London & South East Transfusion Science *TAG* 1

Meeting held on Thursday 6th February 2020

at The Harris Birthright Lecture Theatre
Foetal Medicine Research Institute
King's College Hospital

Sponsored by Arena Instrumentation, Haier BioMedical and Immucor

1 Attendance Record:

Apologies for absence *italicised*

Name	Based at
Adrian Marsh	*NHSBT*
Andy Perry	*NHSBT*
Arul Anand	*BSPS*
Bindi Kandiah	
Carol Stenning	St Richard's
Chris Robbie	*MHRA*
Claire Whitham	*NEQAS*
Cristina Lobato	*GSTT*
David Johnson	St Mary's
David Mold	Royal Free
Donna Wiles	TDL
Doris Lam	*NHSBT*
Edgar Malundas	Lister
Emily Carpenter	*KCH*
Eve Hayes	*NHSBT*
Helen Nabakka	Epsom & St Helier
Ismay Humphreys	Conquest
James Hayes	*NHSBT*
Jane Tidman	*GSTT*
Jasmine Walker	Medway
Jennifer White	*NHSBT*
Jeyakumar Visuvanathan	St Peters (Chair)
Joanne Lawrence	Royal Surrey County Hospital
Joyce Overfield	SPIRE Montefiore
Ken Amenyah	Kings College
Lucy Ncube	*HCA* Laboratories
Matthew Ginger	Watford
Mohamed Elmi	Homerton
Nelsonseelan Johnson	*BSPS*
Patricia Richards	Lewisham and Greenwich
Pauline Bigsby	Viapath
Penny Eyton-Jones	Great Ormond Street
Peter Struik	Itinerant Scribe

Rachel Nicholas	Medway/Darent Valley
Randa Bonis	Parkside
Rashmi Rook	Redhill, East Surrey
Richard Whitmore	*NHSBT* Tooting
Samantha Marston	Whittington
Sarah Haskins	Dartford & Gravesham
Selma Turkovic	*PBMP*
Senait Tesfazghi	Spire Healthcare
Sibel Bafekr	Eastbourne
Sophie Shepherd	*NHSBT*
Susan Mitchell	East Kent
Trevor Deetlefs	Western Sussex
Xiaohui Tang	Queens
Zoe Sammut	St Richard's
Harry Pomfer	Haier
Tina G---	Immucor
Sue Bradley	Immucor

2 Chairman's Opening Remarks:

Jey welcomed the rather fewer than usual attendees (although more than had at first been feared) apologising for holding the meeting during a half-term holiday which he felt explained at least in part there being so many absences, and said we would do our best not to do this again. We had received quite a few apologies for absence but he stressed how how important it is that attendance or absence is confirmed when the invitations are sent out as it is important that fairly accurate numbers are known in advance for arranging the catering etc.
He especially thanked Emily and the King's College team for organising the use of such a magnifient venue, and so close to a station His suggestion that we try to use this as a permanent home was met with general agreement.
He reminded people to send in any discussion points for the next meeting.
He thanked the three sponsors who would have a chance to talk to us later and be available over the lunch break and without whom the group could not survive.

3 How *RCI* Train Staff and Assess Competencies:

Training: It is not just new staff who need training but also locums, support staff, staff absent for a long period (eg >3 months) for whatever reason, as well as existing staff if procedures are changed in any way.
It is necessary to have an initial meeting with the staff member for the manager to find out 'where they are' so that a training plan can be developed – what needs to be done, what can be done to help them and a suitable timescale identified (people learn at different rates!) They are also assigned a 'go to' person who will act as a guide.
The trainer and trainee need to review progress at regular intervals and, if necessary, the programme/timescale can be amended.
RCI have developed a training booklet for new starters which details what they need to do, read etc and what progress they need to make. This includes mandatory training exercises, reading documents (eg *SOPs*),observing and being observed carrying out processes, testing known samples (*NEQAS, IPEx,* patients') and knowledge checks (in house questions). This is signed off by the trainer when both parties are satisfied with the module outcome.
Existing staff need training whenever new or changed procedures are introduced, or when they are amended in response to a major incident as part of *CAPA*, if appropriate.

All *RCI* procedures are divided into 24 modules, each set with the lowest banding of staff required.

Competency: the ability to apply knowledge and skill – needs to be assessed regularly.
ISO15189 states this can be done by direct observation, monitoring the recording and reporting of examination results, review of work records, assessment of problem solving skills and examination of specially provided samples.
Evidence can be work based (eg training on a new *SOP*), tests and knowledge checks, reflective learning, group study (eg a case, *SHOT* reports), external *QA* exercises, review of *NEQAS* exercise with colleagues, or study/re-reading of guidelines.
Managers also need to demonstrate competence – they are required to document evidence of their continuing competency activities which is reviewed as part of their annual appraisal. They also do *NEQAS* and other practical competency exercises (marked by deputy or line manager when appropriate)
HCPC expect some activity every month to show you have undertaken suitable activities.
It is useful as part of CAPA to review training records and to make sure that people understand the processes etc.

4 Uncertainties of Measurement (*UoM)* in Transfusion:

ISO15189 offers the only guidance
One hospital using *Immucor* analysers which provide a numerical score for reaction strength, used this approach for calculating the *UoM* for group, antibody screen and Rh/K testing, not because it added anything useful but purely because *UKAS* wanted it.
Although results are qualitative (positive or negative) they are based on quantitative measurements. Analyser manufacturers establish a predetermined cut-off point and results closest to this are most at risk and should be used in determining the *MoU* of the examination method.
They gathered routine *QC* data (reaction strengths) from the analysers for a period of 6 months, calculated the mean and standard deviation and then, with cut off values supplied by the manufacturer, calculated the *UoM* (Apologies: the exact details of this wizardry were somewhat beyond the comprehension of your humble scribe)
It is necessary to recalculate the *UoM* at regular intervals, and after analyser maintenance.
There was general admiration for the way that this had been done coupled with wonder as to why. It was acknowledged that there is no added value to doing this whatsoever as *UoM* applies only to quantitative and not qualitative measurements. As managers we should be more able to challenge *UKAS* inspectors: the amount of work needed to provide evidence of *UoM* for blood grouping is in no way commensurate with the risk. It was also pointed out that *NEQAS* samples are not necessarily representative of patients' samples and so the result may not be satisfactory.
There is no point in being assessed to standards which add no value and are not achievable, a situation which isn't helped by inspectors being inconsistent. This is a problem for all laboratories and really needs to be challenged collectively.

5 Laboratory Matters:

LIMS – Legacy Data: Patient Special Requirements

Mapping of one system to a new one is complex!
It is necessary first to decide whether all data is transferred or just an appropriate portion (eg the last 5 years) If you are not absolutely confident that all data was transferred correctly then you must maintain the old system as well – th transfer needs to be validated very robustly. It can be helpful to maintain the old system as read-only and check on both systems to check data for the first few months.
If you do have a legacy system then it is vital that knowledge of it is maintained – as people leave this will be lost unless sufficient information on how to use it is written down.

CMV Platelets for Transplant Patients

The *SABTO* recommendations are complex and although the guidelines say that leucodepletion is satisfactory, different transplant centres have different policies as regards use of *CMV* negative products. You need to do a risk assessment at your site: the risk is slightly higher with apheresis platelets so it may be better to give pooled platelets.

6a Immucor

Do not just do automation but many other products 'to make life easier'. These include reagent *RBC* (antibody screening & identification,ficin treated panels, reverse grouping, 'coombs' control cells) antisera, antibody removal reagents, competency kits, validation panels and *HIT PF4* kits.
Tests are easy to perform and need minimal specialised equipment, and reducing the numbers of samples referred to reference laboratories leads to reduced costs, improved *TATs* and increased staff satisfaction.
They now offer a gel system which can be bought as a complete system or individual components, including a reader which can be linked to your *LIMS*.
RiSE is a competency assessment system – each *BMS* has a logon to a central site to enter their results and receives a certificate back.

http://www.immucor.com/

6b Haier Biomedical

Have an ever growing product range of blood refrigerators (300L to 1300L) and transport cool boxes (5 – 35 blood bags). The refrigerators are either standard, or advanced: a range with touchscreens offering much increased functionality (eg fingerprint recognition for access)
They also offer a range of pharmacy refrigerators, including an underbench model.
They also produce a 'one system, wide application' wireless monitoring system based on a range of transmitter sensors and tailored software to enable monitoring and controls for a wide range of applications. Being wireless this works independently of local *IT* and wifi, transmitting to a local gateway which has battery backup in case of power failures and can run 200 transmitters, sending data to a central point. Once the infrastructure is in place then any sensors can be connected and data sent via a *GPRS* connection to the Cloud. All data can be accessed remotely by any suitable device (PC, mobile etc) and the dashboard display tailored for individual users to offer as much, or little, control as they require.
Some sensors have been functioning without problems for 15 years.

https://www.wolflabs.co.uk/manufacturers/haier-biomedical-uk

6c Arena Instrumentation

Regular and very generous sponsors of these meetings.
Arena has the ability to support a wide range and varied range of laboratory equipment.
This includes temperature mapping, probe and data logger calibration, equipment servicing, calibration and repair, equipment validation and equipment moves (including de-commission and validation)

http://www.arena-instrumentation.com/ mailto:info@arena-instrumentation.com

7 Latest *SABRE* Findings (2019 data):

Although there has been no increase in the number of *SAE*s received there has been an increase in component expiry, return to stock and storage errors. Storage errors occur in both laboratory and clinical areas but *BSQR* relate to product safety so incorrect storage anywhere must be reported.
Incorrect storage of components is most likely to occur in clinical areas. Errors include storage in unmonitored drug fridges, decommisioned blood fridges or at the incorrect temperature and often involve untrained (including bank and locum) staff. Storage and quarantine processes can be improved, and all staff involved in the handling and storage of components must be trained. Identify staff for training, ensure training material is thorough and that competencies are assessed. Ensure new, locum and bank staff are informed of storage arrangements before they are allowed to handle components - it is important that untrained staff are aware of what they can't

do and what they shouldn't do. When a large number of people are trained then each individual may not do that task very often and may have forgotten details of the procedure. Rotas and staff availability create obvious problems but it should be considered whether it is always necessary to train everybody to do everything, reviewing which staff need to be trained.
There has been an increase in pretransfusion testing errors and improvements to *QMS* (process design, *SOP* content, and training) and although it is recognised that inadequate staff numbers to cope with the workload is a very real issue, only 90 of over 1000 reports was considered solely attributable to this.
Overall there were fewer laboratory errors although the reasons or this are unclear – it could be that laboratory quality systems are improving with a consequent improvement in component and patient safety.

8 *NHSBT* Update

Fax machines: If you are removing a fax machine and implementing an alernative means of communication you must inform *NHSBT* – also any hospital with which you have shared care patients. Hospitals moving to email must provide a generic email address (*NHSBT* cannot send communications to personal email addresses) and ensure that it is constantly monitored and can be accessed by all *OOH* staff.
Once notified *NHSBT* will update their database, send a letter, test the alternative communication method and send a final confirmation letter.
This method is only for use when ordering components when *OBOS* is down and for the recall of components – it does not include referrals to *H&I, RCI* etc.

Red Cell Investigations: It is vital that you phone your *RCI* laboratory about samples requiring urgent results (<5 working days) to discuss what you need and alert them to the incoming sample. This is especially important outside core hours. This applies to all cases where crossmatched blood is required and all investigations of positive *FMH* screens.

***RCI* Accreditation Status:** the *UKAS* accreditation staus has been published on the Hospitals and Science website so is available to Lab Managers during their individual inspections.

***OBOS*:** all components manufactured from *UK* donations are now tested for *HEV* so the tick box on *OBOS* has been disabled. *EDN* files will still transmit *HEV* test results so no change to *LIMS* will be required.

Transport Journey Times: it is important to identify the type of box in order to validate the transportation time to confirm that the cold chain has not been breached during transportation. *NHSBT* have three types for long, medium or short journeys and have produced a visual guide including specifications for component and capacity, temperature stabilisation material and maximum journey time.

Cold Chain Times: the despatch note has been improved and now includes the time the products were removed from temperature controlled storage and the type of transport box used. This will enable hospitals to quickly and easily confirm the cold chain when signing to confirm receipt of the consignment.

Transport Boxes: please do not overfill them with *PCMs.* Drivers may sometimes not be able to take back empty boxes through lack of space in the van, especially at the end of a round, but they will be picked up on the next round. If you are left with too many boxes you can phone *NHSBT* and they will do their best to arrange to have them picked up.

Colindale *RCI* Reports: after a review, and with the aim of improving the process and increasing standardisation, there will be a slight change in the standard antenatal report which will no longer include the sentence describing details of prophylactic anti-D the patient has been given. After much discussion as to the reasons for this and the wishes of individual hospitals there was a slightly grudging acceptance of this change.

9 *UKTLC* Update: Senior Staff Training and Competencies

There is ongoing work on this but there are worse starting points than Rudyard Kipling's

I keep six honest serving men
(They taught me all I knew);
Their names are What and Why and When
And How and Where and Who

Who are the senior staff who need training? Transfusion staff aren't the only people involved in quality and following regulations so we need to include Quality Officers and Managers, Heads of Service (and deputies), Pathology managers, *IT* and significant hospital personnel.You won't develop quality if you don't concentrate on key people.
Training in what? This list is significant because it is not exhaustive (Transfusion isn't included!) but it is, as you probably too often forget, just some of what you do every day.

time management	accreditation stds ISO	changes/project managment	validation
supervision	lean / kaizan	quality incidents / CAPA	risk management
delegation	quality control	root cause analysis	trend analysis
trouble-shooting	cost improvement	human factors awareness	contingency planning
communication skills	auditing proficiency	complex analytical principles	staff capacity planning
report writing	document control	equipment	process mapping
regulation MHRA,HTA,HSC	haemovigilance	finance	presentation skills

Evidence of training can be attendance at meetings, conferences etc, examples of documents or templates, training documents and competencies, certificates, reflective practice or screen prints – this is, of course, all part of *CPD*- but remember, not everyone is covered by *CPD.*
Learning, training and development never ends.

10 AOB:

SEC *RTT*: there will soon be a vacancy for a laboratory manager on this group and a volunteer is required.

Sp-ICE: Most hospitals have now agreed to share their data on *Sp-ICE* but the agreement is not retrospective – ie reports issued before the agreement still remain flagged as not shareable and so will not become retrospectively visible to other users.

11 Future Meetings:

TAG: dates in late May/early June and late September were suggested
- exact dates and venues to be confirmed

London *RTT* Education Day: *BMS* only.
- 30th March at *NHSBT* Tooting