratory, Glasgow, UK, and ⁸Norfolk and Norwich University Hospitals NHS Foundation Trust, Blood Transfusion, Norwich, UK

Received 28 April 2014; accepted for publication 19 August 2014

SUMMARY

The SHOT Adverse Incident Reporting Scheme has consistently reported an unacceptably high level of errors originating in the laboratory setting. In 2006 an initiative was launched in conjunction with the IBMS, SHOT, RCPATH, BBTS, UK NEQAS, the NHSE NBTC and the equivalents in Scotland, Wales and Northern Ireland that led to the formation of the UK TLC. The UK TLC in considering the nature and spread of the errors documented by SHOT concluded that a significant proportion of these errors were most likely to be related to either the use of information technology or staff education, staffing levels, skill mix, training and competency issues. In the absence of any formal guidance on these matters, the UK TLC developed a series of recommendations using the results of two laboratory surveys conducted in 2007 and 2008.

In producing the initial (2009) recommendations the UK TLC had intended to provide guidance on 'best practice' in these areas. In doing so, it was anticipated (by the UK TLC) that laboratories complying with these recommendations would see a fall in the errors reported to SHOT by them, thereby leading to an overall reduction of errors reported to SHOT by all laboratories. The UK TLC considered the expected level of error reduction and agreed that a 50% reduction in reportable errors originating in the laboratory could be achieved by September 2012.

This target was not met and in response, the UK TLC undertook a new survey of laboratories in 2013. Using the results of this new survey, the UK TLC has revisited its recommendations and developed them further into minimum standards for education, training, competency and the use of information technology for the hospital transfusion laboratory (the UK TLC standards).

Compliance with the UK TLC standards described below has now been accepted by both the United Kingdom Accreditation Service (UKAS)/Clinical Pathology Accreditation (UK) Ltd (CPA) and the Medicines and Healthcare products Regulatory Agency (MHRA) as evidence to support their inspection programmes for laboratories.

BACKGROUND

Prior to 2009 the SHOT Adverse Incident Reporting Scheme (SHOT, 1996–2013) consistently highlighted that 30–40% of 'wrong blood' incidents were due to errors originating in the hospital blood transfusion laboratory, with a disproportionate number of these occurring outside core hours (core hours for these standards being defined as that period of the working day when the majority of the staff establishment are present).

In 2006, SHOT approached the IBMS to facilitate a meeting between themselves and other relevant stakeholders working in

Correspondence: Hema Mistry, UK Transfusion Laboratory Collaborative, c/o SHOT Office, Manchester Blood Centre, Plymouth Grove, Manchester, M13 9LL, UK.

Tel.: +44(0)161 423 4235; fax: +(0)161 423 4395; e-mail: shot@nhsbt.nhs.uk

Bill Chaffe, Deborah Asher, Paula Bolton-Maggs, Anna Capps-Jenner, Hedley Glencross, Joan Jones, Hema Mistry, Mike Murphy, Julie Staves and Lorna Williamson on behalf of the UK Transfusion Laboratory Collaborative, c/o SHOT Office, Manchester, UK.

The UK Transfusion Laboratory Collaborative membership is: Institute of Biomedical Science (IBMS), Serious Hazards of Transfusion (SHOT), The Royal College of Pathologists (RCPATH), British Blood Transfusion Society (BBTS), United Kingdom National External Quality Assessment Service (UK NEQAS), NHS England National Blood Transfusion Committee (NHSE NBTC) and the equivalents in Scotland, Wales and Northern Ireland

the transfusion laboratory arena, to consider the causes of this error rate and to find possible solutions to an increasingly significant problem. This meeting saw the formation of the UK TLC, who agreed that any resolution must be both evidence-based and come from within the laboratory community itself. As a first step, it was agreed to run a workshop, which was followed by a survey of transfusion laboratories to seek the appropriate evidence. This was further followed by another survey in order to develop some points arising from the workshop and the earlier survey.

Evidence from the workshop and the surveys revealed the following:

- 55% of transfusion laboratory staff lacked any formal transfusion qualification;
- 20% of lead biomedical scientists in transfusion laboratories were working on call or shift and therefore were often unavailable during core hours;
- 6% of laboratories may have no staff with transfusion qualifications working on a given day;
- knowledge and competency assessment although being undertaken was only achieved for 75% of transfusion laboratory staff within the previous 12 months;
- 53% of laboratories had agreed their 'ideal' staffing levels however, 53% of those laboratories routinely ran services with less than these levels on any given day;
- 90% of laboratories had the facilities in place to use electronic issue of red cells for transfusion at all times, but only 49% of these laboratories were actually doing so.

It is also known that staff who work unsupervised outside of core hours often may not have the benefit of being able to consult with colleagues, as they would be able to when working in core hours. These staff and their managers will therefore need to be sure that their education, training, and competency are appropriate for the types of situations that may require immediate and complex decision making or judgements in isolation.

In understanding the above matter, it is also necessary for the initial education, training and competency of these staff to be in place, upon which the necessary skills and attitudes to facilitate non-core hours working can be built.

These data and conclusions and the establishment of the UK TLC led to the publication of the initial (2009) UK TLC recommendations (Chaffe et al., 2009a,b). These evidence-based UK TLC recommendations were developed to assist organisations in reducing blood transfusion laboratory errors by providing a framework for the education and training of laboratory staff, and the use of information technology.

In 2008, SHOT data showed that the proportion of laboratory errors was 19% of the total number of reports made to SHOT. In considering this error rate, the UK TLC expected that compliance with the recommendations would lead to a 50% reduction in laboratory errors by September 2012. In 2012, SHOT data showed that this proportion of laboratory errors had only fallen to 16% of the total errors, which although a decrease was well short of the expected percentage fall in laboratory errors (SHOT, 2012). Since 2012, SHOT data has shown that

the level of laboratory errors has continued at an unacceptably high level and remains stubbornly above the initial percentage reduction target (SHOT, 1996–2013).

In response, the UK TLC undertook a further survey in 2013 (IBMS, 2014), the results of which confirmed that a number of the revised UK TLC recommendations (Chaffe et al., 2010) had not been addressed by a significant number of laboratories. These results are summarised as follows:

- the percentage of staff, supervising or taking responsibility for the work of a transfusion laboratory, without a suitable qualification in blood transfusion had risen from 44 to 47%;
- only a small number of laboratories (approximately 20%) undertake an annual review of staffing levels through their organisational governance structure;
- the percentage of laboratories working at an agreed staffing level had fallen from 81 to 72%, a statistically significant decrease using a χ^2 distribution ($P = 0.002$);
- 42% of laboratories reported a reduction in educational funding.

It was also evident from the 2013 survey (IBMS, 2014) and supported by evidence from serial SHOT Annual Reports (SHOT, 1996–2013) that the number of laboratory errors related to misunderstanding or misuse of information technology systems had increased year on year.

Within the survey, opportunity was given for free text comments and an often made quote from laboratory staff was '*although the recommendations were excellent, management saw them as recommendations that carried no mandatory action requirement*'.

Each of the above points and findings have a direct impact on the ability of a hospital transfusion laboratory to provide a safe and efficient transfusion service that meets professional guidelines or recommendations and legal or regulatory requirements. Whilst the relationship between the workload, its complexity, the staffing levels, their skill-mix, qualifications and experience, and the increased use of technology is a fine balance, the number of errors originating in the laboratory provides an effective marker for the provision of safe laboratory transfusion service. The observations that:

- laboratory errors are not decreasing by the anticipated amount;
- laboratories are not prioritising conformance to the UK TLC recommendations.

point to a necessity to both increase compliance with and to enhance the profile of the UK TLC recommendations. The UK TLC has therefore undertaken a review of the recommendations, and has redrafted them as standards, using evidence from three national surveys of UK transfusion laboratories (IBMS, 2014). By increasing compliance with the UK TLC standards and by the constant vigilance of all staff, as the transformation of pathology services gathers pace, it is anticipated that a significant

reduction in laboratory errors can be achieved by December 2016.

The UK TLC standards (below) are intended to help minimise the risk of laboratory errors, through supporting and encouraging the effective and appropriate education, training, competency, utilisation of staff, and the use of technology in hospital transfusion laboratories within the current UK legislative requirements for blood transfusion services. These standards will also help hospitals and organisations to ensure their members of staff achieve the standards of proficiency and practice set by The Health and Care Professions Council (HCPC, 2007) and as required by the UK Blood Safety and Quality Regulations (as amended) (BSQR SI50/2005).

THE UK TLC STANDARDS

1 Staffing

- 1.1 It is expected that appropriate laboratory staffing levels will be in place to ensure the safe and effective delivery of all transfusion service activities and that they will be subject to annual review, risk assessment and agreement through local governance structures (NHSE, 2014).
- 1.2 It is expected that laboratories as part of their capacity planning process (BSQR SI50/2005) will have operational protocols to make certain that sufficient staff with an appropriate skill-mix are available to match the workload and its complexity at all times.
- 1.3 It is expected that when considering 1.1 and 1.2 above that all of the requirements of a quality management system (BSQR SI50/2005) will be included as part of the workload and service delivery (NHSE, 2014).
- 1.4 It is expected that in circumstances when staffing levels are such that standard 1.3 cannot be met, appropriate senior members of staff will have protected time agreed and available in order to provide the quality management system elements of the workload and service delivery (NHSE, 2014).

2 Information Technology

- 2.1 It is expected that all laboratories will have complete walk-away automation which is in use 24 h, 7 days a week, with bidirectional interfaces to the laboratory information system. In the absence of complete automation, documented measures must be taken in order to mitigate procedural laboratory errors (BCSH, 2006).
- 2.2 It is expected that electronic issue of red cells will be introduced when the laboratory infrastructure is robust and supports this procedure as described in both the British Committee for Standards in Haematology (BCSH) guidelines on the specification and use of information technology systems in blood transfusion practice (BCSH, 2006) and MHRA electronic issue guidance (MHRA, 2005).
- 2.3 It is expected that where remote issue of components is being considered as part of service delivery, consideration

will also be given to installing complete blood tracking (vein to vein) as an integral feature of this development.

3 Knowledge and skills

- 3.1 It is expected that all members of staff working at career framework stage 7 (DH, 2005) 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 (NHSE, 2014).
- 3.2 Those members of staff, as defined in standard 3.1 currently in post who do not hold one of the qualifications listed in Appendix A, must have their knowledge and skills locally assessed (NHSE, 2014) against the aims and learning outcomes of either an IBMS Higher Specialist Diploma in Transfusion Science (IBMS, 2013b), an MSc in Transfusion and Transplantation accredited by the IBMS (University of Bristol, 2013, University of Edinburgh, 2014) or an IBMS accredited MSc with a transfusion specialism (IBMS, 2013a). Guidance on local assessment against learning outcomes will be available on the IBMS website.
- 3.3 In order to maintain their skills, those members of staff as defined in standard 3.1 must complete and document at least 10 working days per annum of autonomous, independent or lone-working in a hospital blood transfusion laboratory, and also meet standards 1.3 and 1.4 above. As part of an annual appraisal system, documentation of this work must also include appropriate reflective learning on their professional practice in transfusion.
- 3.4 To help facilitate compliance with the BSQR SI50/2005 those members of staff as defined in standard 3.1 will be expected *to participate* in the following:
 - a programme of practical and knowledge-based competency as detailed in standard 3.13 as a participant;
 - a programme of practical and knowledge-based competency as detailed in standard 3.13 in both the setting and assessment of competency of peers and subordinate staff;
 - regular and appropriate scientific, managerial, leadership and quality management education, training and CPD.
- 3.5 To help facilitate compliance with the BSQR SI50/2005 it is expected that those members of staff as defined in standard 3.1 will be *excluded* from the following:
 - the staff establishment required for core hours practical service provision;
 - the rota for non-core hours service provision if there is any impact on core hours availability.
- 3.6 It is expected that those members of staff, as defined in standard 3.1 will be available to provide appropriate specialist transfusion advice at all times. This may require

- local collaboration with other hospitals and organisations to cover non-core hours.
- 3.7 It is expected that all members of staff working at career framework stage 6 (DH, 2005) 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 (NHSE, 2014).
 - 3.8 It is expected that unsupervised, lone-working members of staff, as defined in standard 3.7 currently in post who do not hold one of the qualifications listed in Appendix B, will have their knowledge and skills locally assessed (NHSE, 2014) against the aims and learning outcomes of either an IBMS Specialist Diploma in Haematology with Hospital Transfusion Practice (IBMS, 2011) or an IBMS Specialist Diploma in Transfusion Science (IBMS, 2011). Guidance on local assessment against learning outcomes will be available on the IBMS website.
 - 3.9 It is expected that all members of staff working at career framework stage 6 (DH, 2005) or above will be assessed and documented as competent in local work practices prior to any unsupervised lone-working (NHSE, 2014).
 - 3.10 In order to maintain their skills, it is expected that all members of staff currently in post who work unsupervised in a blood transfusion laboratory at any time, but who are not permanently established in blood transfusion will complete at least 10 working days per annum of supervised working in a hospital blood transfusion laboratory.
 - 3.11 It is expected that all members of staff working at career framework stage 5 (DH, 2005) or above who work alone within a blood transfusion laboratory, but are *supervised*, will hold or be working towards obtaining one of the qualifications listed in Appendix C (NHSE, 2014).
 - 3.12 It is expected that all non-registered members of staff or support staff working in a transfusion laboratory will always be supervised by a member of staff registered with the HCPC who also holds a qualification, appropriate to their career framework stage, from those listed in appendices A and B. Support staff must also have a locally defined scope of practice using a professional framework that sets the appropriate limits on their activities (IBMS, 2013c).
 - 3.13 It is expected that there will be a locally defined, annual programme of practical and knowledge-based competence assessment. All members of staff working at any

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- time within a blood transfusion laboratory must actively and regularly participate in this programme. The programme must cover all aspects and levels of competency and include appropriate scientific, methodological, scenario and case-based activities (NHSE, 2014).
- 3.14 It is expected that individuals who manage 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 3.1, when matters arise that have the potential to impact on the provision of transfusion services.
 - 3.15 It is expected that any individual temporarily employed to work within a blood transfusion laboratory must be subject to all of the standards (as appropriate) included in section 3.

EVALUATION

The UK TLC standards have been written to accord with the requirements of the BSQR SI50/2005, the MHRA blood regulations (MHRA, 2005), UKAS/CPA/International Standards Organisation (ISO) standards of accreditation for medical laboratories (CPA, 2013) and to complement both the key performance indicators for pathology RCPATH, 2013) and the recently published Pathology Quality Assurance Review (NHSE, 2014). The UK TLC standards are designed to address and minimise known factors contributing to laboratory process failure in the relentless pursuit of patient safety (Mid Staffordshire NHS Foundation Trust Public Enquiry 2013) The impact of the UK TLC standards on the frequency and severity of laboratory incidents will be continually monitored by SHOT reporting via the MHRA Serious Adverse Blood Reactions and Events (SABRE) reporting system (MHRA, 2005–2010) and by annual surveys undertaken by the UK TLC.

ACKNOWLEDGMENTS

The collaborative committee members who developed the standards were: B. C. (UK NEQAS); H. G. (IBMS), J. J. (IBMS); D. A. (SHOT/Laboratory Manager), P. B.-M. (SHOT), H. M. (SHOT); J. S. (BBTS); A. C.-J. (Independent laboratory sector); Marie McQuade, Scottish Clinical Transfusion Advisory Committee (SCTAC)/IBMS). The RCPATH Transfusion Committee (Chairman: Lorna Williamson) and the NHSE NBTC (Secretary: Mike Murphy) commented on the final draft.

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APPENDICES

The qualifications below in appendices A, B and C 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 for any updates using the correspondence details on the front page of this document.

APPENDIX A

- Fellowship of the Institute of Biomedical Science (FIBMS) by examination (Special Exam, 2-part Fellowship or Higher Specialist Diploma) in blood transfusion or transfusion science.
- MSc or FIBMS in another discipline in conjunction with an IBMS Higher Specialist Diploma in Transfusion Science.
- MSc in Transfusion and Transplantation accredited by the IBMS.
- IBMS accredited MSc with a transfusion specialism of at least 120 (60 taught, 60 practical/project) level 7 CATS points.

APPENDIX B

- Registration via the Council for Professions Supplementary to Medicine (CPSM) or IBMS logbook in haematology and hospital-based transfusion practice.
- Registration via the CPSM or IBMS logbook in blood transfusion.
- BBTS Specialist Certificate in Transfusion Science Practice.
- IBMS Specialist Diploma in Haematology with Hospital Transfusion Practice.
- IBMS Specialist Diploma in Transfusion Science.

APPENDIX C

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