UK NEQAS Scheme developments and learning points

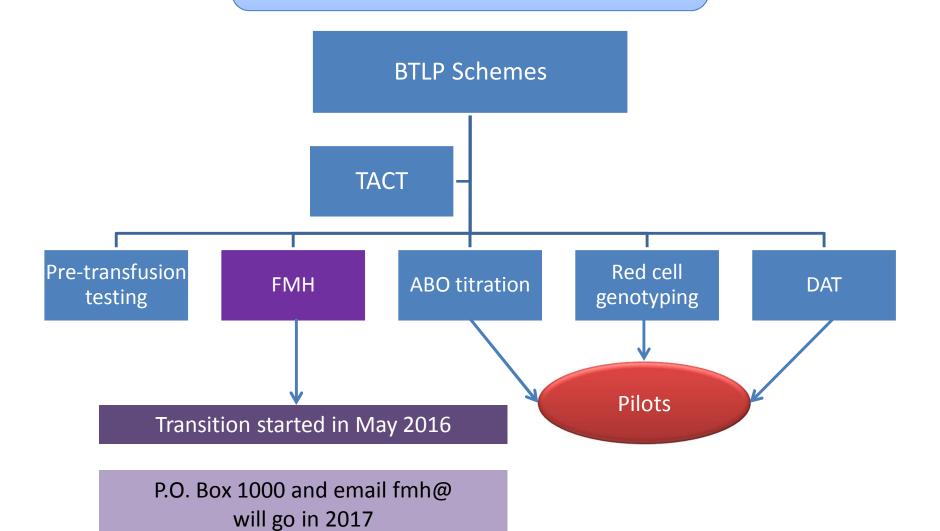
Clare Milkins, Jenny White, Claire Whitham UK NEQAS/BBTS November 2016



Outline

- Scheme structure
- Exercise material; El and EQA
- " Learning points 16R9
- Annual practice questionnaire
- " Pilots
 - . ABO titration
 - . Red cell genotyping
 - . DAT
- " TACT

New BTLP Structure



Problems with material

In-house Capture results

Sample ID	Interp.	Flags	R-ID 1	R-ID 2	R-ID 3	R-ID 4	R-ID 5	R-ID 6	R-ID 7	R-ID 8
16R9P2RPT	Complete	*	4+	0	4+	0	0	4+	0	0
				•		•				
Sample ID	Interp.	Flags	R-ID 9	R-ID 10	R-ID 11	R-ID 12	R-ID 13	R-ID 14	Pos Ctrl	Neg Ctrl
16R9P2RPT	Complete	*	0	0	0	0	0	4+	4+	0
	12.2			•		•	•			

Anti-K

Sample ID	Interp.	Flags	R-ID 1	R-ID 2	R-ID 3	R-ID 4	R-ID 5	R-ID 6	R-ID 7	R-ID 8
16R9P1	Complete	*	1+	?	2+	0	1+	?	?	0
				•		•	•		•	
Sample ID	Interp.	Flags	R-ID 9	R-ID 10	R-ID 11	R-ID 12	R-ID 13	R-ID 14	Pos Ctrl	Neg Ctrl
						1 1 1 1 1 1 1		IN ID IT	1 00 0111	
16R9P1	Complete	*	?	?	?	0	0	0	4+	0

Inert









NHSBT Reagents

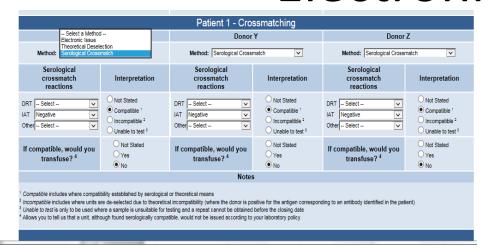


UK NEQAS

Participants



Electronic issue



16R7: P3 B D pos, all donors A D neg

One UK lab missed all 3 ABO incompatibilities by 'EI'





0% of UK labs would use EI without the donations being securely entered into the LIMS

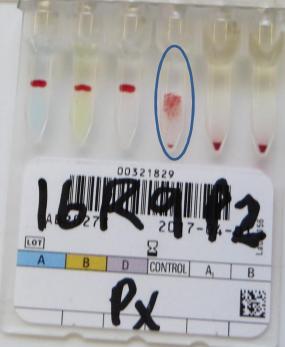
We are not assessing EI!

Learning points

16R9 AB D positive with positive DAT

16R9 AB D pos with a pos DAT





30/09/2016 17:06

Provisional data

Technology	Ctrl Pos	Ctrl Neg	
BioVue	120 (69%)	53 (31%)	
Other	11 (3%)	326 (97%)	

131 pos controls

34 used 2nd technology 88 BioVue only

7 other technique only

00321829
20 7-12-28
A B D CONTROL A, B

Where recommended by the manufacturer, a diluent control should always be tested......If pos (even weakly) the test result is invalidated

32 (5 UK) interpreted group as
AB positive

Provisional data

Technology	Ctrl Pos	Ctrl Neg
BioVue	120 (69%)	53 (31%)
Other	11 (3%)	326 (97%)

BioVue	Ctrl Pos	Ctrl Neg
Auto	115 (72%)	45 (28%)
Manual	5 (38%)	8 (62%)

8 neg controls (manual)

45 neg controls (auto)

1 used 2nd tech

34 used 2nd tech

18 reported BioVue only

18 (9 UK) interpreted group as AB positive

Annual practice questionnaire May 2016





Group-check policy



Comments/suggestions for improvements

Web entry for titrations

Web entry pages not user-friendly

Reduce input required on techniques page

Would you like a formal customer satisfaction questionnaire?

Yes: 126

Improvements to actual questionnaire



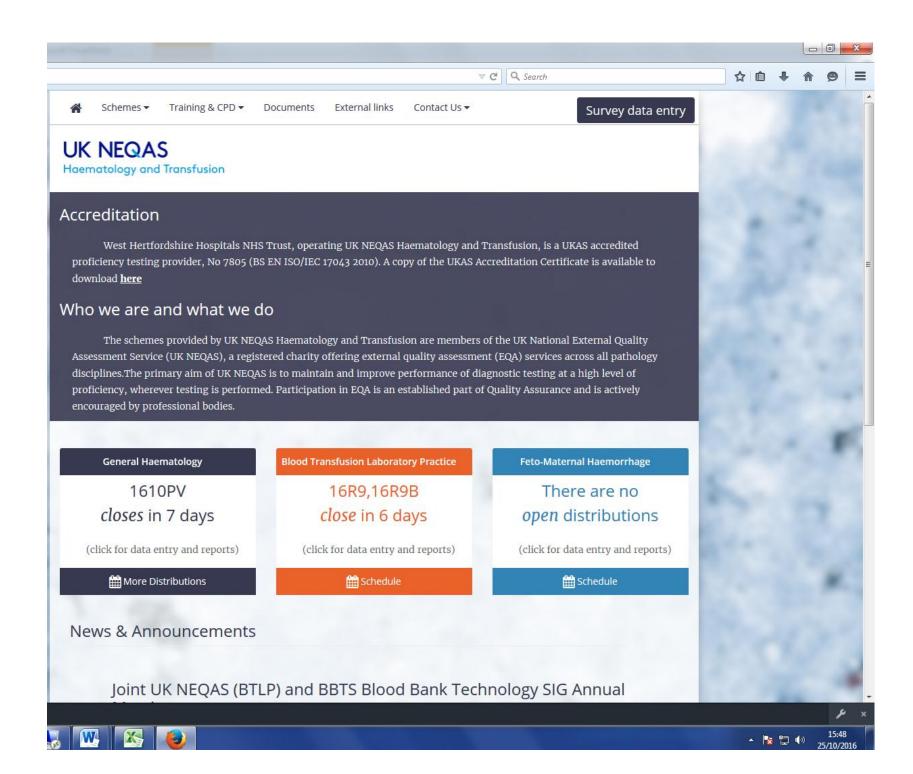
Next year

No: 121

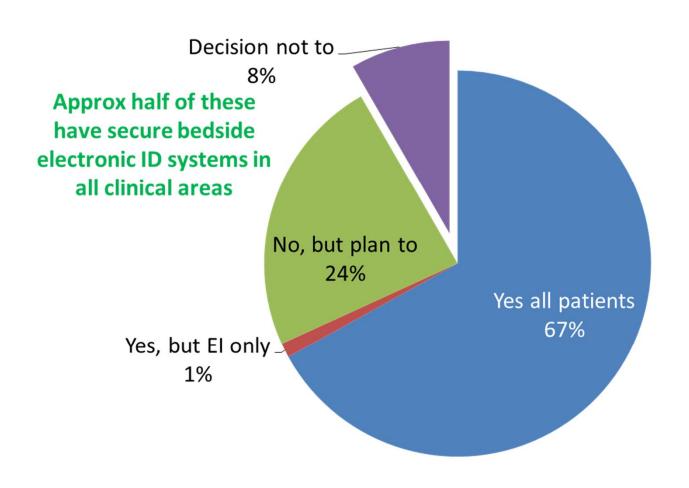
Whole blood sample

Website unclear with white on grey

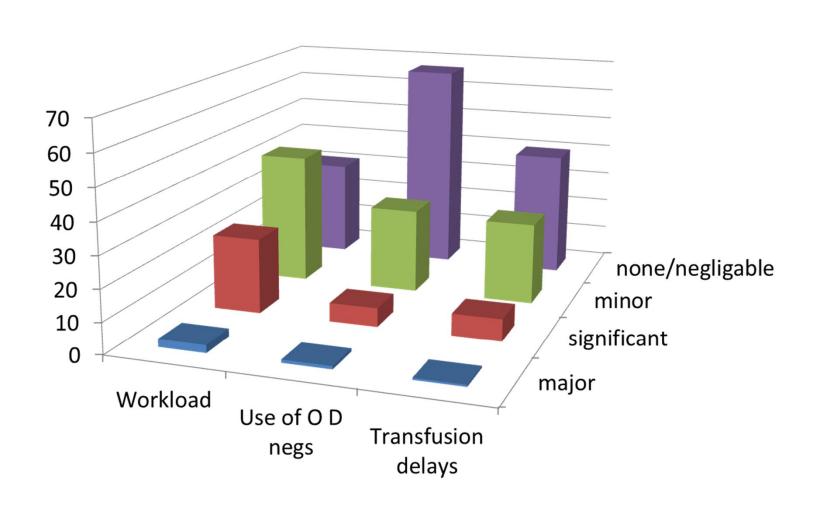




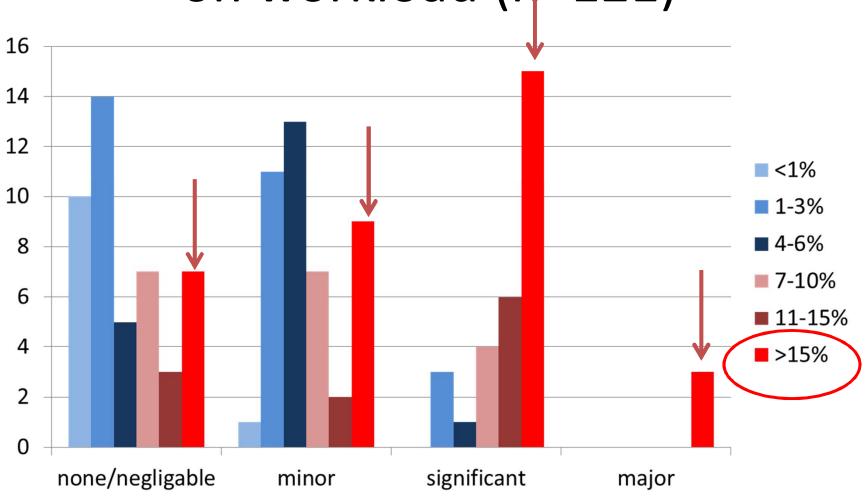
Group-check policy (n=252)



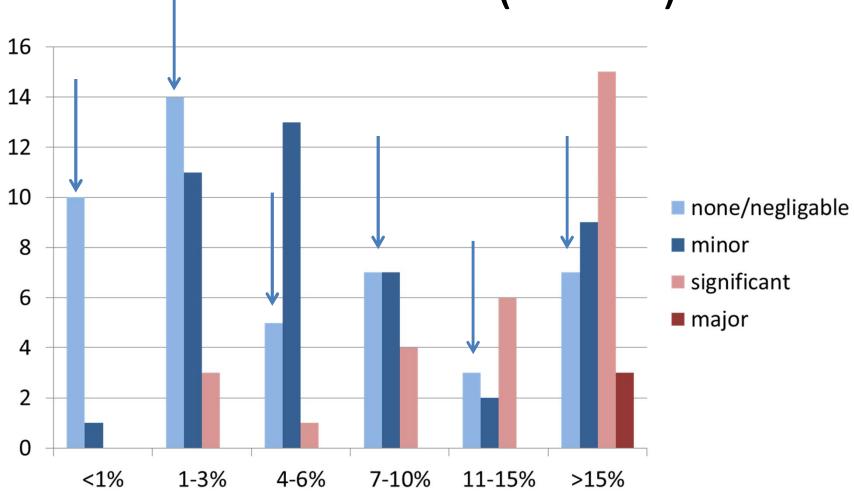
Reported impact (n=161)



Impact of group-check on workload (η =121)

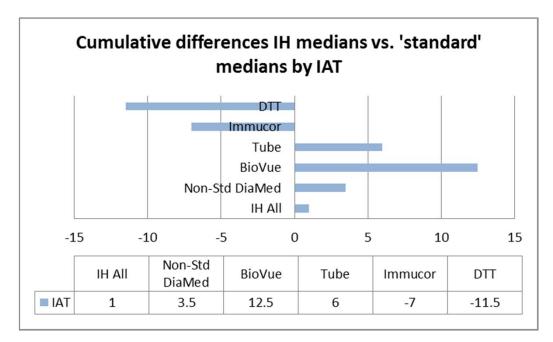


Impact of group-check on workload (n=121)



ABO titration pilot scheme

- " 2010 2016 pilot aim to support ABOi renal transplant
- " 'Standard' technique initially to facilitate EQA
- "Still variation by technique... trends 2014/15 data
- Automation now available



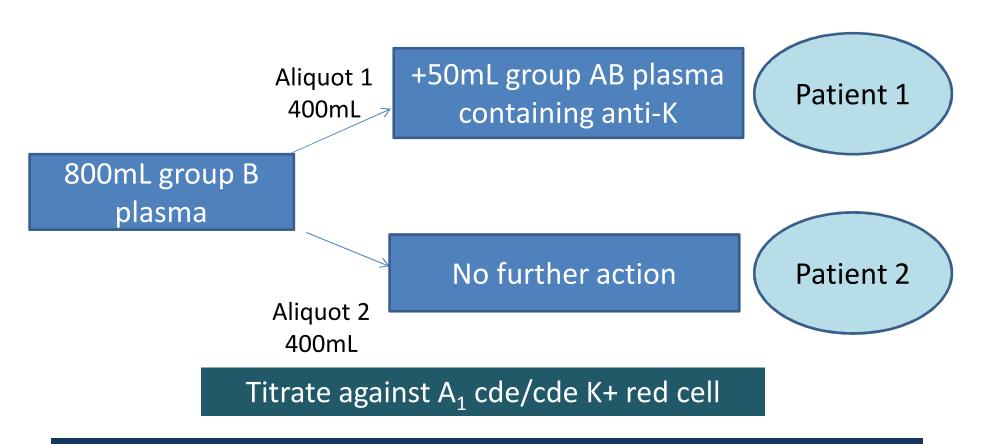
ABO titration pilot collaborations





- " NHSBT living kidney donor transplant strategy group looking to achieve standardisation across UK:
 - equitable access to ABOi renal transplant programmes
 - safe cut-off limits on day of transplant
- NIBSC reference preparation 14/300 (high titre anti-A & anti-B)
 - . available since Dec 2015

Red cell antibody (anti-K) – Dec 2015



90/97 returns (43 supporting ABOi renal transplant)

Direct Agglutination at Room Temperature (DRT) Results

DRT technique	No. results	P1 median (range)	P2 median (range)
Standard	63	1 (0 – 4)	2 (0 – 8)
IH DiaMed	13	1 (0 – 4)	1 (0 – 8)
IH BioVue	7	2 (0 – 4)	2 (0 – 4)
IH tube	20	1 (0 – 4)	1.5 (0 – 4)
IH Immucor	7	0 (0 – 2)	1 (1 – 4)
IH Grifols	2	0.5 (0 – 1)	2 (2 – 2)



Indirect Antiglobulin Test (IAT) Results

IAT technique	No. results	P1 median (range)	P2 median (range)
Standard	76	128 (4 – 512)	1 (0 – 8)
IH DiaMed	5	128 (128 – 256)	2 (0 – 4)
IH BioVue	7	128 (8 – 128)	2 (1 – 8)
IH tube	6	64 (16 – 128)	3 (1 – 8)
IH Immucor	9	64 (16 – 256)	0 (0 – 4)
IH Grifols	2	64 (64 – 64)	0.5 (0 – 1)

Anti-K Anti-A

Is an antibody screen included when a titration is requested?

35/89 stated that they do not routinely include an antibody screen



13/35 support ABOi renal transplant

Questionnaire data 2013

Acceptance on programme
Median 512
Range 128 - 4096

Max titre on day of transplant

Median 8

Range 2 - 16

Transition to full UK NEQAS Scheme

- Scoring accepted by NQAAP 2016
 - . For technology groups >= 20, using median result
 - Premise that one dilution either side of median is OK
- " IT being developed
 - . for more secure data entry
 - . to eliminate manual analysis for scoring and manipulation of data to mailmerge into reports
- " To be added to scope for ISO17043 in 2017

Red cell genotyping pilot 2016/17

Scientific advisory group

- " Jill Storry
- " Geoff Daniels
- Sylvia Armstrong-Fisher
- " Martin Maley
- Shane Grimsley

Participants

- Recruited 45 labs in 22 countries
- " First exercise June 2016



Red cell genotyping pilot 2016/17

- 4 exercises per year
- " Haemoglobinopathy patient testing scenario
 - . 2 samples non-leucodepleted whole blood
 - . D, Cc, Ee, MN, Ss, Kk, Fy^a Fy^b Fy, Jk^a Jk^b, Do^a Do^b
 - . Genotype / predicted phenotype / Qs on practice
- " 16/17G1 reported commentary from Geoff Daniels
 - . 5 errors (4 labs), 3 data entry / interpretation, 2 possibly testing
 - . Some possibly due to lack of knowledge
 - . Main issue with results is terminology
 - . ? Lead to problems recording in LIMS for use in clinical practice

DAT pilot UK NEQAS (BTLP)

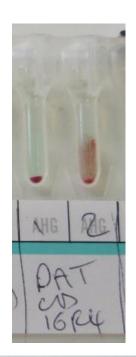
Summary of findings from 16R4 (distributed 18/04/2016) 16R7 (distributed 18/07/2016)

To date....

- Five pilot exercises sent
 - . 15R7 (13/07/2015)
 - ❖ DAT 1 negative
 - ❖ DAT 2 4+ coated with monoclonal anti-D
 - . 15R9 (12/10/2015)
 - ❖ DAT 1 2+ coated with monoclonal anti-D
 - ❖ DAT 2 2+ coated with polyclonal anti-K
 - . 16R4
 - ❖ DAT 1 negative
 - ❖ DAT 2 2+ coated with C3d
 - . 16R7
 - ❖ DAT 1 weakly positive coated with monoclonal anti-D
 - ❖ DAT 2 2+ coated with monoclonal anti-D
 - . 16R9
 - ❖ DAT 1 negative
 - ❖ DAT 2 2+ coated with monoclonal anti-D

In summary

- Positive reactions reported for cells coated with differing antibody specificities and strengths, and with complement
- SurveyMonkey questionnaire edited to include questions regarding internal negative controls, and result entry into the LIMS
- "Sample quality and reaction grade data from all exercises shows the samples are stable for one week





In summary

- " Feedback from some participants:-
 - . Cell suspension is not strong enough to process on automation
- Sample packaging to be addressed



Conclusions

- With thanks to all participants for testing the samples twice each exercise
- From 17R1, we will be asking participants to test the samples only once
- " There will be a one week exercise period
- Scoring system to be developed
- " A full report with data analysis will be issued soon
- " High likelihood of proceeding to a full DAT scheme during the next financial year



Overcoming a resource hurdle

Claire Whitham MSc MIBMS, Snr EQA Scientist, UK NEQAS BTLP

On behalf of the TACT team, UK NEQAS BTLP.

Training, Assessment and Competency Tool (TACT)

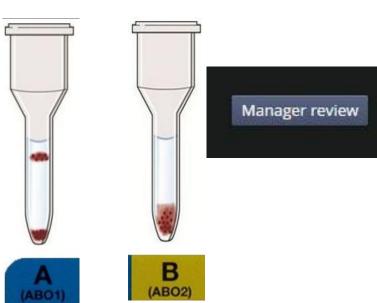




Released this year



- "Increased number of antibody specificities and combinations
- " ABO/D grouping anomalies
 - . Mixed field/dual population
 - . Weak reactions vs. anti-A, anti-B and anti-D
 - . Logic rules and scoring linked to patient demographics and clinical condition
- " Fully randomised patient demographics
- " Increase in variety of clinical conditions
- " Manager review feature
- Gross request form and sample label mismatches





How does TACT work?



Future TACT direction



"Coming soon:-

- . Reason for 'fail'
- . Anomalous scenarios flag, for 'best practice'
- . Multiple requests in the in-tray
- . 'Group check' sample request
- . Electronic crossmatch

