UK NEQAS
Haematology and Transfusion

UK NEQAS for
BLOOD TRANSFUSION LABORATORY PRACTICE

2016-17 Biennial Report to Participants

Director: Dr Megan Rowley

Manager: Ms Jenny White

Location: Watford General Hospital

West Herts Hospitals NHS Trust

UK NEQAS
Haematology and Transfusion

1. Introduction and scope

UK NEQAS BTLP is hosted by West Herts Hospitals NHS Trust and is located on the ground floor of the Pathology Block at Watford General Hospital. It shares premises and administrative and logistics staff with UK NEQAS (H). The UK NEQAS Unit is part of pathology within the Clinical Support Directorate, and the legal oversight and working arrangements are described in a Memorandum of Agreement with the Trust.

The BTLP schemes are advised by and report to the BTLP Steering Committee and Specialist Advisory Groups (see Section 2 for membership as of December 2017) and reports unsatisfactory performance to the National Quality Assurance Advisory Panel for Haematology. The professional oversight of our Steering Committee and Scientific Advisory Groups, as well as the daily interaction with participants, ensures that the Scheme remains relevant to differing models of hospital blood transfusion service delivery as well as to the more specialised reference laboratories.

Following many years of successful collaboration between the Haematology and Blood Transfusion Laboratory Practice schemes to share the operation and management of the FMH Scheme, a strategic review was undertaken early in April 2016 and the decision was taken to streamline the processes by fully incorporating FMH into the BTLP Scheme operations, with a single management structure. FMH already reported to the BTLP Steering Committee, and the Steering Committee Chair, along with other relevant stakeholders and the participants were informed of the transition process during May and June. The transition process was completed by the end of 2016.

Due to these management changes and an expansion in the scope of tests assessed, in 2017 Blood Transfusion Laboratory Practice (BTLP) became the generic name for the UK NEQAS transfusion schemes. The BTLP main scheme was renamed Pre-Transfusion testing (PTT) and other schemes under the BTLP umbrella are Fetomaternal haemorrhage (FMH), ABO titration (ABOT) and pilot schemes for red cell genotyping (RCG) and Direct Antiglobulin Test (DAT). This report covers the combined activity of Blood Transfusion Laboratory Practice UK NEQAS BTLP schemes during 2016-17.

The Scheme contributes to the wider field of transfusion practice by collaborating with organisations such as the BBTS, BSH transfusion taskforce, SHOT, RCPath, IBMS and UK Transfusion Collaborative. Work with international organisations such as WHO and ISBT is undertaken where relevant and in line with Scheme priorities.

2. Scheme staff and committee members

The Scheme Manager (Clare Milkins) retired at the end of April 2017, following a period from Feb 2017- April 2017 where there were proleptic appointments for the newly appointed Scheme Manager and Deputy Scheme Manager.

BTLP Scheme staff December 2017

- Scheme Director: Dr Megan Rowley
- Scheme Manager and Deputy Director: Jenny White
- Deputy Scheme Manager: Richard Haggas
- Senior EQA Scientist and TACT lead: Claire Whitham
- Senior EQA Scientist and FMH lead: Katy Veale
- EQA Scientist: Arnold Mavurayi
- Executive Assistant – Ms Isabella De-Rosa
- Business Manager – Mrs Nazia Hussain

BTLP Steering Committee membership December 2017

- Dr Peter Baker (Chair), Royal Liverpool University Hospital
- Mr Martin Maley, RCI, NHSBT, Newcastle
- Mrs Anna Capps-Jenner, Ealing Hospital and TDL
- Ms Catherine Lorenzen, Kent & Canterbury Hospital
- Dr Rekha Anand, NHSBT, Birmingham
- Mr James Taylor, Birmingham Children's Hospital
- Dr Mallika Sekhar, Royal Free NHS Foundation Trust
- Ms Michelle Weston (co-opted), NHSBT Reagents, Liverpool
- Mrs Debbie Asher (Observer - NQAAP representative), Norfolk and Norwich Hospital
- Dr Megan Rowley, Scheme Director, UK NEQAS
- Ms Jenny White, Scheme Manager, UK NEQAS
- Mr Richard Haggas, UK NEQAS

FMH Scientific Advisory Group (SAG) December 2017

- Mr Matthew Hazell (Chair), IBGRL, Bristol
- Mrs Diane Howarth, St James's Hospital, Leeds
- Ms Lynne Porter, Welsh Blood Service
- Dr Sylvia Armstrong-Fisher, SNBTS
- Mr Dan Pelling, St Mary's Hospital, London
- Mr John Eggington, NHSBT, Liverpool
- Dr Megan Rowley, UK NEQAS
- Ms Jenny White, UK NEQAS
- Mr Richard Haggas, UK NEQAS
- Ms Katy Veale, (Secretary), UK NEQAS

ABO Titration SAG December 2017

- Dr Fiona Regan (Chair), NHSBT/Hammersmith Hospital
- Ms Tracey Tomlinson, RCI, NHSBT Colindale
- Mr Ian Skidmore, RCI, NHSBT Birmingham
- Mr David Bruce, RCI, NHSBT Newcastle
- Dr Peter Baker, Royal Liverpool University Hospital
- Professor David Briggs, H&I, NHSBT, Birmingham
- Dr Jack Galliford, Hammersmith Hospital
- Dr Simon Ball, University Hospital Birmingham
- Mr Arnold Mavurayi, UK NEQAS
- Ms Jenny White, (Secretary), UK NEQAS
- Dr Megan Rowley, UK NEQAS
- Mr Richard Haggas, UK NEQAS

Red Cell Genotyping SAG December 2017

- Dr Jill Storry (Chair), Lund University, Sweden
- Dr Geoff Daniels, retired, formerly IBGRL Bristol
- Mr Shane Grimsley, IBGRL Bristol
- Dr Sylvia Armstrong-Fisher, SNBTS
- Mr Martin Maley, RCI, NHSBT, Newcastle
- Ms Jenny White, (Secretary), UK NEQAS
- Mr Richard Haggas, UK NEQAS
- Dr Megan Rowley, UK NEQAS

3. Summary of participation

This report represents data from UK and the Republic of Ireland, although the details regarding unsatisfactory performance relate to the UK only.

Tables 1 & 2 show the number of laboratories participating in the PTT Scheme over the past six years. Table 3 shows participation at the end of 2017 by registrations and includes pilot schemes.

Following a significant fall in in UK BTLP participation within the NHS sector during 2015, UK participation remained stable during 2016 and 2017. Overseas participation in pre-transfusion testing has increased in 2017, mainly due to a 12% rise in participation in Turkey. There was a continued increase in non-UK participation during FMH in 2017.

Table 1: Trends in participation in pre-transfusion testing and POCT

BTLP - PTT	End 2017	End 2016	End 2015	End 2014	End 2013	End 2012
NHS laboratories	283	283	284	293	294	295
UK clinical private	51	50	48	47	47	49
POCT	67	60	63	56	54	47
Non-UK and other[1]	675[2]	630	631	576	482	346
Total	**1076**	**1023**	**1026**	**972**	**877**	**737**

[1] includes Channel Islands and non-clinical laboratories

[2] includes 291 laboratories in Turkey (*cf.* 260 in 2016)

Table 2: Trends in participation in FMH

FMH	End 2017	End 2016	End 2015	End 2014	End 2013	End 2012
NHS laboratories	225	226	225	235	242	244
UK clinical private	2	1	1	1	1	2
Non-UK and other	73	64	55	49	46	45
Total	**300**	**291**	**281**	**285**	**289**	**291**

Table3: Registrations at December 2017

Scheme	UK[1]	Non-UK
Pre-transfusion testing 10 exercises ('R' and 'E')	334	153
Pre-transfusion testing 4 'R' exercises	6	224
POCT for D typing	67	0
3 'R' exercises (Turkey)	0	292
FMH - quantification by acid elution (AE) only	133	26
FMH - quantification by flow cytometry (FC) only	11	27
FMH – quantification by AE and FC	14	3
FMH – screening only	47	4
FMH screening by AE and quantification by FC	6	3
ABO titration pilot	35	62
DAT pilot	217	126
Red cell genotyping pilot	10	33
TACT – subscriptions (memberships)	>2000 [2]	0

[1] – Includes Channel Islands and non-clinical laboratories

[2] – Includes Republic of Ireland

4. PTT exercise summaries and results

Summary of distributions

Table 4 - Summary of Distributions for PTT 2016

Exercise Code	Date Distributed 2015	Contents	Main aims
16R1	18 January	ABO/D, AS, ABID, XM, PH	Detection (and identification) of anti-Fy^a in the crossmatch, identification of an antibody mixture and Rh phenotyping.
16E2	15 February	AS, ABID	Identification of anti-c+Fy^a, with and without provision of a phenotype
16E3	14 March	AS, ABID	Selection of a new 'standard' anti-D
16R4	18 April	ABO/D, AS, XM	Sensitivity of IAT crossmatch for detection of IgG antibodies using an urgent scenario, with a mix of antibodies, including an antibody to a LFA
16E5	16 May	AS, ABID, Q	Reproducibility of the new anti-D 'standard'; identification of an antibody mixture.
16E6	20 June	AS, ABID	Detection and ID of a weak antibody, and ID of an antibody mixture
16R7	18 July	ABO/D, AS, ABID, XM, PH	Incompatibility due to anti-A, -E and -Fy^a.
16E8	19 September	AS, ABID	Identification of an antibody mixture, including one with an enzyme only anti-D component
16R9	17 October	ABO/D, AS, ABID, XM, PH	Interpretation of an AB D positive with a positive DAT; detection of weak antibodies.
16E10	14 November	AS, ABID	Detection and ID of a weak antibody, and ID of an antibody mixture

AS - Antibody Screen ABID - Antibody Identification
XM – Crossmatch PH – Phenotyping
Q – Annual practice questionnaire

Table 5 - Summary of Distributions for PTT 2017

Exercise Code	Date Distributed 2017	Contents	Main aims
17R1	23 January	ABO/D, AS, ABID, XM, PH	Detection and identification of an antibody mixture Detection of incompatibilities due to anti-K and anti- Fy[a] Rh phenotyping
17E2	20 February	AS, ABID	Detection of UK NEQAS 'standard' anti-D Identification of an antibody mixture
17E3	20 March	AS, ABID	Identification of antibody mixtures where patient phenotypes are not available
17E4	24 April	AS, ABID	Identification of an antibody mixture Detection and identification of a weak antibody
17R5	22 May	ABO/D, AS, ABID, XM, PH, Q[1]	D typing of a D negative, DAT positive sample Identification of anti-S in the presence of an enzyme 'non-specific' antibody (ENS)
17E6	19 June	AS, ABID Q[2]	Identification of an antibody mixture
17E7	17 July	AS, ABID, IgG titration, Q[3]	Detection and identification of a weak antibody Identification of an antibody mixture Titration of an IgG antibody (optional and non-scoring)
17R8*	11 September	ABO/D, AS, ABID, XM, PH, extra 'emergency' sample, Q[4]	1Detection of incompatibility due to IgG and ABO antibodies Detection of a weak antibody Provision of blood in 10 minutes
17E9	23 October	AS, ABID	Detection and identification of an antibody mixture Detection of a weak antibody
17R10*	20 November	ABO/D, AS, ABID, XM, PH	Detection and identification of a weak antibody Detection of incompatibility vs. 'homozygous and heterozygous' cells

[1]Customer satisfaction questionnaire

[2]Annual practice questionnaire

[3] Use of antenatal titration results in clinical practice & interest in pilot scheme

[4] Provision of blood components in an 'emergency', i.e. within 10 minutes

AS - Antibody Screen ABID - Antibody Identification

XM – Crossmatch PH – Phenotyping Q - Questionnaire

General information relating to exercise summaries and material

- Data relates to UK clinical laboratories (including Republic of Ireland). Detailed results are not shown for non-UK laboratories as this group is so large and disparate; however, the overall error rates for UK and non-UK are shown in section 5.
- Antibody titres quoted are those obtained in the UK NEQAS laboratory on the closing date, by LISS tube IAT, against red cells bearing heterozygous expression of the relevant antigen, unless otherwise stated.
- Error rates and return rates reported may include late results, and any amendments made following appeals.
- Each 'patient' whole blood sample comprises a pool of four or five donations, which may be whole blood or red cells to which ABO compatible FFP and Alsever's has been added.
- Each 'patient' plasma sample comprises a pool of ABO compatible plasma donations, some of which contain red cell antibodies.
- Each 'donor' sample comprises a single red cell donation, diluted in modified Alsever's solution to a red cell concentration of 7-10%.
- Preparation of the plasma pools and 'donor' samples is subcontracted to the NHS Blood and Transplant Reagents Unit, although this material may also be prepared or further manipulated within the UK NEQAS Unit.

Details of material and key results

16R1 – January 2016

Main aims:

Patient 1 – AB D pos, inert	Donor W – O D pos, Ro (cDe), Fy(a+b-), K-
Patient 2 – A D pos, inert	Donor Y – O D pos, R_1r (CDe/cde), Fy(a+b+), K-
Patient 3 – O D pos, anti-K+Fy^a, titres 4 & 2	Donor Z – O D pos R_2R_2 (cDE/cDE), Fy(a-b+), K-

Return rate: 98.2%

Results

Procedural errors

- One laboratory transposed samples 2 and 3 when adding accession numbers,
    - Subsequent checks, in place for clinical samples, were omitted, resulting in one false negative and one false positive antibody screen.
- Another laboratory transposed all results for Patients 1 and 3 at data entry
- A further 2 laboratories made data entry errors and another transposed DW and DZ during testing or reporting.

ABO/D, antibody screening and identification

- No other errors

Crossmatching (excluding procedural errors already noted)

- Three laboratories, using manual BioRad technology, each missed one incompatibility (one DW, 2 DY)
    - 2 repeated after closing date, and both obtained a clear positive reaction - cause unknown.
- A fourth, using automated BioRad, missed the incompatibility with DY
    - The original machine printout was examined and showed a very weak cell suspension in the crossmatch column
    - A positive reaction was obtained on repeat after closing.
- Nine laboratories reported a false positive reaction between P3 and DZ
    - 3 theoretical de-selection
    - 6 positive reaction by IAT (5 BioRad, 1 BioVue)

Phenotyping

- 10 laboratories recorded 7 false negative and 7 false positive reactions, equating to 11 incorrect sets of Rh results
- 8 were assigned the correct shorthand interpretation, e.g. R_1r for DY, so could have been data entry errors

- 38 sets of correct reactions were assigned an incorrect shorthand interpretation

- 24 did not take the D type into account
- 4 did not record a shorthand interpretation for any of the donors, and 2 reported 'other' for all 3 donors
- An additional 15 selected 'other' for DW, probably because the option was R_0, rather than R_0r or R_0R_0.

Comments/learning points

The reported highlighted that labelling samples is a critical point in the pre-transfusion process and that patient demographics on the sample should be re-checked prior to validation of results.

16E2 – February 2017

Main aims:

'Patient' 1: Inert
'Patient' 2: Anti-c+Fy^{a} (titre 8 for both) – phenotype not provided
'Patient' 3: Anti-c+Fy^{a} (titre 8 for both) – phenotype provided
'Patient' 4: Inert

Return rate: 98.7%

Results

Antibody screening

- Three labs reported a false positive screen for P4, based on non-specific reactions in Capture.

Antibody identification

- One laboratory reported anti-c+E only, for both samples
- On investigation it was found that anti-Fy^{a} (and other specificities) could not be excluded and this had been noted on the panel sheets at the time but not reported to the Scheme.
- One laboratory reported P2 as anti-c and P3 as anti-c+S, with no reference to anti-Fy^{a}.
- One laboratory reported only anti-c for P2, and another anti-c+N for P2
- Both recorded anti-Fy^{a} as not excluded.
- One laboratory reported anti-c+Fy^{b} for P3 (presumably data entry error)

UI submissions

- 36 UI submissions were reviewed
- 26 for P2 (no phenotype)
- 10 for P3 (phenotype)
- 35 were agreed at the time
- The last one was agreed retrospectively, as the participant emailed to say that they would not conclusively identify anti-c without the phenotype.
- Many could have identified both antibodies as the EQA samples have a maximum of 2 in any sample, but they applied clinical criteria, so we agreed them
- Others gave incomplete or inaccurate explanations but were agreed based on the panel profiles submitted.

Exercise summaries and learning points

- Several laboratories could not distinguish between anti-Fy^{a} and anti-N. The report highlighted that a room temp panel would have excluded anti-N.
- There was a significant increase in conclusive identification of anti-c+Fy^{a} where more than 15 cells were used for identification.

16E3 – March 2016

Main Aims:

Summary of material

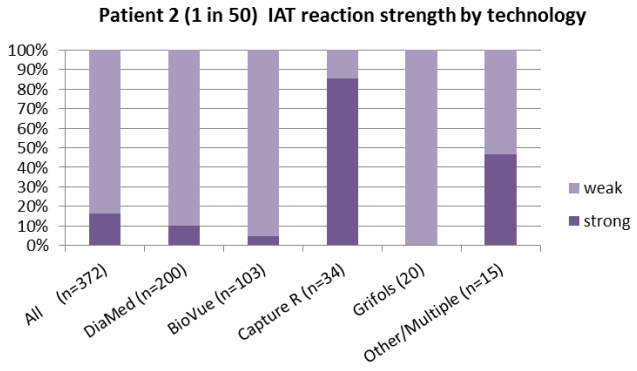
'Patient' 1: Anti-K (titre 2)
'Patient' 2: Anti-D (titre 1) 1 in 50 dilution
'Patient' 3: Anti-D (titre 1) 1 in 60 dilution
'Patient' 4: Anti-D (titre 1) 1 in 70 dilution

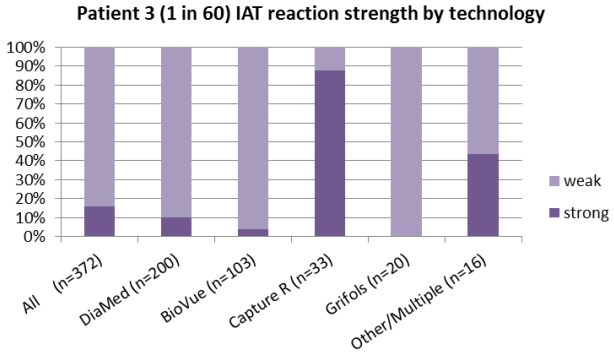
Return rate: 98.4%

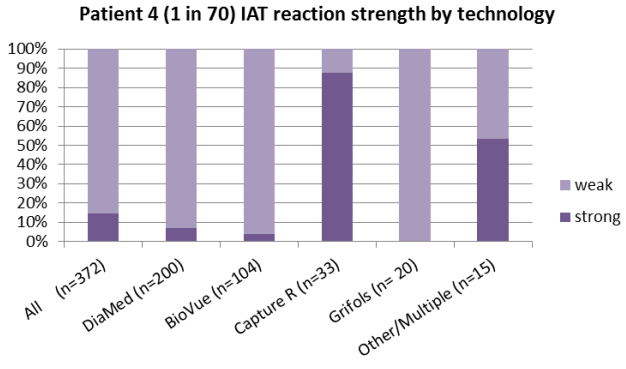
Results

Antibody screening

- Anti-D was detected all laboratories in all samples. Reported reaction grades are shown in the 3 figures below:







To develop the anti-D 'standard', four polyclonal anti-Ds were pooled and then the pool diluted to 1 in 50 for 'Patient' 2, 1 in 60 for 'Patient' 3 and 1 in 70 for 'Patient' 4. All of these dilutions were detectable by IAT in 100% UK laboratories. The histograms show the reaction strength by IAT technology for each sample. Technologies are shown individually where the number using a single technology (once or more than once) is >10. Reaction grades obtained with technologies where the number is <10, or with multiple technologies, are displayed together.

Antibody identification

- All laboratories identified the antibodies present
- 2 laboratories reported anti-D+C^w for Patients 2, 3 and 4
- One reported anti-D+UI but did not make a UI submission.

Exercise Comments/learning points

- The 1 in 70 dilution (Patient 4) will be used as the new UK NEQAS anti-D standard. It gave weak reactions in 85% laboratories (similar to the previous standard).
- The report emphasised that antibodies of low clinical significance or to low frequency antigens (e.g. anti-C^w) do not need to be excluded.

16R4 – April 2016

Main aims:

The main aim of this exercise was to assess the sensitivity of the serological IAT crossmatch for detection of IgG antibodies. To achieve this, we initially requested anti-Wr^a to add to plasma containing anti-c+K, so that even if antibody identification were to be undertaken, it would be unlikely that the anti-Wr^a would be identified, demonstrating the importance of the IAT crossmatch in patients with atypical red cell antibodies. A Wr(a+) donation was not available, so the specificity of the third antibody was changed to anti-C^w. The anti-C^w provided was subsequently found not to have an IgG component and was consequently not detectable by Capture technology. Given that an IgM anti-C^w is not regarded as clinically significant, donor Y was withdrawn from scoring. This was logged as a QI as the aims of the exercise were compromised.

Summary of material

Patient 1: O D positive, anti-S (titre 2)
Patient 2: O D positive, anti-c+C^w+K (titre 1, 2 & 2)
Patient 3: B D positive, inert

Donor W – O D positive, c+,C^w-, K-, S+s+
Donor Y – O D positive, c-, C^w+, K-, S+s+
Donor Z – O D positive, c-, C^w-, K-, S+s-

Return rate: 98.2%

Results

Procedural errors

- One laboratory inadvertently tested execise16R1 instead of 16R4
- Four laboratories appear to have transposed 2 donor samples'
    - One subsequently confirmed that this occurred during transcription from the analyser to a form, and had given sequential accession numbers to Z, Y, and W (rather than W, Y and Z).
- One laboratory used the whole blood samples to undertake the antibody screen
- Another did a screen on the whole blood and the plasma due to restrictions on the LIMS, but the wrong result was transferred to the LIMS.
- One laboratory reported an incorrect ABO group due to ticking the wrong box on the web page.

ABO/D

- Two laboratories reported the ABO group for P2 as UI, due to a negative reaction against A cells in the reverse group. This may have been due to using the plasma sample instead of the whole blood sample, as the ABO groups did not match on this occasion.

Antibody screening

- Four laboratories reported a false positive result for P3, each using a different technology

Crossmatching (excluding procedural errors already noted)

- Thirteen laboratories missed the incompatibility due to anti-C^w
    - 6 used Capture, 5 tube, 1 BioVue and 1 BioRad
- One laboratory missed two incompatibilities (anti-S and anti-c) but obtained weak positive reactions on repeat testing
- Two laboratories each missed a single incompatibility (one anti-S and one anti-c)
- Seven laboratories reported 12 false positive results.

Exercise Comments/learning points

Even though the aims of the exercise were compromised, the report still highlighted that an IAT crossmatch is essential in patients with red cell antibodies, even where antigen negative blood is selected for the antibodies identified, as it provides the opportunity to detect incompatibility due clinically significant specificities that might have been masked, misidentified or incorrectly reported due to procedural error.

16E5 – May 2016

Main Aims:

Patient 1: Inert
Patient 2: Inert
'Patient 3: Anti-E+M (titre 4 and 2 respectively)
Patient 4: Anti-D (titre 1) – 'Standard'

Return rate: 100%

Results

Antibody screening

Two laboratories reported a false positive screen for P2, based on non-specific reactions in Capture.

Antibody identification

- One laboratory did not positively identify anti-D, but made a UI submission, which was not agreed. This was later overturned as the panel cells showed that the anti-D gave negative reactions with an R0 cell, even with enzyme treated cells. This was confirmed in-house, whilst other D+ cells gave 3-4+ reactions in enzyme even when weak or negative by IAT.
- A 2nd UI submission was agreed for P3, as no enzyme panel was available to confirm the presence of anti-E (only one E+ M- cell).

Exercise comments/learning points

The anti-D gave a similar pattern of reactions by all technologies as in 16E3 and is therefore suitable to use as the 'Standard' in the future.

16E6 – June 2016

Main Aims:

Summary of material

'Patient' 1: Inert
'Patient' 2: Inert
'Patient' 3: Anti-E (titre 2)
'Patient' 4: Anti-K+Jk^{a} (titre 4 and 2 respectively)

Return rate: 97.6%

Results

***Antibody screening*:** No errors

Antibody identification

- One laboratory reported anti-c±E for P2, presumably due to data entry error
- Two laboratories reported anti-Jk^{a}+E for P3, due to data entry error
- One laboratory reported anti-Jk^{a} with anti-K as not excluded, but did not make a UI submission.

Exercise Comments

The report highlighted that the antibody identification process is often manual, and particular care is required to avoid transcription error.

16R7 – July 2016

Main Aims:

Summary of material

'Patient' 1: A D negative, anti-E+Fya (titre 2 & 1)
'Patient' 2: AB D negative, inert
'Patient' 3: B D positive inert

'Donor' W: A D neg (rr), Fy(a+b+), Jk(a-b+)
'Donor' Y: A D neg (rr), Fy(a+b+), Jk(a+b-)
'Donor' Z: A D neg (r"r), Fy(a-b+), Jk(a+b+)

Return rate: 98.7%

Results

Procedural errors

- One laboratory reported P1 as D positive, presumably due to transcription error (negative reactions vs 2 anti-D reagents)
- One laboratory reported P1 as anti-E+Fy^{b}, presumably due to data entry error
- One laboratory used the whole blood samples for crossmatching, instead of the plasma samples
- One laboratory missed the ABO incompatibility between P3 and DZ presumably due to data entry error as they reported a weak positive reaction by IAT
- One laboratory missed all 3 ABO incompatibilities having ticked 'EI'

Antibody screening

- Two laboratories reported a false positive reaction and interpretation for P3
    - One BioRad manual and the other BioRad auto.

Antibody Identification

- One laboratory identified anti-Fy^{a} but did not record anti-E as present or not excluded.

Crossmatching

- Nine laboratories missed 12 incompatibilities for P1, all recording a negative reaction by IAT
    - One missed all 3 incompatibilities, and identified problem with how the cell suspensions had been prepared.
    - Four missed one or both incompatibility due to anti-Fy^{a}, and four missed the anti-E
        - 2 used automation
            - 1 used an analyser that was subsequently found to have a fault and taken out of service. They recorded a weak positive reaction on repeat with another analyser
            - 1 was unable to determine a cause but recorded a weak positive reaction on repeat with the same analyser.
        - 6 used manual methods: 5 BioRad & one tube; 5 reported the results of repeat testing:
            - The tube user recorded a negative reaction on rpt. They returned their samples and we were able to detect the incompatibility in-house by tube.
            - The BioRad users all detected the incompatibility on repeat.
                - 2 suspected that the cell suspensions were inappropriate
                - 1 overlooked a weak positive reaction during reading

Exercise Comments

The discussion included the following statement: “Although the option to establish compatibility using electronic issue (EI) has been made available in EQA exercises, it is difficult to see how this could represent clinical use of EI, as the donations are not bar-coded and would have to be entered manually into the LIMS. The inclusion of an option to select EI will be reviewed at the next BTLP Steering Committee.” This was discussed at the November Steering Committee meeting and it was unanimously agreed to remove the EI option from the result entry page. A show of hands at the Annual Participants’ Meeting also showed support for this move.

16E8 – September 2016

Main Aims:

Patient 1: Inert
Patient 2: Anti-C+D (titre 2 and 0 respectively – anti-D only detectable by enzyme)
Patient 3: Anti-D+Fy^a (titre 16 and 1 respectively)
Patient 4: Inert

Return rate: 99.2%

Problems with Material

The intention was to distribute anti-C on its own. The supplier informed us that a plasma donation containing a weak anti-D was inadvertently added to the pool. We decided to continue with the exercise rather than waste the anti-C, with the intention of making learning points about anti-G and also about the use of enzyme panels, without penalty scoring.

In-house results

The anti-D was:

- detectable by enzyme in Grifols vs. R_2R_2 and R_0 cells throughout the exercise
- detectable by enzyme in BioRad vs R_2R_2 cells only, at pre-acceptance testing but not subsequently
- not detectable at all by BioVue, Capture or tube.

Performance monitoring

Patient 2 was not intended for scoring as there was no definitive correct interpretation, although the 'correct' result was shown as anti-C+D (could also have been anti-C+G, or -C+D+G). The anti-D was not detectable against all D+C- cells by all technologies.

Results

Antibody screening

One laboratory reported a repeatedly false negative antibody screen using a manual LISS tube technique, although the anti-C was detectable in our in-house testing by tube. Another laboratory reported false positive screens for P1 and P4, based on non-specific reactions in Capture. In total, 9 Capture users reported unsatisfactory sample quality due to non-specific reactions.

Antibody identification errors

- One laboratory reported anti-Fy^a as a single specificity for P3, due to data entry error

Antibody identification for Patient 2

- 95 (27%) reported anti-C+D
- A further 57 (16%) reported anti-C + another specificity:
  - ENS (n=23)
  - UI (n=21)
  - E (n=12)
  - C^w (n=1)
- 202 (57%) reported anti-C only. As single technologies:
  - 4/16 Grifols (25%)
  - 81/159 BioRad (51%)
  - 77/89 BioVue (87%)
  - 5/7 Capture (71%)
  - 2/3 tube (67%)

Exercise comments/learning points
Several laboratories made comments relating to anti-G. Others commented that if the patient was pregnant they would not want to report anti-D without ruling out the possibility of it being prophylactic anti-D Ig.

The discussion included points about:

- Anti-G and its significance in young female patients
- Prophylactic anti-D Ig
- Misinterpretation of weak anti-D as anti-E and D antigen site density on R_2R_2 cells
- Importance of giving Rh 'matched' units to patients with Rh antibodies.

16R9 – October 2016

Main Aims:

Summary of material

'Patient' 1 - B D negative, inert	'Donor' W – O D neg rr, K-, Fy(a-b+)
'Patient' 2 - AB D positive, DAT (2+), anti-E (titre 2)	'Donor' Y – O D neg, r"r, K-, Fy(a+b-)
'Patient' 3 - A D negative, anti-K (titre 2)	'Donor' Z – O D neg, rr, K+, Fy(a-b+)

Performance monitoring

AB D positive and UI were accepted as correct results for Patient 2.

Return rate: 98.7%

Results:

D errors

- One laboratory reported P1 as D positive. The sample was rejected x4 on the automation so was set up manually at 01.00 by a newly qualified BMS. Instead of recording the reaction grades and interpretation on a sticker (for the request form) the BMS wrote the interpretation on a form and typed this straight into the LIMS, without any checking.

Crossmatch errors

Procedural:

- One laboratory transposed results at data entry
- One laboratory used the whole blood samples by mistake

Testing:

- One laboratory missed the incompatibility between anti-E and the r"r cell using a manual technique – detectable on repeat.
- Four laboratories recorded 5 false positive reactions and interpretations.

Phenotyping

- Four laboratories made errors:
  - One in data entry
  - One reported donors Y and DZ as Fy(a+b+) – cause not known.
  - Two reported Fy(a-b-) for one of the donors.

ABO/D typing Patient 2

Positive reagent control

- Positive control recorded by 69/384 (18%)
  - 68 BioVue; 1 tube
  - 52 (75%) made interpretation of UI for ABO and D
  - One made interpretation of UI for ABO but D positive
  - Another two made interpretations of AB UI
  - 14 reported the group as AB D positive
    - 10 recorded the use of a 2nd technique
    - 4 apparently used only BioVue

Negative reagent control by BioVue

- 62 laboratories reported using BioVue as their sole technology
  - Reagent control was unexpectedly reported as negative by 10 of these (with an interpretation of AB D positive)
    - 3/51 (6%) using automation
    - 7/11 (64%) using a manual technique

Exercise comments

The red cells from Patient 2 (AB D positive) were coated with anti-D to give a 2-3+ positive DAT. This caused a positive reaction in the control well of BioVue grouping cassettes, invalidating the ABO and D typing results. The majority of laboratories using BioVue either reported an interpretation of UI or undertook repeat testing with a second technique enabling them to make an interpretation of AB D positive. However, four laboratories made an interpretation of AB D positive, a fifth reported AB UI and a sixth UI D positive. It is of course possible that these six laboratories undertook additional testing without recording it at data entry. In addition, 10 laboratories using BioVue recorded a negative reaction with the reagent control and all made an interpretation of AB D positive. Again, it is possible that additional testing was undertaken but not recorded on the web entry pages; alternatively, the positive control could have been overlooked in manual testing or overridden in automated testing. BCSH guidelines[1] state the following: “Where recommended by the manufacturer, a diluent control should always be tested against the patient’s red cells, as part of the ABO and/or D grouping procedure. If positive (even weakly) the test result is invalidated”.

16E10 – November 2016

Main Aims:

Summary of material

Patient 1: Inert
Patient 2: Inert
Patient 3: Anti-c+K (titre 16 and 32, respectively)
Patient 4: Anti-c (titre 4)

Return rate: 98.7%

Problems with material and performance monitoring

During routine in-house testing immediately prior to exercise distribution, Patient 2 was found to contain an unexpected weak anti-Jk^{a} detectable only by enzyme IAT and by Capture-R. It was not possible at this stage to make a change to the exercise instructions that listed Patient 2 as Jk(a+), and this sample was therefore withdrawn from scoring for antibody screening. The supplier subsequently confirmed that one of the nine plasma donations used to make the pool contained a weak anti-Jk^{a} detectable only by enzyme IAT (not tested by Capture-R).

Results

Antibody screening

- No errors
- Two Capture laboratories did report an antibody in P2, and another 2 reported (by email) what looked like anti-Jk^{a} but did not report formally as the patient was Jk(a+).

Antibody identification

Patient 3 (anti-c+K)

- 7 (2.0%) reported anti-c only
  - 1 transposition error (samples or results)
  - 4 recorded anti-K as not excluded (no UI submission)
  - 1 – anti-K masked by anti-c (no exclusion process)
  - 1 did obtain a positive reaction with a c negative cell, but did not follow it to a conclusion as they said they would refer.
- 1 (0.3%) reported anti-c+Jk^{a}
  - They excluded anti-K in error and concluded that the 2nd antibody was anti-Jk^{a} based on a single Jk(a+) c negative cell.
- 6 reported anti-c+UI
  - 5 were agreed.
- 1 reported UI (agreed)

Patient 4 (anti-c)

- 4 (1%) reported an additional antibody, not actually present
  - 1 made a transposition error (samples or results)
  - Anti-Le^a (x2); anti-Kp^a (x1)
- 2 (0.6%) reported anti-c+UI
  - ❖ One was agreed.

Exercise comments

The contaminating anti-Jk^a allowed us the opportunity to make an educational point regarding the clinical significance of Kidd antibodies, even if weak. We included the following text in the report: "Anti-Jk^a should always be considered of potential clinical significance, even when it is only weakly detectable. Kidd antibodies are prone to evanescence with the antibodies often becoming rapidly undetectable: mean three months (range 1-26 months) [1]. This means that they may be missed in routine pre-transfusion testing, leading to haemolytic transfusion reactions (HTR) following transfusion of antigen positive red cells. They can be difficult to identify even post HTR, as they often show dosage and may require the presence of complement or use of more sensitive techniques, e.g. enzyme IAT. It is of interest that this anti-Jk^a was also weakly detectable by some Capture-R users (against Jk(a+b-) cells), even in the final pool."

17R1 – January 2017

Main Aims: Detection and ID of anti-K+Fy^a and Rh phenotyping.

Material
Patient 1 – A D positive, anti-K+Fy^a (titre 2 and 4)
Patient 2 – O D positive, inert
Patient 3 – B D negative, inert

Donor W – O D pos R_1r, Fy(a-b+), K+
Donor Y – O D pos, R_1R_2, Fy(a+b-), K-
Donor Z – O D neg, r''r, Fy(a+b+), K-

Return rate: 99.2%

Performance monitoring
Patient 3 was withdrawn from scoring for crossmatching because a significant number of labs (n=26) deselected Donors W&Y (D positive) for the D negative patient, contrary to the instructions.

Results

Procedural errors:

- 3 laboratories recorded the correct reaction grades but an incorrect D interpretation, due to data entry error
- One lab used the whole blood samples for crossmatching
- One lab missed 2 incompatibilities due to data entry error
- Two labs transposed samples or results for donors Y&Z at some stage, resulting in two incorrect phenotypes.

D typing

- One laboratory obtained the correct D typing results for Patient 3 using their routine automation. However they also undertook a manual group in line with their in-house policy for patients requiring a crossmatch; this was misinterpreted as D positive and reported as the final results. The process used for clinical samples was not followed as this involves reaction grades being entered into the LIMS, with the LIMS making the interpretation.

Antibody identification

- Two laboratories reported anti-Fy^a as a single specificity, having excluded anti-K based on a false negative reaction by IAT with a K+, Fy(a-) cell
    - One, using Capture-R, obtained a positive reaction on repeat
    - The other performed an IAT in BioVue cassettes using CellStab as a diluent (due to supply problems with the BioVue panel).
- Two laboratories identified anti-Fy^a but misidentified the 2nd specificity and did not record anti-K as 'not excluded'. Neither followed a process of exclusion / inclusion.
    - In one case, anti-K and anti-Le^b were both completely masked, but anti-K was overlooked and anti-Le^b reported as present
- 2 UI submissions were made
    - One was disagreed as there were two K+ Fy(a-) cells but the screening panel had been overlooked.

Crossmatching

Three laboratories missed one or more incompatibility; all obtained positive reactions on repeat.

- 1 using manual testing, missed all three incompatibilities; the cause was not established.
- 1 missed both incompatibilities due to anti-Fy^{a}. The cause was not conclusively established, but they think they may have omitted the plasma.
- 1 missed the incompatibility against donor Z only.

Phenotyping

- 7 laboratories recorded eight false negative reactions and one false positive reaction, resulting in nine incorrect sets of results.
    - 2 assigned the correct Rh shorthand interpretation (i.e. R_1r for Donor W and r"r for Donor Z), so could have made data entry errors
- 33 sets of correct reactions were assigned incorrect shorthand interpretations:
    - 27 did not take the D type into account
- 5 did not assign any shorthand interpretations.

Discussion / learning points

- Checks are required at critical points in the pre-transfusion process, e.g. sample labelling, performing and interpreting manual tests and transcribing information.
- Every antibody investigation should include a systematic process for exclusion and positive identification of antibody specificities, and all reactions should be accounted for before a conclusion is reached.
- All techniques used for testing clinical and EQA samples should be validated by the manufacturer and / or in-house. In this exercise, the use of reagent red cells suspended in a diluent designed for one column agglutination technology (CAT) but used in another caused insensitivity in the IAT, resulting in a false negative reaction which contributed to misinterpretation of anti-K+Fy^{a}. Each CAT system employs a diluent with a specific ionic strength, designed along with the volume of plasma required, to give the optimal ionic strength of the final mixture of reactants.

Further work

It is not clear to what extent and in what context (written/verbal) Rh shorthand interpretations are used in clinical laboratories in the UK or overseas. Their inclusion in the EQA exercises makes the report very 'untidy' and we would only wish to continue collecting this information if it reflects clinical practice. A question on the use of Rh 'shorthand' was included in the 2017 annual practice questionnaire.

17E2 –February 2017

Main Aims: To assess detection of the UK NEQAS 'standard' anti-D, and identification of an antibody mixture.

Material:

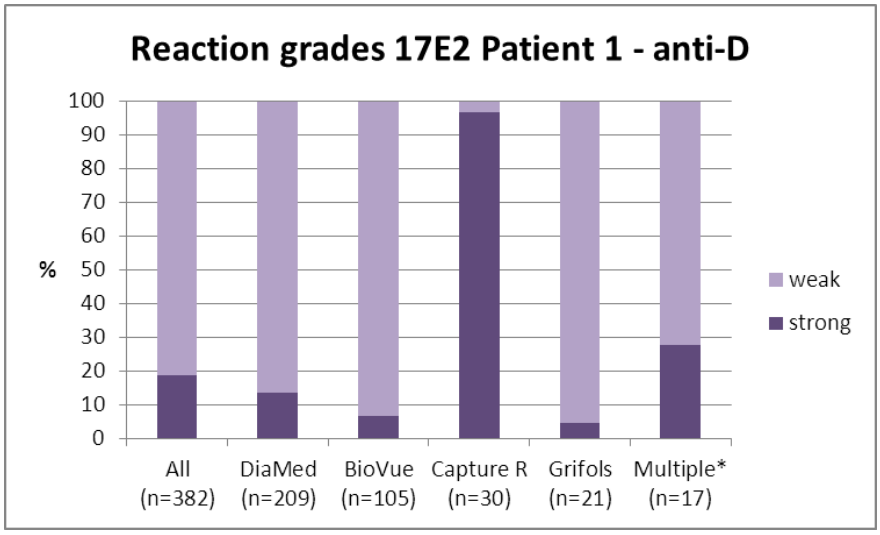
Patient 1 – anti-D (NEQAS Standard)
Patient 2 – inert
Patient 3 – inert
Patient 4 – anti-D+M (titre 4 and 8)

Return rate: 98.7%

Results
All detected the UK NEQAS 'standard' anti-D, and the reaction grades returned are shown in Figure 1. These results are similar to those returned for the UK NEQAS 'standard' anti-D the last time it was distributed in June 2016.

Antibody screening

For Patient 1, the antibody screening reaction grades obtained by technology were very similar to those reported in exercise 16E5 (the last time that the UK NEQAS anti-D standard was distributed).



Antibody identification - Patient 4 (anti-D+M)
One laboratory misidentified the second specificity as anti-Jkb. One UI submission was received and agreed.

Discussion / learning points

- The UKNEQAS 'standard' anti-D is still suitable for use to monitor sensitivity in antibody screening.
- An enzyme panel can be used to exclude Rh antibody specificities.
- It is good practice where an Rh antibody is detected, to provide Rh matched red cells for transfusion.

17E3 –March 2017

Main Aim: Identification of antibody mixtures where patient phenotypes are not available.

Material
Patient 1 - anti-c+K (titres 2 and 4)
Patient 2 - inert
Patient 3 - anti-E+Fy^{a} (titres 2 and 1)
Patient 4 - inert

Return rate: 99.0%

Results

Antibody screening
The only two errors reported were caused by the transposition of results between Patient 3 and Patient 4 at data entry.

Antibody identification - Patient 1 (anti-c+K)
40/353 (11.3%) laboratories did not report anti-c+K

- 6 identified anti-c only
- 10 identified anti-c but misidentified the second specificity
  - 4 anti-Fy^{b} (4)
  - 3 anti-S (3)
  - 2 anti-Jk^{b} (2)
  - 1 anti-Le^{b}
- 1 reported anti-E+Fy^{a} due to transposition of results with Patient 3 at data entry.
- 1 reported UI, but no UI submission was received
- 22 UI submissions were received and 21 of these were agreed

Antibody identification - Patient 3 (anti-E+Fy^{a})
Three laboratories did not report anti-E+Fy^{a}

- 1 identified anti-Fy^{a} only
- 1 reported anti-c+Fy^{a} due to data entry error
- 1 reported anti-c+K due to transposition of results with Patient 1 at data entry)

Discussion / learning points
Number of cells and panel profiles

- ID and screening panel profiles influence detection and >25 cells improved completion of antibody identification cf. <15 cells.

Variability anti-K reactivity in a two-stage enzyme test

- Anti-K should not be excluded on this test alone
- Anti-K that is detectable by IAT will react in an enzyme IAT - can be useful in differentiating between anti-K and specificities where the corresponding antigen is denatured by enzyme, e.g. anti-Fy^{b}.

UI submission

- Use the UI facility where all clinically significant antibodies cannot be excluded in EQA samples.

Further work

Using some of the ID and screening panel combinations returned as part of UI submissions, it was not possible to identify anti-c+K, including one where anti-K was masked by anti-c. The manufacturer of this panel was contacted and a meeting took place to discuss panel profiles.

A UK NEQAS study was planned to investigate antibody identification panel profiles (in conjunction with the corresponding screening panel) from all manufacturers willing to participate - abstract submitted to BBTS ASM 2017 and accepted as a poster (see Appendix 1).

17E4 –April 2017

Main Aim: Identification of an antibody mixture, and detection / identification of a weak antibody.

Material

Patient 1 - Anti-E (titre 8)
Patient 2 - Anti-E+M (titres 8 and 2)
Patient 3 – Inert
Patient 4 - Anti-E (titre 1)

Performance monitoring

Further testing of Patient 4 revealed the unintended presence of anti-Wr^a, so anti-E and anti-E+Wr^a were both accepted as correct antibody interpretations for Patient 4.

Return rate: 99.2%

Results

Antibody screening

Four laboratories did not detect the anti-E in patient 4.

- 3 had equivocal reactions in the initial screen
    - 2 discounted a weak positive reaction in the antibody screen
        - 1 on the basis of a field safety notice relating to screening QC samples
        - 1 due to a pre-existing problem with false positive reactions in the screen
    - 1 did not follow their own protocol for investigating an equivocal screen
- 1 obtained a negative initial screen, and on repeat testing after the closing date a negative result was obtained on one analyser and a positive result on another.

Antibody identification

One laboratory correctly identified all the antibody specificities, but entered anti-E as anti-c+/-E for Patients 1, 2 and 4 due to data entry error. One laboratory in the Republic of Ireland correctly identified anti-E and the contaminating anti-Wr^a in Patient 4.

Discussion / learning points

Weak reactions

- Knowledge of current issues or problems related to different technologies or current testing environments can influence interpretation of antibody screening results.
- Importance of having clear protocols for dealing with equivocal / weak reactions in antibody screening or identification panels.
- For laboratories using automated technologies, any issues relating to comparability of results between analysers should be referred to the supplier.

Antibodies to low frequency antigens

- Antibodies to low frequency antigens are often not detected by antibody screening cells or first line antibody identification panels.
- Antibodies to some low frequency antigens, e.g. Wr^a, can be clinically significant, but as the likelihood of a donation being antigen positive is low, there is no requirement to detect these antibodies in routine testing.

17R5 – May 2017

Main Aims: D typing of a D negative, DAT positive sample, and identification of anti-S in the presence of an enzyme 'non-specific' antibody (ENS)

Material:
Patient 1 - O D negative, DAT positive, anti-S+Enzyme non-specific (ENS) (anti-S titre 2)
Patient 2 - B D positive, inert
Patient 3 –A D negative, anti-C+D (titres 4 and 16 respectively)
Donor W - O D positive R_2r (cDE/cde), S-, Jk(a+b+)
Donor Y - O D negative rr (cde/cde), S+, Jk(a+b-)
Donor Z - O D negative r'r (Cde/cde), S-, Jk(a-b+)

Performance monitoring

- UI was accepted for ABO and D typing for Patient 1 (D negative, DAT positive).
- Patient 1 withdrawn from scoring for crossmatching vs. Donor W (D positive), as although serologically compatible, it was eligible for deselection (based on instructions that allow deselection of D positive donors for a D negative patient with a positive antibody screen, and with consideration of the demographic details provided (female aged 35)).
- Patient 1 plasma pool had anti-Wr^a, so anti-S, anti-S+ENS, anti-S+Wr^a and S+UI were accepted.

Return rate 99.0%

Results

D typing

Patient 1 (D negative (DAT positive) reported as D positive or D variant) 9 errors

- 1 data entry error (DiaMed user)
- 8 interpretation errors (BioVue users) see Table 7:

Table 7 - Patient 1 results for 8 BioVue laboratories reporting an incorrect D type

Lab	Automated / manual	Reaction grades recorded			DAT	Interpretation
		Anti-D 1	Anti-D 2	Reagent control		
A	Fully-Automated	Weak	No result	Weak	Positive	O D Positive
B	Fully-Automated	Weak	No result	Weak	Positive	O D Positive
C	Manual	Weak	No result	Negative[1]	No result	O D Positive
D	Fully-Automated	Strong	Strong	Negative[2]	No result	O D Positive
E	Fully-Automated	Weak	No result	Negative[1,3]	No result	O D Variant
F	Fully-Automated	Weak	Weak	Weak	Positive	O D Variant
G	Fully-Automated	Weak	No result	Negative[2]	No result	O D Variant
H	Fully-Automated	Weak	No result	Weak	Positive	UI (ABO) D Variant

[1] Control weakly positive on repeat after closing [2] Initial control incorrectly recorded as negative
[3] Used a panel of anti-Ds (by IAT) to investigate D variant before initial reporting (without a DAT control)

66 laboratories recorded positive reactions vs. anti-D reagent(s) and/or the reagent control

- All reported using BioVue as their primary ABO/D typing technology
- All reported UI (D) or D negative (except those in Table 7)

Table 8 shows the results for 105/110 BioVue laboratories that recorded reaction grades

- 5 positive reaction vs. anti-D and a negative control; 4/5 leading to incorrect D interpretations.

Table 8 - Reaction grades vs. anti-D reagent(s) and reagent control by BioVue laboratories

Reaction vs. Anti-D	Reaction vs. reagent control			
	Negative	**Weak**	**Strong**	**MF**
Negative	39	1	0	2
Weak	3[1]	32	0	3
Strong	1[2]	1	1	0
Mixed field (MF)	1[3]	6	0	15

[1] Laboratories C, E and G in Table 7 [2] D in Table 7 [3] not confirmed with the laboratory; reported as UI(D)

Antibody screening

Two errors (1 lab), due to transposition of samples for Patient 2 and 3 at labelling

Antibody identification

Patient 1 (anti-S+ENS), 3 errors

- Anti-S+K (data entry error)
- Anti-S+D (interpretation of enzyme panel error)
- Anti-e+/-C (interpretation and data entry error)

Patient 3 (anti-C+D), 2 errors

- 2 Anti-D only; positive reaction vs. r'r (Cde/cde) cells not taken into account at interpretation

Crossmatching

11 laboratories made a total of 25 errors:

18 procedural

- 1 lab (4 errors) switched samples for Patients 2 and 3
- 1 lab (5 errors) transposition of Patient 1 and Patient 3 at data entry
- 1 lab (3 errors) transposition of Donors W and Y at data entry
- 1 lab (2 errors) transposition results or testing of Donors Y and Z vs. Patient 3
- 1 lab (3 errors) reported results based on DRT rather than IAT reactions
- 1 lab (1 error) reported incompatible on a negative reaction by IAT (Patient 3 vs. Donor Y)

7 other errors

- 4 labs one missed incompatibility each
- 2 labs three missed compatibilities

Transfusing Donor W (D positive) to Patient 1 (D negative, DAT+ 35 year old female)

- Overall 85/378 (22%) would transfuse
    - 21% reporting D negative
    - 67% reporting D positive or D variant

Phenotyping

25 unable to test for Jk^b

11 laboratories made 14 errors

- 9 false positive
- 5 false negative

1 typed all three donors as Jk(a-)

2 transposed Donors Y and Z

Discussion / learning points

- Risks in interpretation of equivocal D typing reactions
- Positive reagent control invalidates the test
- Importance of following manufacturer's instructions for testing and interpretation, and of understand properties/ limitations of all reagents / technologies used
- Clear policy for identifying , further testing and reporting of anomalous D typing reactions
- Risks of sensitisation to D for females with child bearing potential
- Labelling samples is a critical point - re-check details prior to validation of results

17E6 – June 2017

Main Aim: Identification of an antibody mixture.

Material
Patient 1 - Inert
Patient 2 - Inert
Patient 3 – Anti-D+Fy^{a} (titres 8 and 1)
Patient 4 - Anti-K (titre 8)

Return rate: 99.0%

Results

Antibody screening
No errors.

Antibody identification
Four laboratories made errors in antibody identification:

- Patient 3 (Anti-D+Fy^{a})
  - 1 anti-D only: transcription error
  - 1 anti-D+s: failure to follow antibody inclusion/exclusion protocol
- Patient 4 (Anti-K)
  - 2 anti-K + enzyme non-specific: 'Mixed field' reactions. Repeat testing after centrifuging samples gave negative reactions, and on review the original reactions resembled those seen in clinical practice due to fibrin.

Discussion / learning points
Antibody identification process
To avoid misidentification, every antibody investigation should include a systematic process for exclusion and positive identification of antibody specificities, and all reactions should be accounted for before a conclusion is reached.

Visual inspection of samples
It is good practice to centrifuge clinical and EQA samples prior to testing. Contamination of blood transfusion samples with fibrin or cellular debris can interfere with laboratory results. It is advisable to re-centrifuge and make a visual check of sample quality if any unusual results are obtained, and to request repeat samples for retesting if this is indicated.

17E7 – July 2017

Main Aim: Identification of an antibody mixture.
Detection and identification of a weak antibody
Identification of an antibody mixture
Titration of an IgG antibody (optional and non-scoring)

Material:
Patient 1 - Inert
Patient 2 - Anti-c (titre 1)
Patient 3 - Anti-E+K (titres 2 and 4)
Patient 4 - Anti-K (titre 16)

Return rate: 99.0%

Results

Antibody screening
No errors.

Antibody identification
Ten laboratories made errors in antibody identification:

- Patient 2 (Anti-c)
  - *7 anti-c+E*
  - *1 UI submission* accepted
- Patient 4 (Anti-K)
  - *1 anti-K+Lu^a*
  - *1 anti-K+Kp^a*

Discussion / leaning points

- Difficulty in positively identifying anti-E in a sample containing anti-c
  - Requires c negative and E positive cells e.g. R_1R_Z (CDe/CDE)
  - Blood selected for these patients will be c and E negative
- Clinical significance of anti-Kp^a and anti-Lu^a
  - Not required on antibody screening cells
  - No need to exclude antibodies to low frequency antigens

17R8 – September 2017

Main Aims
Detection of incompatibility due to IgG and ABO antibodies
Detection of a weak antibody

Material
Patient 1 - Group A D negative, inert
Patient 2 - Group AB D positive, anti-c (titre 1)
Patient 3 - Group O D positive, inert

Donor W - Group A D negative rr (cde/cde), S+ s-
Donor Y - Group O D negative rr (cde/cde), S+ s+
Donor Z - Group O D negative r'r (Cde/cde), S- s+

Return rate 99.0%

Results

Antibody identification

- Patient 2 (anti-c)
  - 2 anti-c+E
  - 2 anti-c+Le^{a}

Crossmatching
13 laboratories reported incorrect compatibility testing results

- 5 laboratories made 8 data entry errors
- 2 laboratories did not report ABO incompatibility between Patient 3 and Donor W
  - 1 transposition of donors W and Y during testing
  - 1 incorrect decision on theoretical compatibility
- 2 laboratories missed compatibility between Patient 2 (anti-c) and one or more donors (all c positive)
  - 1 all three donors compatible
  - Used donor samples at original dilution in automated testing; manual misinterpretation in automated testing due to insufficient cells
  - 1 false negative reaction in manual testing; failure to add plasma as a result of distraction
- 4 laboratories missed 7 compatibilities due to false positive reactions in IAT
  - 3 Grifols users
  - 1 BioRad (DiaMed) user

Phenotyping
5 laboratories recorded 7 incorrect phenotyping results

- 1 typed all donors as S Negative
- 1 transposed results or samples for Donors Y and Z
- 3 incorrect results for Donor Z
  - 2 false positive S types
  - 1 false negative s type

Discussion / leaning points

- ABO incompatible red cell issue is normally prevented by the LIMS system.
    - LIMS downtime or failure; system needed to avoid ABO incompatibility
- Preparation of red cell suspension for crossmatching in EQA exercises
    - Where automated systems give an error message that insufficient red cells are present the test should be repeated, rather than interpreted manually
- Effect of distraction when performing critical manual testing

17E9 – October 2017

Main Aims
Detection and identification of an antibody mixture
Detection of a weak antibody

Material
Patient 1 – Anti-D+E (titres 4 and 4)
Patient 2 – Anti-S (titre 4)
Patient 3 - Inert
Patient 4 – Inert

Return Rate 98.7%

Antibody screening
No errors.

Antibody identification

- Patient 1 (Anti-D+E)
  - 1 anti-D+C: data entry error
- Patient 2 (Anti-S)
  - 1 anti-S + enzyme non-specific

Discussion learning points

- Care is required in avoiding transcription errors with manual transcription of results

1710 – November 2017

Main Aims
Detection and identification of a weak antibody
Detection of incompatibility vs. 'homozygous and heterozygous' cells

Material
Patient 1 - Group O D positive, anti-M titre 4
Patient 2 - Group B D negative, inert
Patient 3 - Group A D positive, inert

Donor W - Group O D negative, M+N+, Fy(a+b-)
Donor Y - Group O D negative, M-N+, Fy(a-b+)
Donor Z - Group O D negative, M+N-, Fy(a+b+)

Return rate 99.5%

Results

Antibody identification – Patient 1 (anti-M)

- 2 anti-M+S
- 3 UIs all accepted

Crossmatching

7 laboratories, 9 errors

- 2 confirmed data entry errors
  - 1 Patient 1 vs. Donor Z compatible
  - 1 transposing results for Patient 1 vs. Donors W and Y
- 1 possible data entry error
  - Deselection of Donor Z vs. Patient 2 (inert).
- 1 missed 2 incompatibilities (Patient 1 (anti-M) vs. Donors W and Z (both M+))
  - Whole blood samples used for crossmatch
- 3 false positive results Patient 1 (anti-M) vs. Donor Y (M-)

Phenotyping

4 laboratories 8 errors.

- 1 data entry error
  - Recorded all three sets of results vs. wrong donors
- 1 Donor W recorded as Fy(a-b-)
- 1 Donor W recorded as Fy(a-b-) and Donor Y as Fy(a+b+)
- 1 transposed either samples or results for Donors W and Y.

Discussion / leaning points

- Linkage disequilibrium within the MNS blood group system
  - Rarity of NNSS cells on antibody identification panels.
  - Difficult to identify or exclude an underlying anti-S in a patient with anti-M.
  - Systematic process for exclusion and positive identification of antibody specificities,.
- Checks required at critical points in the pre-transfusion process (sample labelling, performing and interpreting manual tests and transcribing information).

5. FMH exercise summaries and results

Six exercises, each comprising two samples, were distributed in in both 2016 and 2017. The range of bleed sizes for distribution on an annual basis is agreed by the SAG and is shown in table 9. The number of returns, method medians and IQ ranges of the samples issued in the calendar year 2016 and 2017 are shown in tables 10 and 11 and those for flow cytometry in Tables 12 and 13.

Table 9 – Plan for range of bleed volumes

BV range (mL)	New no. samples p.a.
0[1]	1[1]
2 – 4[2]	2[2]
4 - 6	1
6 – 10	1
10 - 12	3
12 -16	1
20+	3
Total	12

[1] not intended for scoring by any method

[2] not intended for scoring by acid elution

Table 10 – Summary of distributions and results for acid elution 2016

Survey	Acid Elution			
	No. Returns Analysed	Median (mL)	IQ Range (mL)	Full Range (mL)
1601F - 1[1]	170	8.8	7.7 – 10.0	2.9 – 16.8
- 2[1]	169	8.7	7.6 – 10.0	1.7 – 18.1
1602F - 1[3]	169	4.7	3.9 – 5.9	0.8 – 31.2[2]
- 2	171	26.4	23.0 – 29.6	3.0 – 53.0[2]
1603F - 1	168	15.0	13.1 – 17.5	3.9 – 30.2
- 2	168	6.3	5.5 – 7.3	2.1 – 12.7
1604F - 1[3]	31	0.7	0.2 – 1.7	0.0 – 12.0[4]
- 2	166	14.0	12.0 – 16.4	0.4 – 30.1[4]
1605F - 1[1]	169	25.5	22.6 – 28.7	14.7 – 53.2
- 2[1]	169	25.8	23.3– 28.9	12.5 – 53.0
1606F - 1	170	14.0	12.0 – 16.0	0.7 – 23.3[5]
- 2[3]	167	5.0	4.1 – 6.4	1.7 – 32.4

[1] Prepared from the same pool

[2] One laboratory appears to have transposed the samples or results (revised ranges: P1 0.8-10.8mL; P2 5.6-53.0mL)

[3] Specimens not intended for scoring

[4] Two participants appear to have transposed the samples or results (revised ranges: P1 0-4.4mL; P2 6.0-30.1mL)

[5] One laboratory made a data entry error (revises range 4.8 – 23.3mL)

Table 11 – Summary of distributions and results for acid elution

Survey / Sample		Acid Elution			
		No. Returns Analysed	Median (mL)	IQ Range (mL)	Full Range (mL)
1701F	1[1]	170	28.2	25.9 – 31.2	15.2 – 101.3 (48.4[3])
	2[1]	170	28.2	25.2 -31.4	16.4 – 127.7 (42.4[3])
1702F	1[2]	164	3.4	2.8 – 4.0	1.8 -15.3
	2	170	13.0	11.5 – 14.7	0.4 – 25.4
1703F	1	171	14.6	13.0 – 16.2	6.4 – 25.0
	2	170	5.5	4.6. – 6.4	2.7 – 11.1
1704F	1	169	25.1	22.0 – 27.4	15.8 – 39.4
	2[2]	27	0.4	0.0 – 1.1	0.0 – 3.0
1705F	1[1]	169	13.0	11.1 – 14.6	1.2 – 24.0
	2[1]	169	12.8	11.4 – 15.2	0.3 – 30.0
1706F	1	173	18.1	16.1 – 20.5	5.9 (6.7[4]) – 36.0
	2[2]	172	4.7	3.9 – 5.7	1.8 – 21.4 (17.0[4])

[1] Prepared from the same pool [2] Sample not intended for scoring
[3] Range corrected for grossly outlying result (non-UK) [4] Range corrected for sample transposition

Table 12 – Summary of distributions and results for flow cytometry 2016

Survey		Flow Cytometry			
		No. Returns Analysed	Median (mL)	IQ Range (mL)	Full Range (mL)
1601F	1[1]	58	7.0	6.6 – 7.2	3.8 – 17.0
	2[1]	58	7.0	6.6 – 7.3	2.2 – 9.6
1602F	1	56	3.1	3.0 – 3.4	2.1 – 4.8
	2	55	22.6	21.1 – 24.0	12.3 – 27.2
1603F	1	55	13.4	12.8 – 13.8	8.7 – 15.4
	2	55	5.0	4.5 – 5.1	2.3 – 6.6
1604F	1[2]	55	0.0	0.0 – 0.2	0.0 – 37.3
	2	55	11.0	10.4 – 11.4	6.6 – 41.3[3]
1605F	1[1]	61	24.8	23.7 – 25.7	17.2 – 28.5
	2[1]	61	24.8	23.9 – 25.9	14.7 – 32.9
1606F	1	62	11.7	11.2 – 12.3	4.8 – 217.8[4]
	2	62	2.9	2.6 – 3.1	0.0 – 59.4[4]

1 Prepared from the same pool 2 Sample not intended for scoring
3 One non-UK lab reported high bleeds for both samples – excluding this the revised range is 6.6-14.4mL
4 Both grossly outlying results were submitted by one UK lab also reporting USQ, stating that the positive peak was not clear. Revised ranges are 4.8-20.7mL and 0-14.7mL, respectively.

Table 13 – Summary of distributions and results for flow cytometry 2017

Survey / Sample		Flow Cytometry			
		No. Returns Analysed	Median (mL)	IQ Range (mL)	Full Range (mL)
1701F	**1**[1]	59	26.4	25.3 – 27.6	17.6 – 35.4
	2[1]	59	26.4	25.0 – 27.2	19.8 -43.5
1702F	**1**	62	2.2	2.0 - 2.4	0.0 – 3.2
	2	62	11.0	10.3 – 11.3	3.7 – 31.5
1703F	**1**	58	13.2	12.5 – 13.5	9.7 – 15.8
	2	58	4.3	4.0 – 4.6	3.3 – 7.0
1704F	**1**	61	22.2	21.5 – 23.5	0.2 (15.4[3]) – 28.8
	2[2]	60	0.0	0.0 – 0.2	0.0 – 19.5 (1.5[3])
1705F	**1**[1]	58	11.5	10.8 – 12.0	5.0 – 13.7
	2[1]	58	11.5	10.7 – 11.9	7.2 – 13.4
1706F	**1**	60	15.1	14.5 – 15.9	11.5 -35.0
	2	60	3.2	2.9 – 3,5	2.0 – 7.3

[1] Prepared from the same pool
[2] Sample not intended for scoring
[3] Range corrected for sample transposition

Exercise 1704F included a sample prepared from an adult blood donation to represent a 0mL bleed. 45/169 (26.6%) reported seeing some fetal cells (cf. 39% 84/216 in 2016 and 108/222 – 49% in 2015). 14/45 undertook quantification by acid elution; there was no apparent correlation with kit used. Two UK laboratories would have made a referral for quantification by flow cytometry. Table 14 summarises learning points from FMH exercise in 2016-17.

Table 14– Learning points from FMH exercises

Issue	Exercise(s)	Learning point(s)
Consequence of insufficient follow up testing		
'Potential for sensitisation' errors (Acid elution users only)	1603F 1604F 1606F 1701F 1702F 1703F 1704F	The amount of anti-D Ig issued would not have been sufficient to cover the flow cytometry method median (FCMM), and no follow up testing would have been performed (referral for flow cytometry or repeat sample). This could result in maternal sensitisation and potential HDFN in future pregnancies. Over the course of 12 exercises, four 'Potential for sensitisation' errors were made by UK laboratories, and 25 errors by non-UK laboratories. Where non-UK laboratories made errors, different National Guidelines may have been followed.

Learning points when samples contain no fetal cells		
Fetal cells seen when none are present	1604F 1704F	1604F • 18/52 (35%) acid elution screening only laboratories 84/217 (39%) acid elution quantification laboratories There was no correlation between kit used and fetal cells detected. 1704F • 13/55 (24%) acid elution screening only laboratories 45/169 (27%) acid elution quantification laboratories There was no correlation between kit used and the fetal cell detection rate in either instance. Adult cells can show variable levels of elution and staining, but should be distinguishable from more intensely stained fetal cells. Where no intensely stained cells are present, as for Patient 1, it is useful to review the test slide vs. the positive control slide that was stained at the same time.
Unnecessary testing when no fetal cells are present	1604F 1704F	1604F • 7/52 (13%) acid elution screening only laboratories referred the sample for quantification by flow cytometry • 36/217 (17%) acid elution quantification laboratories triggered quantification 1704F • 3/49 (6%) acid elution screening only laboratories referred the sample for quantification by flow cytometry • 14/169 (8%) acid elution quantification laboratories triggered quantification The rate of fetal cell detection and unnecessary quantification for a sample with a 0mL FMH had reduced from 2016 to 2017.
Risks associated with sample transposition		
Potential for sensitisation	1602F 1603F 1604F 1704F 1706F	Transposition of results (either during testing or during data entry) can result in insufficient anti-D Ig being administered, and/or insufficient follow up testing. This could result in maternal sensitisation and potential HDFN in future pregnancies.
Intra-laboratory reproducibility		
Comparison of results for Patient 1 and Patient 2 when both samples are produced from the same pool of material	1601F 1605F 1701F 1705F	The spread of results when plotted P1 vs P2 by quantification method shows better intra-laboratory reproducibility for flow cytometry. From 1605F onwards, plots were also produced to compare flow cytometry results using an anti-D marker vs. other markers, with better intra-laboratory reproducibility achieved using anti-D markers.

Effects of high HbF in maternal blood		
High HbF in maternal blood	1604F 1606F	1604F - Adult cells can show variable levels of elution and staining, but should be distinguishable from more intensely stained fetal cells. Where no intensely stained cells are present, as for Patient 1, it is useful to review the test slide vs. the positive control slide that was stained at the same time. 1606F - 7 AE and 2 FC laboratories reported Unsatisfactory sample quality which may have been caused by high HbF in Patient 2; 4 AE and 1 FC laboratories reported the same issue for both samples. The increased HbF level does not appear to have impacted on the results of participants for flow cytometry. It is important to refer for flow cytometry using an anti-D marker where a high level of HbF is suspected in a D negative maternal sample, and to have a contingency plan in place for reporting FMH where a high level of HbF is suspected in a D positive maternal sample.

6. ABO Titration ABOT exercise summaries and results

ABO titration remained a pilot scheme during 2016. All plasma samples were sent undiluted and covered a range of titration values, including duplicates (prepared from a single pool in a single exercise) and replicates (same pool used over more than one exercise). The results continue to show a wide range of results within all techniques, including the standard. In March 2016, a scoring system was approved by NQAAP for ABO titration and in-house web result entry and reporting systems were developed and successfully trialled in December 2016.

Summary of material provided and participation during 2017

Table 15 summarises the material provided since ABOT became a full Scheme in April 2017, and shows the median titre obtained for each sample using the 'Standard' BioRad techniques for DRT and IAT.

Table 15 summary of ABO titration material distributed and median titration results reported

Data	17/18 ABOT1 May 2017	17/18 ABOT2 Sept 2017	17/18 ABOT3 Nov 2017
Number of participants registered	98 (42 UK)	96 (41UK)	98 (41 UK)
Return rate	94%	94%	94%
Number Std. results	65 DRT 74 IAT	64 DRT 75 IAT	61 DRT 73 IAT
Number in-house results	51 DRT 31 IAT, 12 DTT[2]	52 DRT 27 IAT, 13 DTT[2]	53 DRT 32 IAT, 13 DTT[2]
Plasma sample 1 **All group O, anti-A titre[1]**	32 DRT 64 IAT	32 DRT 128 IAT	64 DRT 128 IAT
Plasma sample 2 **P1 & P2 group O, anti-A titre[1]** **P3 group A, anti-B titre[1]**	128 DRT 512 IAT	128 DRT 512 IAT	128DRT 512 IAT
Plasma sample 3 **All group O, anti-A titre[1]**	32 DRT 32 IAT	8 DRT 4 IAT	128 DRT 512 IAT
Cells provided for titration	A_1rr	A_1rr and Brr	A_1rr
Replicate samples across exercises	Patient 1	Patient 1	Patient 1
Duplicate samples within exercise	No	No	Yes
Additional information collected	None	None	Use of controls UoM

[1] Titres shown are median results obtained with the standard technique [2] Plasma treated with DTT or equivalent

Results continue to demonstrate variation both within and between technologies, with the same trends as seen throughout the pilot, i.e. BioVue IAT results generally higher than the Standard technique and Immucor IAT results generally lower (due to measuring IgG only).

An example report is included as Appendix 2.

7. Summary of performance PTT

Error rates by analyte
Table 16 compares error rates (data includes laboratories in the Republic of Ireland).
The error rate is based on the number of opportunities for error by all participants returning results, where n equals the number of tests distributed within each category.

Figures shown in brackets following the error rate are the percentages known to be due to transcription or transposition errors (samples or results), or testing the wrong samples.
Error rates do not include data from the POCT D-typing group.

Table 16 – PTT error rates by analyte

Analyte	2017 (17R1 – 17E10)		2016 (16R1 – 16E10)		2015 (15R1 – 15E10)		2014 (14R1 – 14E10)	
	n	error rate (%Tx)	n	error rate (%Tx)	n	error rate (%Tx)	n	error rate (%Tx)
ABO	0	0.00 (0%)	12	0.20 (100%)	10	0.10 (100%)	12	0.11 (80%)
D	13	0.29 (23%)	12	0.04 (50%)	10	0.18 (100%)	11	0.16 (100%)
False Neg Ab Screen	6	0.09 (33%)	20	0.11 (88%)	17	0.08 (100%)	17	0.03 (0%)
False Pos Ab Screen	2	0.03 (100%)	15	0.30 (18%)	19	0.13 (11%)	18	0.0 (0%)
ABID (single)	13	0.37 (23.1%)	7	0.36 (22%)	8	1.2 (0%)	9	1.3 (15%)
ABID (dual)	45	1.16 (13.3%)	8	0.81 (26%)	8	1.2 (9%)	8	0.9 (4%)
Missed Incompatibility	41	0.91 (37%)	15	1.0 (37%)	12	0.48 (17%)	13	0.5 (88%)
Missed Compatibility	23	0.28 (48%)	21	0.49 (29%)	21	0.34 (7%)	20	0.4 (29%)
False Pos Phenotyping	20	1.05 (30%)	10	0.57 (57%)	6	0.51 (57%)	10	1.0 (46%)
False Neg Phenotyping	23	0.43 (30%)	14	0.61 (43%)	16	0.63 (17%)	20	0.5 (42%)

8. Learning points from PTT exercises

Table 17– Learning points from PTT exercises

Issue	Exercise(s)	Learning point(s)
ABO/D Grouping		
Misinterpretation of D typing results obtained with potentiated reagents	16R9, 17R5,	Results of D typing are invalidated where the reagent control is positive. An interpretation of D positive should not be made on the basis of a weak positive reaction vs. anti-D in a sample from a female with child bearing potential or any patient likely to require regular transfusion. BSH guidelines recommend further investigation, with an interim interpretation of D negative.
Antibody Identification		
Exclusion process in antibody identification	16E2, 16E10, 17R1, 17R10	When interpreting antibody identification results it is vital that the presence of additional clinically significant antibodies is systematically excluded, and that all positive reactions are accounted for before a final interpretation is made.
Use of screening panel results and phenotype when interpreting ID results	16E2	When interpreting antibody identification results all available information should be taken into account, including patient phenotype, differential reaction by technique, and results of all cells tested (including the screening panel).
Use of additional techniques for antibody exclusion / identification	16E2, 16R5, 17E2	An enzyme technique can be an invaluable part of the antibody identification process, particularly where there is a mixture of antibodies or where weak Rh or Kidd antibodies require confirmation or need to be excluded. Kidd antibodies are often weak, show dosage and are difficult to identify – they are often significantly enhanced by using an IAT with enzyme treated cells. Room temperature techniques can be used to include and exclude IgM antibodies such as anti-N and anti-M, and can assist in elucidation of antibody mixtures, where antigens to these antibodies obscure the IAT picture. Where Rh antibodies are not reactive with all antigen positive cells, identification can be based on positive reactions with enzyme treated cells.
Exclusion of anti-K using a two stage enzyme technique	17E3	Whilst the K antigen is generally resistant to enzyme treatment, not all examples of anti-K will react in a two stage enzyme technique and exclusion of anti-K requires a negative reaction with a K+ cell by IAT or enzyme IAT.
Positively identifying antibodies not actually present	16E2, 16E3	The specificity of an antibody should only be assigned when it is reactive with at least two examples of reagent red cells carrying the antigen and non-reactive with at least two examples of reagent red cells lacking the antigen. This rule applies independently to each antibody specificity potentially present in an antibody mixture, including antibodies to low frequency antigens.

Issue	Exercise(s)	Learning point(s)
Antibodies of low clinical significance and to low frequency antigens	16E3, 17E4	Once all reactions in the identification and screening panel have been accounted for by the presence of antibodies already identified, there is no need to exclude antibodies of low clinical significance or those directed against low frequency antigens
Selection of antibody ID panels and use of additional panels	17E3	Difficulty in identifying anti-c+K in a sample where no patient phenotype was provided. Ability of complete the ID was influenced by panel profiles and number of cells available.
Considering anti-G when apparent anti-C+D is identified	16E8	Reactions with D positive, C negative cells in an apparent anti-C+D could be due to anti-G rather than anti-D, and this has implications for anti-D Ig prophylaxis for women with childbearing potential.
Difficulty in identifying / excluding Rh antibodies	16E8, 17E2, 17E7	It is difficult to differentiate between weak anti-D and anti-E, and to exclude anti-E in the presence of anti-c. BSH guidelines recommend provision of Rh matched blood for patients with Rh antibodies, unless transfusion support will be impeded.
Procedure for recording and interpreting ID results	16E6, 17E9	Interpretation and documentation of antibody identification results is an error-prone manual process, and this should be considered when establishing procedures for reporting antibody identification for both clinical and EQA samples.
Non-specific reactions	16E2	Non-specific reactions by IAT can make it difficult to identify or exclude clinically significant antibodies and have the potential to delay transfusion.
Screening		
Equivocal reactions in the antibody screen	17E4	False negative screens were reported where equivocal reactions had been noted but disregarded due to a background of known problems with technology. A clear policy is required for investigation of equivocal reactions.
Compatibility testing and selection of red cells for transfusion		
Risk of technical / procedural error to the sensitivity of the serological crossmatch	16R7	Re-testing of XM false negative reactions in 16R7 gave weak positive reactions without change to IAT XM technique.
Selection of D red cells for a young female, based on anomalous D typing results	17R5	D positive red cell components should not be transfused to young female patients or those who are likely to be transfusion dependent until the D type has been confirmed.
General areas		
Use of validated techniques	17R1	All techniques should be validated. Use of a non-validated technique (substituting a diluent for use with a CAT technology with one designed for a different CAT technology) led to insensitivity in the IAT and misidentification of an antibody.
Manual testing and transcribing of results	16R1, 16R9, 17R1, 17R5	Checks should be in place to reduce the potential for procedural error when identifying samples for manual testing, and when transcribing critical test results.

Issue	Exercise(s)	Learning point(s)
Following manufacturer's instructions	17R5	It is important to follow manufacturer's instructions for testing and interpretation, and of understand properties/ limitations of all reagents / technologies used
Distraction causing crossmatching error	17R8	It is important to understand the potential effects of distraction, especially when performing critical manual testing.
Risks in labelling and identification of samples	16R1, 16R4	Labelling samples with a laboratory accession number is a critical step and demographic details on samples should be checked prior to the validation of results. There should be policy for retention of EQA and clinical samples to address the risk of an invalid 'out of date' EQA or patient sample being tested in error.

9. Questionnaires

An extensive standard practice questionnaire was sent to all FMH participants in June 2016 and was reported in May 2017. The report is attached as Appendix 3.

The annual practice questionnaire was issued and reported in 2016, and the report including data from the UK and ROI is attached as Appendix 4

The 2017 annual practice questionnaire, relating to basic pre-transfusion testing procedures, was distributed in May 2017, with a disappointing return rate of approximately 60% (cf. 71% in 2016). The data was analysed, but not reported due to concerns regarding the low return rate, and considering that preliminary analysis showed that practice had not changed significantly since 2016.

Following exercise 17R1, where 33 sets of correct reactions were assigned an incorrect shorthand interpretation, with 27 of these due to not taking the D type into consideration, a question was included to collect data on the number of laboratories that use the 'Rh shorthand' notation, e.g. R1R1, CDe/CDe and in what context. The responses show that 60/114 (52.6%) laboratories use the shorthand notation, mainly in conversation with blood transfusion staff, but also for blood ordering and on the LIMS. Whilst penalty scoring for Rh phenotyping is based on the reactions recorded rather than the shorthand interpretation, it is still potentially worth collecting this data.

A questionnaire was issued with an 'optional' titration sample with exercise 17E7 to gather information on practice in antenatal titration and referral. The report is attached as Appendix 5.

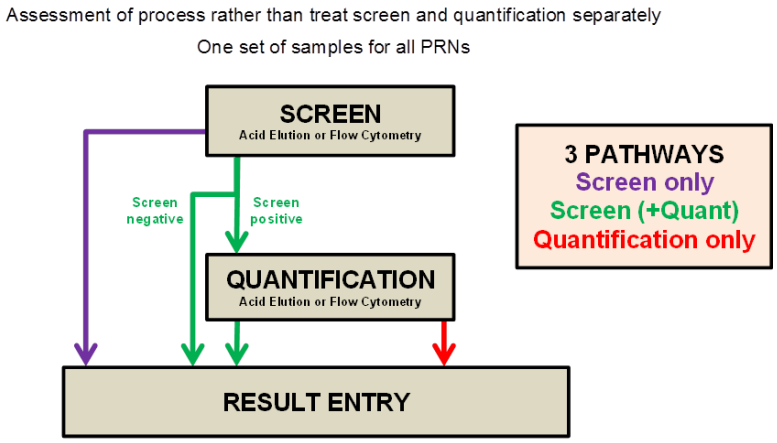
There was a questionnaire included with the 'emergency exercise' 17R8 to collect detail on protocols for issuing red cells within 10 minutes, and the components selected for patients from different demographics. The report is attached as Appendix 6.

A questionnaire to establish the formulae used to calculate FMH outside the UK was issued to non-UK FMH participants and other non-UK laboratories undertaking flow cytometry testing with contacts supplied by UK NEQAS LI. This data was presented at the ISBT meeting in Toronto (June 2018) - see Appendix 7.

10.Scheme developments

Fetomaternal Haemorrhage

A re-design of the FMH Scheme re-design was finalised and an IT specification drawn up during 2017. This new design reflects FMH testing pathways for clinical samples, i.e. in all laboratories registered for screening and quantification, whether by acid elution (AE) or flow cytometry (FC). In laboratories undertaking screening by AC and quantitation by FCEQA samples will progress to quantification only if indicated by the screening result. This model also allows for screening by FC to be assessed.



In 2018 it will be possible to register for one of the three pathways shown above. Where screening is performed by Acid Elution (AE) and quantification by Flow Cytometry (FC), this can be under one PRN, but if the AE and FC testing are managed separately, two PRNs may be used. Where quantification by both AE and FC is required, two PRNs will still be required; it is expected that these will be managed separately and sharing of samples is no longer an option.

ABO Titration (ABOT)

Following full implementation of the in-house software, ABO titration progressed from a pilot to a full UK NEQAS scheme from April 2017. Scoring and performance monitoring has been implemented from mid-2017.

ABO Titration was ISO17043 accredited as an extension to scope, following the July 2017 UKAS visit and subsequent submission of additional information.

All plasma samples were sent undiluted and covered a range of titration values, including duplicates (prepared from a single pool in a single exercise) and replicates (same pool used over more than one exercise). The results continue to show a wide range of results within all techniques, including the standard.

Following initial meetings in 2014-15, liaison with the NHSBT living kidney donor strategy group has continued in 2016-17. The aim is to facilitate standardisation to improve equity of access of patients to ABO incompatible transplant programmes, make protocols for antibody reduction treatments and cut-off titres for suitability for transplant transferrable and to allow meaningful comparison of ABO titre vs. outcome of ABOi renal transplant.

Red cell genotyping pilot (RCG)

Following two pre-pilot exercises undertaken in 2014/15 in collaboration with the ISBT, The UK NEQAS red cell genotyping pilot scheme was established in 2016. In 2017, the red cell genotyping scheme continued to run as a pilot scheme; four exercises were distributed in each year and the level of participation has remained stable.

Each exercise comprises two whole blood samples (representing samples from haemoglobinopathy patients) for DNA extraction and subsequent testing. The genotype and predicted phenotype are requested for D, Cc, Ee, MN, Ss, Kk, Fy^a, Fy^b, Fy, Jk^a, Jk^b, Do^a and Do^b with data entry via SurveyMonkey, collecting responses in ISBT terminology and also in the format reported to clinicians, if this is different. Specifications for new in-house software were agreed in 2017, the first phase of which is to replace SurveyMonkey for data entry in 2018.

The results of the pilot exercises have raised concerns around the high level of errors, made mostly, but not exclusively, by non-UK laboratories. Whilst the causes are not confirmed, considering patterns in the data and consultations with the SAG, it is probable that these include a few testing errors and errors of interpretation of predicted phenotype due to lack of knowledge, and a high proportion of transcription errors that may have occurred during data entry.

Additional questionnaire data has been collected throughout 2017 on the methods for transferring clinical results from testing platforms to IT systems or paper for reporting, and on methods (electronic or otherwise) for translating genotyping results into predicted phenotypes. In two thirds of the participating laboratories, there are manual steps in transcription of results for reporting and /or interpretation of predicted phenotypes. The 2017 RCG exercise reports included educational content where it was felt that lack of knowledge may have contributed to errors. (see Appendix 8 for an example report).

The SAG has had one face-to-face meeting in May 2017 and one teleconference in November 2017.
Following discussion at the May SAG meeting it was agreed that Shane Grimsley (IBGRL Laboratory Manager) will shadow Geoff Daniels (retired from IBGRL) as the Scheme advisor, in advance of taking over this role in 2018.

Direct Antiglobulin Test (DAT) pilot

Following two preliminary exercises in 2015, a full pilot scheme was launched in 2016, with 2 samples being distributed with each 'R' exercise. Stability over a one week period has now been demonstrated with five

examples of IgG coated cells, with strength of reaction ranging from weak to strong positive, and one C3d coated cell (2+ positive).

In 2017, the DAT pilot samples continued to be issued with the four PTT 'R' exercises, but with a one week closing date and results submitted through SurvyeMonkey. Overall eight samples were distributed during 2017, four IgG coated with strength ranging from weak to 3+, two negatives and one complement coated.

The samples have an increased red cell concentration following participant feedback and negotiation of this change with the supplier of the material (NHSBT Reagents). However, feedback from a few participants suggests that the samples are still of an insufficient concentration to allow testing on some automated equipment. We are still in the process of increase the cell suspension in incremental stages. Samples with a DAT positive for IgG and one sample coated with C3d have been successfully distributed, but the supply of sufficient fresh AB serum for C3 coated cells potentially remains an issue that could limit the number of participants.

The scoring system approved by NQAAP in 2016 has been modelled using 2017 data and has been shown to identify the intended levels of UP and PUP.

On-line competency assessment scheme

In the last year the updates to the TACT core system based on priorities identified by the Scheme and Advisory Group and on participant feedback. These updates include:

- Assessment of major mismatches of the request form and sample label
- Rules for selection of components for patients with specific requirements
- Flagging of reason for a 'red mark' for 'complex' participations in the participation summary
- Improved security of the TACT system with a single login point
- Facility to 'toggle' between the live environment and the laboratory manager's front office
- Generation of an engagement and performance certificate for members
- Managers' access to staff engagement data
- Facility for managers to clear the initial participation history of a new TACT member
- Automated email for managers to send to prompt staff engagement with TACT

The continuing aim of this system is to provide laboratory staff and managers with an interactive knowledge-based training and competency assessment tool, not solely focussed on the practical applications of training, but on the theoretical knowledge of Biomedical Scientists working in blood transfusion laboratories.

Currently, TACT features a single scenario based on routine request handling, representing a typical request received in a hospital blood transfusion laboratory, but we have plans to expand upon the current system iteration to bring you a second scenario type.

By the end of 2017, there were over 100 active subscribers with over 2000 purchased memberships.

11. IT and website development

IT Systems

All full UK NEQAS schemes (PTT, FMH and ABOT) are 100% web entry and all reports are issued electronically.

During 2016/17 data collection for the red cell genotyping pilot is through SurveyMonkey, with data analysis in Excel. Individual pdf reports were mailmerged and emailed to participants. Data collection for the DAT pilot was also through SurveyMonkey, and the data was analysed in Excel. There are currently no individual reports, but an overall report is emailed to participants.

The new information website was launched in March 2015. Several developments were implemented during 2016 and 2017:

- Facility for participants to be able to make amendments to their own registration details and passwords, and to add new tests (e.g. red cell phenotyping) but not remove them or de-register altogether
- Hashing of passwords to improve security
- Facility for participants to print certificates of registration.

12. Other scheme activities 2017

Presentations

Educational and professional activities

ISBT Dubai September 2016:

- ISBT Academy invited presentation (JW)
- One abstract accepted as an oral presentation (CM)
- Immucor satellite educational meeting – 'Crossmatching and electronic issue' (JW)
- ISBT Working Party for Immunohaematology (IH): Results of IH practice questionnaire (JW)

BBTS Harrogate September 2016:

- Four abstracts were accepted for poster presentations; one was scheme related, whilst the other three were related to external responsibilities (see publications for details).
- Two oral presentations at the Blood Bank Technology SIG session:
    - How aggressive can passive antibodies be? (CM)
    - Observations from UK NEQAS data (JW)

InnoTrain educational meeting, Frankfurt, November 2016

Presentation: 'EQA for 'routine' red cell genotyping the UK NEQAS experience' (JW)

UK NEQAS/BBTS SIG annual meeting York, November 2016:

All senior staff gave update presentations. 'Transfusing wisely in a pathology network' (MR)

BioRad transfusion science educational meeting, Beijing/Shanghai, December 16

Presentation: Quality Assurance in the UK (JW)

TACT invited presentations and demonstrations (CW):

- January 2016 – Edinburgh
- April 2016 – BGS Reading
- May 2016 and 16/11/2016 – UK TLC
- September 2016 – Cambridge
- November 2016 – Clinisys user group meeting
- November 2017 – London

ISBT Congress, Copenhagen, June 2017:

- One abstract was accepted as an oral presentation (JW), and two posters (one KV and one CW – presented by RH) -see publications for details.
- ISBT Working Party for Immunohaematology (IH): short presentation on UK practice for D typing (JW)

BBTS ASM, Glasgow, September 2017:

- One abstract was accepted for an oral presentation (JW) and another for a poster presentation (KV) - see publications for details
- Two invited oral presentation at the Blood Bank Technology SIG session
  - Maintaining patient/transfusion safety during IT downtime (RH)
  - The benefits of IT alerts, flags and warnings – lessons from SHOT (MR)

IBMS Congress, Birmingham, September 2017:

- Two invited presentations in the Transfusion Science Programme
  - Dicing with Death (an interactive session) (KV)
  - Antenatal Transfusion Practice (JW)

UK NEQAS/BBTS SIG annual meeting, Birmingham, November 2017:

- TACT update (CW)
- Red cell genotyping pilot update (JW)
- FMH Update (KV)
- Participant satisfaction questionnaire feedback (RH)

UK NEQAS Consortium, Birmingham, November 2017

- What can the quality working group do for you? (CW)

Hellenic Blood Transfusion Society meeting, Athens, April 2017

- Risk Management in Blood transfusion (RH)

Yorkshire & Humber Regional Transfusion Committee, Leeds, May 2017

- IT failure the quality management perspective (RH)

SpR FRCPath training course, Colindale, June and October 2016 and 2017

- Teaching session on EQA and UK NEQAS BTLP Schemes (CM / JW)

BioRad User group, Manchester, November 2017

- Titration in Immunohaematology (JW)

Publications

Scheme publications

Publication (oral presentation)
Red cell antibodies – clinical significance or just noise. Vox Sang 2016, vol 111, suppl. White J. Also available as a webcast from ISBT Dubai.

Abstract (oral presentation)
A UK NEQAS pilot exercise demonstrates the importance of including an antibody screen when undertaking ABO titration to support ABO incompatible renal transplantation. Vox Sang 2016, vol 111, suppl 1. Milkins C.E, White J, Mavurayi A, Rowley M.R.

Abstract (poster)
A UK National External Quality Assessment Scheme (UK NEQAS) pilot for the direct antiglobulin test (DAT) - assessing stability of IgG-coated red cells. Transfusion Medicine, vol 26, suppl 2. Whitham C, Milkins C.E, White J, Mavurayi A, Rowley M.R.
Abstract (poster)
Delayed haemolytic transfusion reactions (DHTR) and simple alloimmunisaton are associated with different antibody specificities. Transfusion Medicine, vol 26, suppl 2. C Milkins, H Mistry, D Poles, P Bolton-Maggs.

Abstract (poster)
Risk and impact of haemolytic transfusion reaction (HTR) due to passive ABO antibodies as evidenced by SHOT data. Transfusion Medicine, vol 26, suppl 2. C Milkins, J Ball, D Poles, J Bark, P Bolton-Maggs.

Abstract (poster)
Innovations in programme delivery of the British Blood Transfusion Society (BBTS) Specialist Certificate in Transfusion Science Practice (SCTSP) improve the learning outcomes for students. Transfusion Medicine, vol 26, suppl 2. R Quereshi, J White, M Bruce, E Cook, M Cheetham, D Noble.

May 2016 – TACT article published in Converse (Irish science magazine)

Book chapter
Rowley, M., Cantwell, C, Milkins, C. Laboratory Aspects of Blood transfusion, in Dacie and Lewis Practical Haematology, Bain, B., Bates, I., Laffan M., Lewis, M. 2016, Elsevier.

Abstract (oral presentation)
J White, C Milkins, R Haggas, A Mavurayi and M Rowley. Pilot EQA Scheme for routine red cell genotyping identifies errors in testing and reporting. Vox Sanguinis. 2017 June, 112(S1):33 (3B-S10-04)
http://onlinelibrary.wiley.com/doi/10.1111/vox.12530/pdf

Abstract (poster)
Veale K, White J, Mavurayi A, Haggas R, Whitham C, Milkins C, Rowley M. UK NEQAS (BTLP): EQA as an opportunity for education. Vox Sanguinis. 2017 June, 112(S1):210 (P-464)
http://onlinelibrary.wiley.com/doi/10.1111/vox.12530/pdf

Abstract (poster)
Whitham C, Milkins C.E, White J, Haggas R, Veale K, Mavurayi A. A National External Quality Assessment Service (UK NEQAS) pilot for the Direct Antiboglbulin Test (DAT) – an assessment of sensitivity by technology. Vox Sanguinus 2017 June, 112(S1): 194-195 (P-412).
http://onlinelibrary.wiley.com/doi/10.1111/vox.12530/pdf

Abstract (oral presentation)
Whitham C, White J, Haggas R, Whitham C, Mavurayi A. Training Assessment and Competency Tool (TACT) Benchmarking Data. Transfusion Medicine. 2017 September; 27(S2): 3-23.
http://onlinelibrary.wiley.com/doi/10.1111/tme.12470/pdf

Abstract (poster)
Veale K, White J, Haggas R, Whitham C, Mavurayi A. How easy is it to identify common antibody mixtures using only one antibody screen and panel combination? Transfusion Medicine, 2017 September; 27(S2): 24-70. (PO50)
http://onlinelibrary.wiley.com/doi/10.1111/tme.12471/pdf

Publication
Whitby L, White J, Fletcher M, Whitby A, Milkins C, Barnett D. Paroxysmal nocturnal haemoglobinuria testing in blood transfusion laboratories: do they go with the flow?
Transfusion Medicine. 2017 Aug 18. doi: 10.1111/tme.12449. [Epub ahead of print]
https://www.ncbi.nlm.nih.gov/pubmed/28833743

Related Publications

Serious Hazards of Transfusion (SHOT) annual report 2016.
https://www.shotuk.org/2016-annual-shot-report-published-12-july-2017/

Guideline for blood grouping and red cell antibody testing in pregnancy. White J, Qureshi H, Massey E, Needs M, Byrne G, Daniels G, Allard S. Transfusion Medicine, 2016, 26, 246–263

Scheme representations

UK NEQAS (BTLP) has been represented on or associated with the following committees/organisations etc. during 2016/17:

- BSH Transfusion Task Force (JW)
- BBTS Specialist Interest Group for Blood Bank Technology (CW)
- Serious Hazards of Transfusion (SHOT) Working Expert Group and Steering Group (MR and CW)
- UK Transfusion Laboratory Collaborative (CW and MR)
- BSH guideline writing group for Estimation of FMH (JW, KV)
- BSH guideline writing group – blood grouping and red cell JW)
- NHSBT RCI FMH working group (JW)
- NHSBT anti-D quantitation working group (JW)

Other personal transfusion related appointments / activities

Scheme Director (MR)

- Chair of BBTS HoTSIG committee (2016)
- Chair of Transfusion Medicine SAC for RCPath (2016)
- Chair of JPAC Clinical Transfusion Medicine SAC (2016)
- RCPath Examiner for Haematology and Transfusion Science
- Chair of BBTS Clinical Transfusion PAEC Subcommittee
- Chair of JPAC SAC for Clinical Transfusion Medicine
- Educational Supervisor for haematology trainees in Scotland.

Scheme Manager (JW)

- Member of the BBTS Council and Executive Working Group
- Member of ISBT Immunohaematology Working Party
- Member of ISBT Academy Standing Committee
- Chair of the BBTS Professional Affairs and Education Committee
- Manchester University External Examiner for the BBTS Transfusion Science Practice Certificate
- RCPath Examiner for Transfusion Science
- Abstract reviewer for ISBT and BBTS

Deputy Scheme Manager (RH)

- Tutor and Examiner for IBMS / University of Ulster Certificate of expert practice in quality management
- Abstract reviewer for BBTS

Scheme Scientist (KV)

- Oral presentation judge, BGS Dublin meeting

13. Key Performance Indicators

The Scheme's KPIs for 2016 and 2017 are shown in tables 18 - 21. Where the targets were not met, this is addressed in the footnotes to the table.

Pre-transfusion testing

All KPIs relating to exercise distribution, reporting and the quality of the samples were met or exceeded. The ongoing problem with haemolysis of the whole blood samples for ABO/D grouping for non-UK participants noted in the 2016 report continues to produce the greatest number of USQ reports, but this has fallen below the KPI limit during 2017. Data for ABO titration has not been included in this report, as this became a full UK NEQAS Scheme part way through this year. The data will be collected and summarised for 2018 report. Data has been included for the separate distributions to Turkey.

Table 18 PTT KPIs 2016

Category	No. of Events	Target	Target Achievement Rate	Actual Achievement Rate
Exercise Distributions	16	On schedule	100%	**100%**
Report Distributions	16	Within 4, 6 and 8 days of C/D for FMH, E and R exercises respectively	90%	**100%**
Complaints	13	Acknowledged in one week. Dealt with in 4 weeks	100% 70%	**100%** **100%**
New Unsatisfactory Performers (pretransfusion testing)	21	Make telephone contact	90%	**72%** [1]
		Within 5 days of C/D	80%	**100%**
Borderline Performers (pretransfusion testing)	31	Make telephone or written contact	50%	**29%** [2]
		Within 10 days of C/D	80%	**100%**
Unsatisfactory performance letters (FMH)	6 exercises	Posted before the subsequent exercise closes	100%	**100%**
Reported Sample Quality – Plasma	45	≤2% unsatisfactory	90% of samples	**96%** **(mean 0.8%)**
Reported Sample Quality – Whole Blood Samples (R exercises)	21	≤5% unsatisfactory	90% of samples	**29%** [3] **(mean 6%)**
Reported Sample Quality (FMH)	12	≤5% unsatisfactory	75% of samples	**100%** **(mean 1.5%)**
Reported Sample Quality – Red cells in Alsever's	21	≤2% unsatisfactory	90% of samples	**100%** **(mean 0.8%)**
Integrity of Samples	26671	<0.5% unsuitable for testing per exercise	9/10 E/R 5/6 FMH	**100%** **(mean <0.01%)**

[1] 8 labs not phd: not a clinical labx1; should have made a UI submission x1; trivial ID error for all 3 samples x3; data entry error x3 [2] high number of apparent data entry error and false positive screens; this KPI needs to be reconsidered. [3] Achievement rate was 100% (mean 1.6%) within the UK and RoI

Table 19 – PTT KPIs 2017

Category	No. of Events	Target	Target Achievement Rate	Actual Achievement Rate
Exercise Distributions	13	On schedule	100%	**100%**
Report Distributions	13	Within 6 and 8 days of closing date for E and R exercises respectively	90%	**100%**
Complaints	29	1. Acknowledged in one week. 2. Dealt with in 4 weeks	1. 100% 2. 70%	**1. 100%** **2.100%**
New Unsatisfactory Performers	32	Make telephone contact within 5 days of C/D	100%	**100%**
Individual unsatisfactory performance letters	31	Letters posted to laboratories before the subsequent exercise closes	90%	**25%**[1]
Reported Sample Quality – Plasma	45	≤2% unsatisfactory	90% of samples	**100%** **(mean 0.37%)**
Reported Sample Quality – Whole Blood Samples	33	≤5% unsatisfactory	90% of samples	**97%** **(4.8% mean)**
Reported Sample Quality – Red cells in Alsever's	21	≤2% unsatisfactory	90% of samples	**100%** **(mean 0.6%)**
Integrity of Samples	43723	<0.5% unsuitable for testing per exercise	90% (i.e. 9/10 exercises)	**100%** **(mean <0.01%)**

[1]Whilst the KPI for making initial contact with Unsatisfactory Performers was met, that for UP letters to UP was not; this KPI is being reviewed to take into consideration tests included in subsequent exercises.

Fetomaternal haemorrhage

Table 20 FMH KPIs 2016

Category	No. of Events	Target	Target Achievement Rate	Actual Achievement Rate
Exercise Distributions	6	On schedule	100%	**100%**
Report Distributions	6	Within 4 days of C/D	75%	**100%**
Unsatisfactory performance letters	6 surveys	Posted, before the subsequent exercise closes	100%	**100%**
Complaints	2	1. Acknowledged within one week. 2. Dealt with in 4 weeks	1. 100% 2. 70%	**1. 100%** **2. 100%**
Reported Sample Quality	12	≤5% unsatisfactory	75% of samples	**100%** **(mean 1.5%)**
Integrity of Samples	3494	≤0.5% unsuitable for testing per exercise	75% (i.e. 3/4 exercises)	**100%** **Mean (0.0%)**

Table 21 FMH KPIs 2017

Category	**No. of Events**	**Target**	**Target Achievement Rate**	**Actual Achievement Rate**
Exercise Distributions	6	On schedule	100%	**83%***
Report Distributions	6	Within 4 days of C/D	75%	**100%**
Unsatisfactory performance letters	6 surveys	Posted, before the subsequent exercise closes	100%	**100%**
Complaints	7	1. Acknowledged within one week. 2. Dealt with in 4 weeks	1. 100% 2. 70%	**1. 100%** **2. 100%**
Reported Sample Quality	56/3568	≤5% unsatisfactory	75% of exercises	**100%** **(mean 1.6%)**
Repeat samples sent due to poor quality	1/1785	≤0.5% unsuitable for testing per exercise	75% of exercises	**100%** **Mean (0.06%)**

* 1704F distribution was delayed due to a delay in NAT testing at NHSBT. The decision was made to delay by one day to ensure virological safety for participants.

At the annual quality review 2017 it was agreed that the achievement rates for distributing exercises on time should be changed from 100% to 83% to reflect the difficulties in obtaining suitable material in a short time frame. The achievement rates for satisfactory reported sample quality and repeat samples were also changed to 83% (from 75%) as this represents one exercise per year now that the FMH scheme distributes six rather than four per year.

14. Accreditation status

The UK NEQAS Centre at Watford is now accredited under the name: West Herts Hospitals NHS Trust, operating UK NEQAS Haematology and Transfusion. Successful annual surveillance visits took place in July 2016 and August 2017 and UKAS accreditation to ISO 17043 has been maintained for the BTLP (PTT) and FMH schemes.

An application for extension of scope to include the ABO titration scheme was made, with assessment during the July 2017 visit and subsequent submission of additional paperwork; this was granted with no findings.

IT – UK NEQAS Haematology and Transfusion information website

The following new developments are underway and for implementation during 2018/19:

- A secure area for Steering Committee and SAG communications (ready now)
- Extend automatic production of participation certificates to POCT and RCG schemes
- Investigate allowing access to all reports through the website
- Allow viewing and downloading of dynamic schedule for BTLP schemes
- Allowing participants to make membership changes on-line
- Emailing groups of participants through the website
- Change to KPMD database to allow more flexibility in registration 'contact types', facilitating separate main contact and sample delivery address.

Longer term plans still include the possibility of finding an electronic means of transferring EQA data from the participating laboratories' LIMS directly into the UK NEQAS database, which would avoid the majority of transcription errors that do not reflect clinical practice.

15. Annual Participants' Meeting

The 2016 and 2017 meetings were organised in collaboration with the BBTS SIG for Blood Bank Technology. All senior BTLP staff gave Scheme related talks. See Appendix 9 and Appendix 10 for the programmes.
The inclusion of one delegate fee for the annual meeting in the annual UK NEQAS subscription for both PTT and FMH was offered in 2016 and 2017 and included participants in the Republic of Ireland. This continues to be popular, with 307 participants registering for a place in 2017, but 97 (31%) of these were unable to send a delegate to the meeting, which is approximately the same proportion as in 2016. It is unlikely that this reflects the venue and/or programme as overall the attendance on the day was the highest for many years at 309 (252 paying delegates, 32 committee / staff members and 25 sponsors). It is likely that staff shortages and restrictions on staff leave for training were at least partly responsible for the 'no shows'.

An evaluation form was provided to delegates attending the 2017 annual meeting in Birmingham. Completed forms were received from 43% of delegates. The comments received have been summarised for discussion at the Steering Committee and are being taken into consideration for planning the 2018 meeting. Feedback from the attendees was excellent, with 99.2% rating the programme content as good or excellent.

16. Participant feedback

The Unit has a policy for assessment of participant satisfaction. The policy includes formally feeding suggestions from participants into the quality improvement plan, and collating all other forms of solicited and unsolicited feedback. Specific examples from 2017 are outlined below.

Customer Satisfaction Questionnaire 2017

Following the 2016 annual practice questionnaire, where just over 50% of respondents stated that they would like a customer satisfaction questionnaire; this was distributed in May 2017. A summary of the questionnaire results and the scheme's response to participants' comments and suggestions for change was presented at the annual meeting in November 2017; see Appendix 11

Quality Improvement Plan

The four items noted in last year's report as having been added to the BTLP Quality Improvement Plan (QIP) have been addressed and will be available during 2018:

- Electronic access to exercise instructions
- EQA for extended red cell phenotyping
- Assessment of FMH screening by flow cytometry
- Understanding and the different FMH formulae used in non-UK laboratories and potential impact on the FMH scheme.

Items were placed on the BTLP QIP as a direct result of participant complaints or suggestions during 2017.

Complaints

There were 29 complaints/appeals logged during 2017 (*cf.* 15 in 2016); 23 complaints were upheld, with remedial and corrective action taken, and eight new preventive actions were identified and logged as QIPs. All responses met the KPIs. The complaints covered a wide range of categories and root causes.

All KPIs relating to complaints were met.