40 YEARS OF QUALITY

1969 UK NEQAS 2009

BBTS

BRITISH BLOOD TRANSFUSION SOCIETY

Joint UK NEQAS (BTLP) & BBTS Blood Bank Technology SIG 20th November 2013

Grateful thanks are extended to the following companies for the unconditional educational grants received:

Bio-Rad Laboratories Ltd

Deva Medical Electronics Ltd

Grifols UK Ltd

IBG Immucor

Labcold

MSoft eSolutions

Ortho-Clinical Diagnostics

Timestrip UK Ltd & Helapet Ltd

Tutela Medical Systems

RCA Case Study

With thanks to Angela Green MSc

Transfusion Coordinator & Quality Lead for Haematology & Blood Transfusion

Large NHS Foundation Trust

- 5 Hospitals serving population of 759,000
- Pathology services on 3 sites
    - Blood sciences including full Blood transfusion
- Clinical inpatient Haematology is centralised to one site
- Day case Tx given on 3 soon to be 4 of the sites.

The Patient (IG)

- 53 year old female

- Medical Hx
    - Intermittent haematuria
    - Breast Ca
    - On warfarin
    - Lupus
    - Requiring Tx support

Patient IG Transfusion History

Date	Hb g/l	Units Tx'd	Patient ABO/D group	Patient IAT AbSc
13/05/13	76	3	O+	Neg
22/05/13	75	2	O+	Neg
24/05/13	81	2	O+	Neg
26/05/13	78	0	O+	Neg

Q1: What is the most likely reason for the lack of Hb increment?

A. Recurrence of haematuria
B. Acute phase of haematological disease
C. Delayed Haemolytic Transfusion Reaction
D. Something else

Patient IG Transfusion History

Date	Hb g/l	Units Tx'd	Patient ABO/D group	Patient IAT AbSc
13/05/13	76	3	O+	Neg
22/05/13	75	2	O+	Neg
24/05/13	81	2	O+	Neg
26/05/13	78	0	O+	Neg
28/05/13	80	0	NT	DAT IgG 3+
14/06/13 *	74	0	NT	NT
18/06/13 **	Unknown	0	O+	Pos DAT IgG 1+

* GP acts on this Hb result and arranges for patient to attend for a day case transfusion 1 week later

** Patient has a Haem outpatient appointment for investigation of non incrementing Hb

Q1: Given the updated transfusion history what is the most likely reason for the lack of Hb increment?

A. Recurrence of haematuria
B. Acute phase of haematological disease
C. Delayed Haemolytic Transfusion Reaction
D. Something else

Q1: Given the updated transfusion history what is the most likely reason for the lack of Hb increment?

A. Recurrence of haematuria
B. Acute phase of haematological disease
C. Delayed Haemolytic Transfusion Reaction
D. Something else

Q2: Patient requires transfusion. What action should be taken next?

A. EI 2 units O+ K Neg
B. Refer to NHSBT
C. IAT crossmatch 2 units O+ K Neg
D. IAT crossmatch 4 units and issue most compatible

Q2: Patient requires transfusion. What action should be taken next?

A. EI 2 units O+ K Neg
B. Refer to NHSBT
C. IAT crossmatch 2 units O+ K Neg
D. IAT crossmatch 4 units and issue most compatible

Interim Report from NHSBT

- Patient O Positive, AbSc Positive
- DAT Positive IgG
  - Anti C and Anti-E eluted from patients red cells

<u>NHSBT Advice</u>

- If transfusion required select cells that are C & E antigen negative
- Questioned whether or not patient undergoing a DHTR

Initial site actions Re: Interim Report

1. Added NHSBT information to the LIMS system
2. Phoned site B
3. Faxed interim report to site B
4. Informed site B that a new sample would be needed for XM when patient admitted

Q3: How should site B establish compatibility?

- EI using selected C- E- units
- IAT XM using selected C- E- units
- DRT XM using selected C- E- units
- Refer to NHSBT for compatibility testing

Q3: How should site B establish compatibility?

- EI using selected C- E- units
- IAT XM using selected C- E- units
- DRT XM using selected C- E- units
- Refer to NHSBT for compatibility testing

Q4: What blood would you select?

- R_1R_1 K Neg
- R_1r K Neg
- rr K Neg
- R_0 K Neg

Q4: What blood would you select?

- R_1R_1 K Neg
- R_1r K Neg
- rr K Neg
- R_0 K Neg

Site B actions

- Requested sample to arrive the following day
- Found suitable units
  - Elastic banded 2 units O Neg rr together and added a note to them stating who units were selected for
  - Placed in bottom drawer of stock fridge as ‘selected units’ drawer full
- Attached faxed interim report to request form in the laboratory
- Attached post-it note to request form detailing units had been put aside in BOTTOM drawer

Q5: What would you do if ‘selected units’ drawer full?

A. Just squeeze my units in somehow
B. Start another drawer
C. Review content of ‘selected units’ drawer in hope of creating space
D. Something else

Q5: What would you do if ‘selected units’ drawer full?

A. Just squeeze my units in somehow
B. Start another drawer
C. Review content of ‘selected units’ drawer in hope of creating space
D. Something else

The day of the transfusion

- Haem Senior BMS took over at 8.00am from night shift
  - Ran groups and Ab screens on analyser
  - Performed manual baby group
  - Handed over to Band 5 BT BMS at 09.30, only kleihauer to do

Band 5 BT BMS Actions

- Band 5 BT BMS is signed off as trained **BUT**
    - Not signed off as competent so required work to be checked
    - All staff aware that they were to check work when requested

- Band 5 BT BMS performed a two unit serological crossmatch that was requested and performed the Kleihauer (all checked)

- Issued Anti D 500iu **BUT**
    - Realised that baby was Rh negative (this was manual group performed earlier by senior BMS)
    - Anti D therefore not required- sought advice from Haem Senior BMS, who withdrew Anti-D. Ward had NOT been telephoned and product had NOT left the laboratory.

Patient (IG)

- New sample had arrived and been booked in by Band 4 AHCS and put on analyser
    - Request form had been attached to original request form and NHSBT report.
- Sample grouped as O Positive AbSc positive

Q6: What further tests should be done on the patient before issuing blood?

A. None. NHSBT have already done all that is necessary
B. Antibody identification
C. DAT
D. Antibody identification and DAT

Q6: What further tests should be done on the patient before issuing blood?

A. None. NHSBT have already done all that is necessary
B. Antibody identification
C. DAT
D. Antibody identification and DAT

* Band 5 member of staff decided to go straight to crossmatch

Meanwhile!!

- Haem Senior BMS called back to Haematology
  - GP on phone wondering how his patient now appeared to be in remission from leukaemia but now had high Cholesterol
  - Senior BMS now involved in investigating unexplained results
  - GP surgery had bled patients wife and then labelled with her husbands details.
  - Took time to sort out!

Band 5 BT BMS Actions cont..

- Prior to crossmatching noticed note on request form regarding units that had been put aside
  - Looked in selected units drawer, couldn't find units
  - Selected units from O Pos drawer (Remember: patient has C+E allo antibodies)
  - Saw two units in the O Pos drawer with '1' '2' written on them from previous XM so assumed these were the selected units and picked one other unit

Q7: What measures should prevent the O+ (if inappropriate) being issued?

A. Alert(s) on LIMS
B. Incompatible XM
C. Both
D. Neither

Q7: What measures should prevent the O+ (if inappropriate) being issued?

A. Alert(s) on LIMS
B. Incompatible XM
C. Both
D. Neither

Band 5 BT BMS Actions cont..

- Performed serological crossmatch (IAT)
  - Units compatible (ignored alerts on LIMS)
  - Decided to issue without getting work checked because:
    - » Haem Senior BMS had handed over Kleihauer that didn't need doing so had lost faith in his judgement
    - » Other investigation going on in Haematology

Q8: The most likely reason these 'randomly' selected units are compatible is?

A. All units are R_0
B. XM incorrectly performed
C. All units rr
D. Antibodies adsorbed onto previously transfused cells

Q8: The most likely reason these 'randomly' selected units are compatible is?

A. All units are R_0
B. XM incorrectly performed
C. All units rr
D. Antibodies adsorbed onto previously transfused cells

Band 5 BT BMS Actions cont..

- Band 5 BT BMS asked AHCS to telephone ward to let them know units were ready.
    - AHCS could see units written on form were O Positive and said that O Negative units had been put aside for patient
    - Band 5 BT BMS said those units couldn’t be found and that the units crossmatched were fine.

Band 5 BT BMS Actions cont..

- Crossmatched units were still on the bench
    - AHCS looked at units and could see units were C Positive and queried this with Band 5 BT BMS
    - Band 5 BT BMS informed AHCS that ‘the crossmatch was compatible and that **anti C was one of those antibodies that you don’t worry about if the crossmatch is compatible**, therefore these units were fine for the patient’.
    - Band 5 pulled rank and pointed out she was qualified and therefore knew best.
- Crossmatched units put in issue fridge
    - AHCS went to lunch and on return found the units that had originally been set aside in the bottom of the fridge for patient

Q9: What is the clinical significance of anti-C and anti-E?

A. None
B. May cause HDNF
C. May cause Transfusion reactions
D. Both B &C

Q9: What is the clinical significance of anti-C and anti-E?

A. None
B. May cause HDNF
C. May cause Transfusion reactions
D. Both B &C

Error Detection

- Senior Haem BMS asked by late shift band 6 in BT where to file the interim report that had been faxed over for IG
- Haem Senior BMS was aware that they had not been asked to check this crossmatch
- Asked Band 5 BT BMS if units had been C and E antigen negative- **Told they were**
- Asked to see results of crossmatch, antibody panels and DAT- **Told panels and DAT not perfomed**
- Told BMS 5 to perform panels immediately and a DAT, and checked crossmatch cards

Error Detection!

- Haem Senior BMS intrigued about ?DHTR so looked up patient history on LIMS
- Noted that Hb that morning had been 99g/l (74g/l earlier when tx requested)
- Haem Senior BMS consulted Tx Practitioner saying he thought there had been an inappropriate request and went to withdraw units
- On arriving at issue fridge, 2 units had already been signed out in the preceding couple of hours
- When removing third unit from issue fridge noted it was C positive

Q10: What action(s) should be taken immediately?

A. Recall units that have been taken
B. Quarantine remaining unit
C. Both of the above
D. Ask NHSBT for advice

Q10: What action(s) should be taken immediately?

A. Recall units that have been taken
B. Quarantine remaining unit
C. Both of the above
D. Ask NHSBT for advice

Error detection cont..

- Called clinical area to ask about status of 1st and 2nd units.
- Clinical area engaged
- Senior BMS ran to clinical area- got 2nd unit stopped.
- Retrieved empty bag from first unit
- Both 1st and 2nd units were C Positive

Just to Re-cap Setting The Scene

- Its 16.00 hours on a Friday afternoon
    - Patient who was already undergoing delayed TX reaction has been given further incompatible units
    - The patient is in a day case area and due to go home
    - No senior haematology medical staff on site

Q11: What should be done next?

A. Request post transfusion samples consistent with local policy for investigation of transfusion reaction
B. Report the incident locally
C. Report the incident to MHRA / SHOT via SABRE
D. All of the above

Q11: What should be done next?

A. Request post transfusion samples consistent with local policy for investigation of transfusion reaction
B. Report the incident locally
C. Report the incident to MHRA / SHOT via SABRE
D. All of the above

What Happened Next?

- Medical review by oncall medical team- felt ok
  - » Admit
  - » Observe
  - » Take post tx bloods

- Band 5 BT BMS of staff told of error then taken for a cup of tea and moved into haematology
- All test performed again using pre and post tx bloods
- 6 units of selected units ordered for patients in case of need
- Reported locally and to MHRA/ SHOT via SABRE

Patient IG Outcomes

- Monday
  - Not feeling so well Hb had been 117g/l post tx now dropped to 83g/l
  - Little pyrexial
  - INR now 8.3
- Tuesday
  - Feeling better
  - Still little pyrexial
  - INR lower 1.7
  - Discharge arranged
  - Moved to discharge lounge- collapse falls and requires readmission and CT of Chest/ Head

Patient IG Outcomes cont..

- Readmitted to ward
  - During the next week INR is stabilised
  - Patient required 2 unit Tx of O negative rr units which were transfused uneventfully
  - Patient discharged at the end of week with initially twice weekly haem clinic appointments

Q12: What kind of a failure was this?

A. System
B. Individual
C. Neither
D. Both

Q12: What kind of a failure was this?

A. System
B. Individual
C. Neither
D. Both

Q13: Does this incident warrant a RCA?

A. Yes
B. No
C. Don’t know
D. What is RCA?

Q14:What methods are available to employ when undertaking a RCA?

Q13: Does this incident warrant a RCA?

A. Yes
B. No
C. Don’t know
D. What is RCA?

Patient IG Investigation

- Asked all staff involved to supply a statement
- Set date to interview all staff.

- Process map of the complete patient IG episode.
    - Looking at all systems process to see if
        - safety measures, SOP's , Computer alerts, were adequate and ascertain why they appeared to have failed

Q15: Who should undertake the interviews?

A. Lab manager
B. HR
C. HEAD BMS for Haem and BT
D. Senior BMS on day of incident

Q15: Who should undertake the interviews?

A. Lab manager
B. HR
C. HEAD BMS for Haem and BT
D. Senior BMS on day of incident

Investigation Cont.. Workload

- Look at BT workload that day from 08.00 to 12.00 when crossmatch was issued.
  - Groups performed earlier by early person
  - Some booking in (low numbers) performed by AHCS
  - Small batch of groups and ab screens put on analyser including sample for (IG) performed by AHCS
  - One 2 unit serological crossmatch (checked)
  - One Kleihauer (issued anti D inappropriately)
  - Crossmatch on IG (error)

Investigation Cont..Process Map

- Revealed 11 obstacles that were circumvented or deliberately over ridden to issue the units, these consisted of
  - Patient note pad on LIMS when requesting
  - Patient alert on LIMS when reserving units
  - Note on form
  - Interim report from NHSBT
  - Antibody alerts on LIMS system when issuing
  - LIMS system asking staff to check antigen status of unit
    - » Alert is not cleared by a simple click ‘yes’ must be typed
    - » Alert is for each unit
  - Not forgetting the challenge!

Investigation Cont..

- Initial statement & interview with Band 5 member of staff
    - Both the statement and initial interview flagged up concerns with knowledge
    - Claimed to have worked in busy transfusion laboratory before
    - Reason for not getting work checked – lost respect for senior BMS

Q17: Would you investigate individual further and why?

A. Yes – because concerns over knowledge
B. Yes – concerns over attitude
C. Yes – both
D. No – explanation given and retraining required

Q17: Would you investigate individual further and why?

A. Yes – because concerns over knowledge
B. Yes – concerns over attitude
C. Yes – both
D. No – explanation given and retraining required

Investigation Cont..Complete review of member of staff's personal folder

- Create a time line of career history
  - Large busy transfusion lab in teaching hospital over seas for at least 4 years
  - Volunteer positions in this country
- Insert references to ensure they marry up
  - Good reference from over seas lab
  - Volunteer reference did not want to answer the question 'would you re-employ?'
  - Good reference from another lab in the UK not on timeline
    - » Checked person who gave reference on HCPC web site and they were registered BMS

Investigation Cont..

- Wondered about size of teaching hospital lab
  - Google revealed it to be a large hub with no transfusion and not a hospital!
- Concerned about reference that didn't fit in career HX
- Referred to local Counter Fraud Services

Fraud Investigation

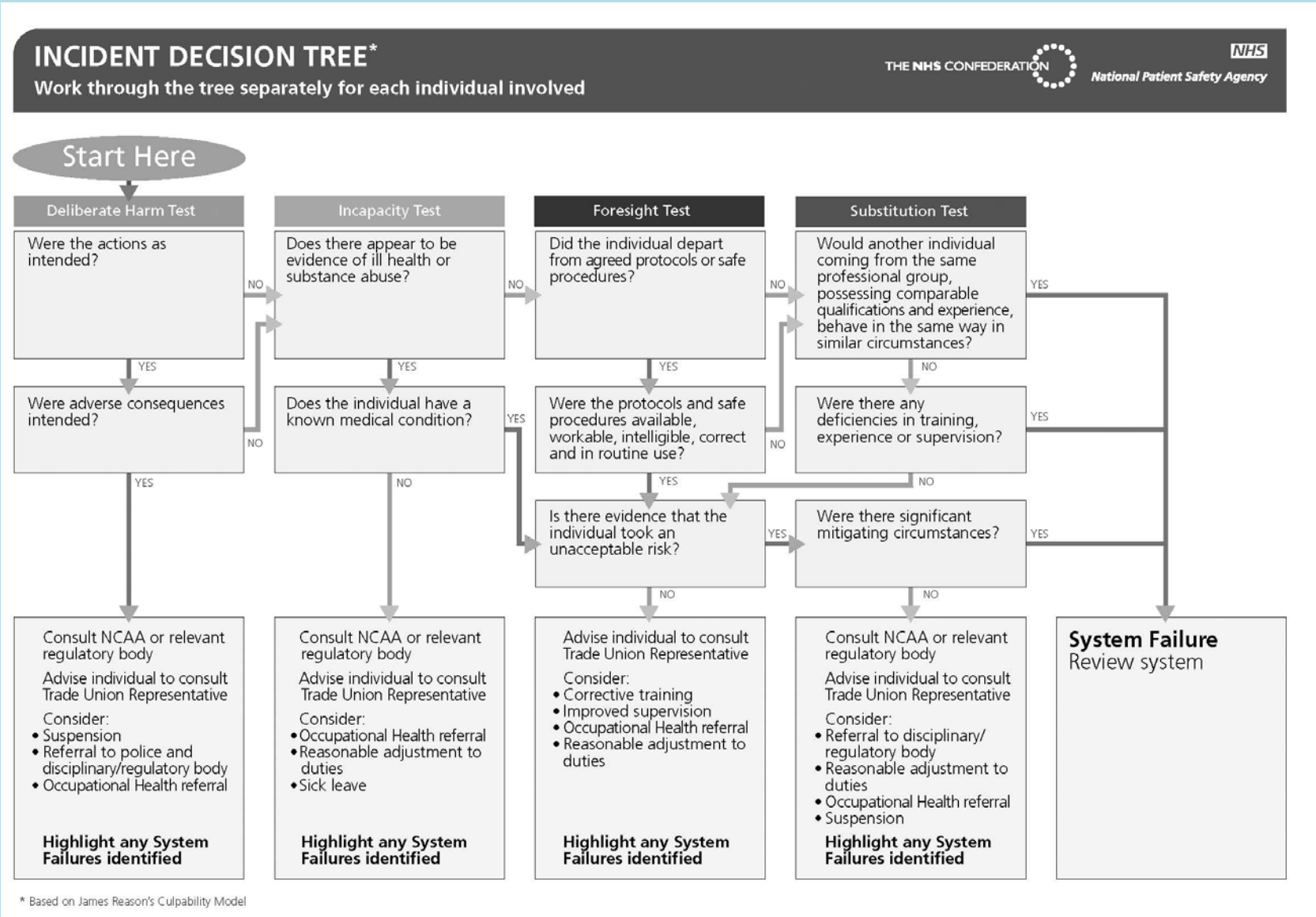
- HR department in large overseas lab
  - Confirmed BMS who gave reference was genuine
  - Member of staff involved in incident had never worked there
  - Reference was false
- HR department from rogue reference site
  - Confirmed that member of staff giving reference was genuine.
  - Member of staff involved in incident had never worked there.
  - Reference was false

- Both of these references given by registered Biomedical Scientists
  - dismissed from their current roles as a result.
  - Reported to HCPC and hearings to take place.

Final Outcome

- Band 5 BT BMS member of staff dismissed
  - Gross professional misconduct
  - failure to follow SOP and procedures resulting in harm to a patient
  - HCPC suspended registration
- Case passed to crown prosecution service
  - Person facing two charges of fraud
    - » Providing false career history
    - » Using false references

Decision Tree



Learning Outcomes CAPA

- Case studies to be given at all interviews with data to interpret- prior to this those attending band 5 &6 interviews did not have a formal knowledge test
- Referee to be contacted via central switchboard never a mobile
- Employment history to be confirmed by HR department and not referee.
- Only good references to be accepted- never to accept comments like ‘I don’t feel I am best placed to answer that question’
- All other newly appointed members of staff had personal folder and certification verified

Learning Outcomes CAPA

- Training
  - Thought processes never challenged
- Competency logs
  - Redesigned now reflect new training systems
- Staffing-rota
  - Design to support staff and ensure that transfusion is adequately covered
- Empowerment of staff
  - All staff encouraged to challenge and challenge again no matter of grade- everyone has potential to make mistakes

Q18: What other areas can you suggest that may benefit from CAPA ?

Q18: What other areas can you suggest that may benefit from CAPA ?

- Knowledge
- Supervision (direct or indirect)
- Teamwork
- Culture
- Selected blood storage?
- LIMS - access to overrides?

THANK YOU

- ANY FURTHER COMMENTS / QUESTIONS?

40 YEARS OF QUALITY

1969 UK NEQAS 2009

BBTS

BRITISH BLOOD TRANSFUSION SOCIETY

Joint UK NEQAS (BTLP) & BBTS Blood Bank Technology SIG 20th November 2013

Grateful thanks are extended to the following companies for the unconditional educational grants received:

Bio-Rad Laboratories Ltd

Deva Medical Electronics Ltd

Grifols UK Ltd

IBG Immucor

Labcold

MSoft eSolutions

Ortho-Clinical Diagnostics

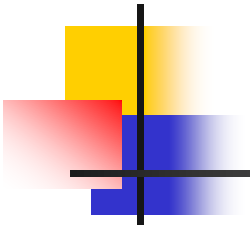
Timestrip UK Ltd & Helapet Ltd

Tutela Medical Systems

- Is this our primary concern?
- As laboratory scientists where should our focus be? Sample positive ID
- Patient positive ID – whose responsibility?
- Root cause is patient ID not laboratory science.
- How are patients identified prior to wristband application?

- If audit demonstrates concern with patient primary ID - best to correct that.
- We know patient ID is being variably performed.
- SHOT 2012 report - hospitals to ensure patients are positively identified at all key stages.
- Right time first time general approach. National initiative.
- Steer it directly to RM depts. What is your RMD's opinion?

- Patient mis ID should be a NHS never event rather than ABO error.
- Yes highlight weaknesses but should we be responsible to fix.
- Already hyper-regulated and under cost pressures and TAT pressures.
- Who agrees on exceptions and are they computer controlled?
- Ever complex rulebases requiring computer control.



- Potential for increased user conflict.
- We know users have attempted to defeat the 2 sample initiative.
- We know some labs have implemented the policy but don't police it.
- Logistical problems and particular phlebotomy problems in paediatrics.

- What about other serious mis-identity in pathology and throughout medicine?
- High numbers of medicine errors. Typically improved by proper governance.
- What about antenatal sampling which could have serious HDFN consequences.
- Theatres report delays due to missing bands.
- Incorrect Hb leading to inappropriate Tx - leading to serious TACO. ? repeat FBC prior to Tx

- Should biopsies for histopathology be split into two?
- Use of group O, pressure on supply. Is it software controlled? Increase mixed field events. BCSH 2006 I.T. system specification states that consideration should be given to use of group O where there are sample concerns but can pose risk from non rbc products.

Alternatives

- 2 people verifying a single phlebotomy event for transfusion testing - more achievable?
- Guidelines - focus the science onto laboratories and general administration to trusts either directly or via other policing bodies.
- ? CQC should focus on such primary matters.

40 YEARS OF QUALITY

1969 UK NEQAS 2009

BBTS

BRITISH BLOOD TRANSFUSION SOCIETY

Joint UK NEQAS (BTLP) & BBTS Blood Bank Technology SIG 20th November 2013

Grateful thanks are extended to the following companies for the unconditional educational grants received:

Bio-Rad Laboratories Ltd

Deva Medical Electronics Ltd

Grifols UK Ltd

IBG Immucor

Labcold

MSoft eSolutions

Ortho-Clinical Diagnostics

Timestrip UK Ltd & Helapet Ltd

Tutela Medical Systems

PERFORMANCE MONITORING FOR FMH AND POINT OF CARE TESTING FOR D-TYPING

DR. MEGAN ROWLEY
UK NEQAS SCHEME DIRECTOR

UKNEQAS

FETOMATERNAL HAEMORRHAGE

The UK NEQAS FMH Scheme

- Accurate measurement of the volume of D positive fetal cells in the D negative maternal circulation
- Appropriate clinical action based on laboratory FMH testing including calculating the dose of anti-D Ig required to prevent sensitisation

The EQA material

- Screening and quantitation of simulated FMH by acid elution
- Confirmatory FMH testing by flow cytometry

UKNEQAS

Changes to FMH EQA

- Increased the number of exercises since 2012
  - 12 samples in 6 exercises
  - Decreased workload per exercise
  - Earlier detection of analytical inaccuracy
- Introduced a second performance monitoring system based on the clinical implications of the testing
  - Significantly outlying results (DI -2 or 3.5)
  - Clinical significance errors (risk of sensitisation)

  UP – single error, PUP - error in 2/3 exercises

Cumulative Performance Score

- FMH accuracy continues to improve!
- New criteria for unsatisfactory performance (UP) and persistent unsatisfactory performance (PUP)

Score and trend	Performance status
80-99	Borderline
100+	UP
100+ and falling	UP
100+ and rising or not falling (inc non-return)	PUP
100+ on two occasions in one 12 month period	PUP

Acid Elution

1305F P1 = 0mL bleed

- 38 AE laboratories reported seeing fetal cells
  - 12 proceeded to quantification
- 12/48 screen-only labs reported fetal cells
  - 6 would have referred for flow cytometry
- Were false positives related to kit?

  includes quantification and screen-only labs
  - Inverclyde 27/82 (33%)
  - Guest 10/31 (32%)
  - Clintech 9/76 (12%)

  P=0.001

UKNEQAS

Flow Cytometry

- Have started to score simulated FMH between 2mL and 4mL (AE non-scoring)
- Not many labs in UK use anti-HbF in EQA exercises (all use anti-D)
  - Measures something different so should it be scored differently/separately?
  - In UK - used either for FMH in RhD positive women or to clarify discrepancies between AE and FC (during pregnancy)
  - Widely used by European participants ? For anti-D dosing

WILL INCLUDE IN NEXT QUESTIONNAIRE!

EQA CAPA Summary (PRN 00000)			
Details of unsatisfactory performance			
Exercise Code:	1203F and 1205F		
Sample(s):	Both		
Area of assessment (tick appropriate box)	Potential for sensitisation	Outlying result √	Score >100
Result Reported:	**1203F:** Overestimation for P1: 22.5mL *cf* median of 10.8mL **1205F:** Overestimation for P1: 52.8mL *cf* median 2.2mL (non scored) Underestimation for P2: 2.4mL *cf* median of 30.5mL		
Details of laboratory investigation			
Participant's assessment of the cause of unsatisfactory performance			
Potential for impact in clinical situation			
Details of CAPA			
Signature (as appropriate) / Date			
Laboratory Manager			
Consultant Haematologist			
Quality Manager			

CORRECTIVE AND PREVENTATIVE ACTION

- New EQA CAPA from to be completed for UP and PUP
- Improves understanding of errors
- Feedback to other participants in annual report

UKNEQAS

EQA in POINT OF CARE TESTING

- UK NEQAS has a point of care testing working group
  - INR testing (including self testing)
  - Blood count/haemoglobin testing
  - And many others……
- Need to consider how POCT testing EQA differs from standard laboratory testing
  - Sample presentation, training, performance monitoring
- CPA standards for point of care testing

UKNEQAS

POCT in transfusion?

- Bedside confirmatory blood group testing in France
  - Not adopted in UK
- Can buy on-line blood grouping tests
  - Blood group diets???
- D-typing of pregnant women attending pregnancy advisory clinics
  - To detect D-negative women for anti-D Ig administration after termination of pregnancy

Is EQA possible in this setting?

EQA for POCT D-Typing

2011/2012 –met with a single provider organisation to look at D-typing systems and to consider EQA

- Single D-type of individual women using bedside testing kit
- Result recorded on patient's notes and on paper 'register'
- Laboratory confirmation of a proportion of samples and anomalous D-typing result

UKNEQAS

External Quality Assessment

- Samples – ‘R’ exercises containing red cells for ABO/D typing
- Frequency – 4 times a year
- Distribution – to individual clinics
- Testing – by nursing staff undertaking bedside D-typing
- Results to local managers and central quality manager

UKNEQAS

Training and Support

- NEQAS provided telephone training of all main contacts before the first exercise
  - Testing, results return, interpretation of reports
- Written instructions with each exercise
  - And telephone support of staff undertaking testing if problems arise
    - Technical - testing samples
    - Web entry of results
- Annual report and review with provider organisation

UKNEQAS

Review of 2012/13

40 participating centres (clinics), participation rate improved (93.5% to 97.8%)

Exercise Code	Date Distributed	Patient 1	Patient 2	Patient 3
12R4 B	16 April 2012	Rh D negative [1]	RhD positive	Rh D negative
12R7 B	16 July 2012	Rh D negative	RhD positive	RhD positive
12R9 B	15 Oct 2012	Rh D negative	RhD positive	RhD positive
13R1 B	21 Jan 13	RhD positive	Dual population [2]	Rh D negative

- False positive errors were all due to transposition of samples
  - none due to DAT+ cell in **12R4B P1**
- False negative results (4) were correct on repeat testing
  - One data entry error
- **13R1B P2** (dual population)
  - 32/44 strong positive, 11/44 weak positive, 1/44 negative

UKNEQAS

Next Steps for NEQAS

- NEQAS will undertake a site visit to review testing systems
- Improve registration and documentation to reflect observed practice
- Reinforce importance of testing EQAS as patient samples; one at a time
- Save samples for repeat testing
- Weak or anomalous reactions need follow up testing before assigning a result

Action for Transfusion Laboratories?

- We are not promoting POCT in transfusion!
- If you are aware of any bedside blood grouping within your organisation - undertake a risk-assessment of the practice
- If you support any clinics undertaking D-typing for the purposes of identifying women for anti-D administration …….EQA is possible!

UKNEQAS

Thanks

- FMH/BTLP Scheme Staff
  - Joint venture BTLP and Haematology
- FMH SAG
  - chair Mark Williams
- BTLP Steering Committee
  - chair Peter Baker

And all our participants, at home and overseas!

UKNEQAS

40 YEARS OF QUALITY

1969 UK NEQAS 2009

BBTS

BRITISH BLOOD TRANSFUSION SOCIETY

Joint UK NEQAS (BTLP) & BBTS Blood Bank Technology SIG 20th November 2013

Grateful thanks are extended to the following companies for the unconditional educational grants received:

Bio-Rad Laboratories Ltd

Deva Medical Electronics Ltd

Grifols UK Ltd

IBG Immucor

Labcold

MSoft eSolutions

Ortho-Clinical Diagnostics

Timestrip UK Ltd & Helapet Ltd

Tutela Medical Systems

The Princess Alexandra Hospital
NHS Trust

2 sample check or not 2 sample check!
That is the question
But what is the answer?

Tracy Nevin
Transfusion Practitioner

The Princess Alexandra Hospital
NHS Trust

Why 2 samples

SHOT (SERIOUS HAZARDS OF TRANSFUSION) REPORT 2011
Half of all errors reported were blood transfusion sample errors, of which 92% had wrong blood in the tube (WBIT) due to misidentification of patients / mislabelling.

DEPARTMENT OF HEALTH - NEVER EVENT LIST 2011
Never misidentify a patient
Never give an ABO incompatible blood transfusion

NATIONAL PATIENT SAFETY AGENCY (NPSA) – SAFER PRACTICE NOTICE 2006
Right patient right blood

The Princess Alexandra Hospital
NHS Trust

DUE TO THE VOLUME OF MISIDENTIFIED PATIENTS AND MISLABELLED SAMPLES

“Unless secure electronic patient identification systems are in place, a second sample should be requested for confirmation of the ABO group of a first time patient prior to transfusion, where this does not impede the delivery of urgent red cells or other components.”

BCSH Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories 2012

The Princess Alexandra Hospital
NHS Trust

- **DGH**
- **489 bed occupancy**

The Princess Alexandra Hospital
NHS Trust

5 Clinical Directorates

Urgent & Ambulatory Care

Acute Medicine
Ambulatory Care
Emergency Department
Emergency Medical Unit

Cancer, Diagnostic & Pathology Services

Haematology Day Unit
Oncology Day Unit

Medicine

Care of the Elderly
General Medicine
Includes - Gastro

Surgery & Critical Care

Out Patients
Pre Op Assessment
ITU / HDU
Main Theatres
Day surgery Unit

Breast surgery
ENT surgery
General Surgery
Lower GI
Ophthalmology
Oral surgery
Orthopaedics
Trauma
Urology
Vascular

Women's and Children's Health

Antenatal
Maternal Foetal Assessment Unit
Labour Ward
Birthing Unit
Pre & Post Natal Care
Neonatal ICU
Paediatric Ward


TRANSFUSION

The Princess Alexandra Hospital
NHS Trust

Initial Assessment

Year	2010	2011	2012
No. of samples	24990	24984	24622
No. of BAD samples	308	260	160
No. WBIT	2	1	1

- ☺Not quite Zero tolerance policy in use
- ☺Yearly collation of BAD sample figures – not all recorded
- ☺Manual request for G&S /XM sample - Clinical areas
- ☺Manual booking in of samples into the lab – barcoded after checks performed
- ☺Technidata system version 11.71.B
- ☺EI on 2 sample - BCSH pre-transfusion compatibility procedures
- ☺WBITs reported to MHRA / SHOT
- ☺Risk Assessment / Business case for electronic tracking system

The Princess Alexandra Hospital
NHS Trust

The beginning of the Journey

The Princess Alexandra Hospital
NHS Trust

Take one step at a time

The Princess Alexandra Hospital
NHS Trust

Phase 1

1. Participate in the 2012 NCA Labelling & Sampling audit
2. Undertake an In House audit on every BAD sample, within the same time frame and using the same proforma

Rationale for both audits

☺Benchmark current practice with previous audit findings & National guidance

☺To collect information on the quality of practice, to determine if;

- Patients are correctly identified at the time of sampling
- There is a robust system in place for sample labelling

☺To understand the reasons why errors are made

☺Identify areas of concern by carrying out more detailed audit In house

☺To reduce the incidence of errors by putting forward recommendations to improve practice, patient safety and outcome

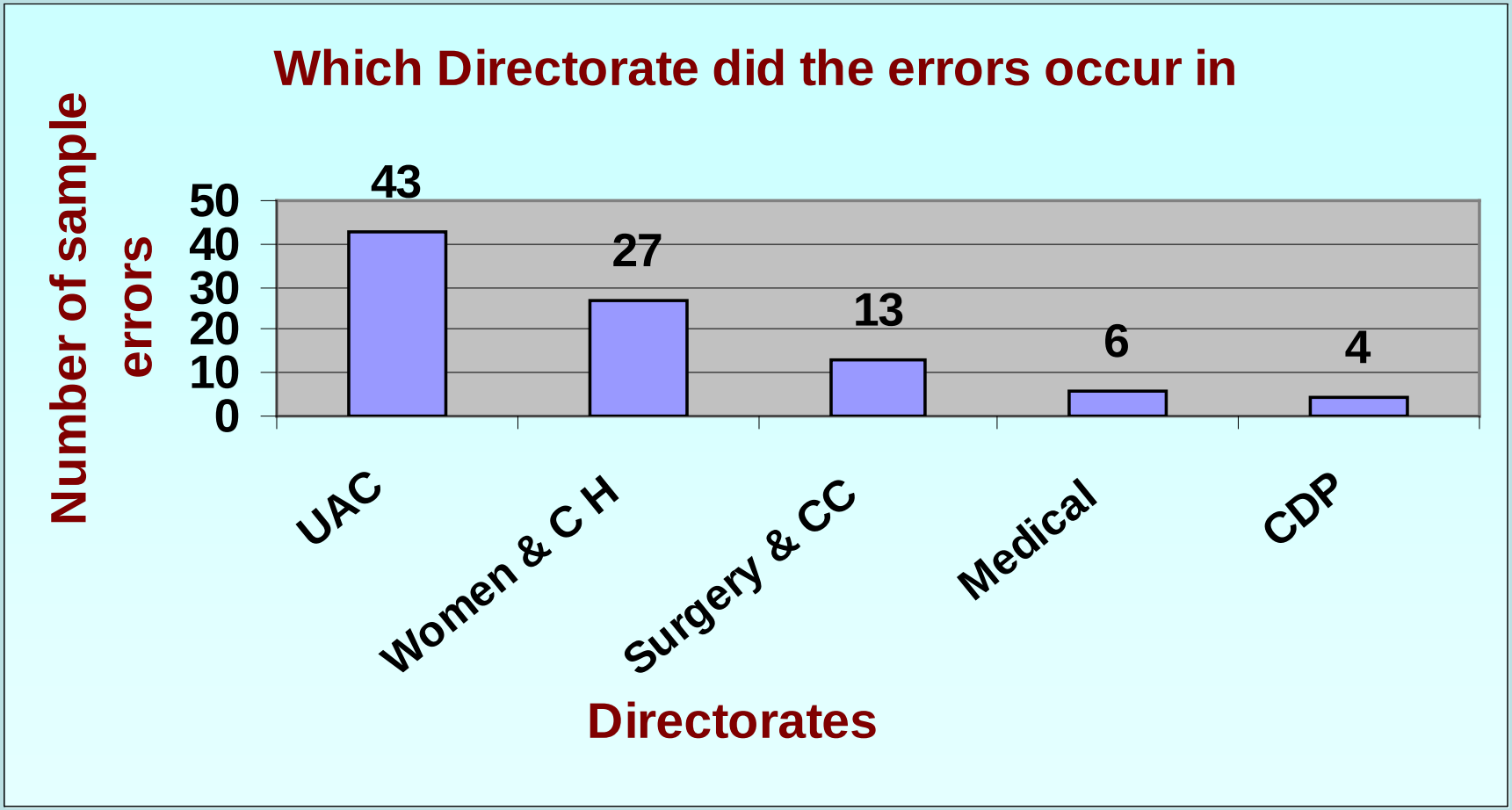
The Princess Alexandra Hospital
NHS Trust

National audit findings

	Nationally	%	Regionally	%	PAH	%
Sample takers	Unknown	38%	Unknown	49.2%	Registered Nurses	26%
Areas / wards	In patient	27%	Emergency Dept	24.9%	Emergency Dept	36%
Data missing	Mismatch tube & form	41%	Mismatch tube & form	36%	Mismatch tube & form	41%
Why error was made	Transcription error	33%	Transcription error	25.4%	Interrupted or distracted	38%
Sample taker competency assessed	Yes	64%	Yes	77.8%	Yes	78%

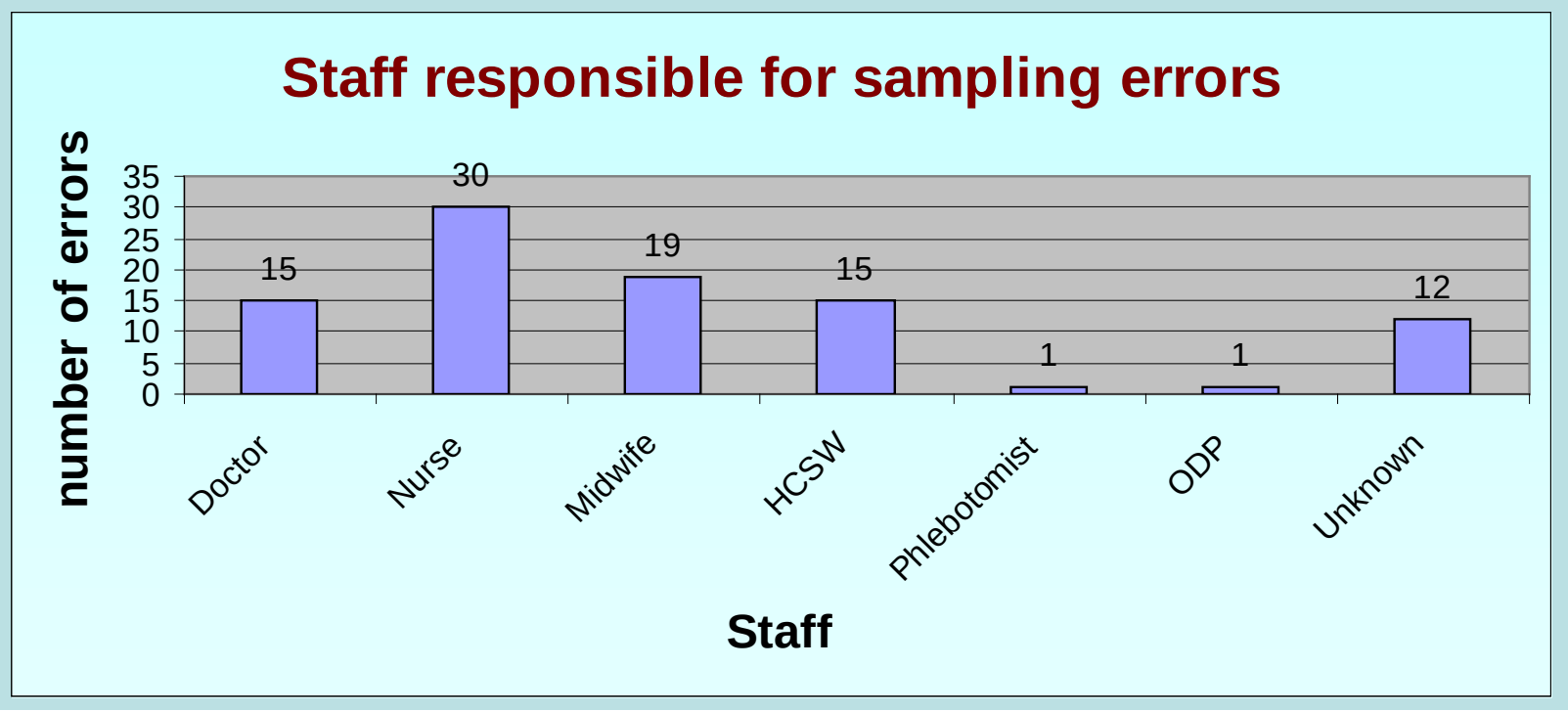
The Princess Alexandra Hospital
NHS Trust

Findings from In House audit



The Princess Alexandra Hospital
NHS Trust

Findings from In House audit

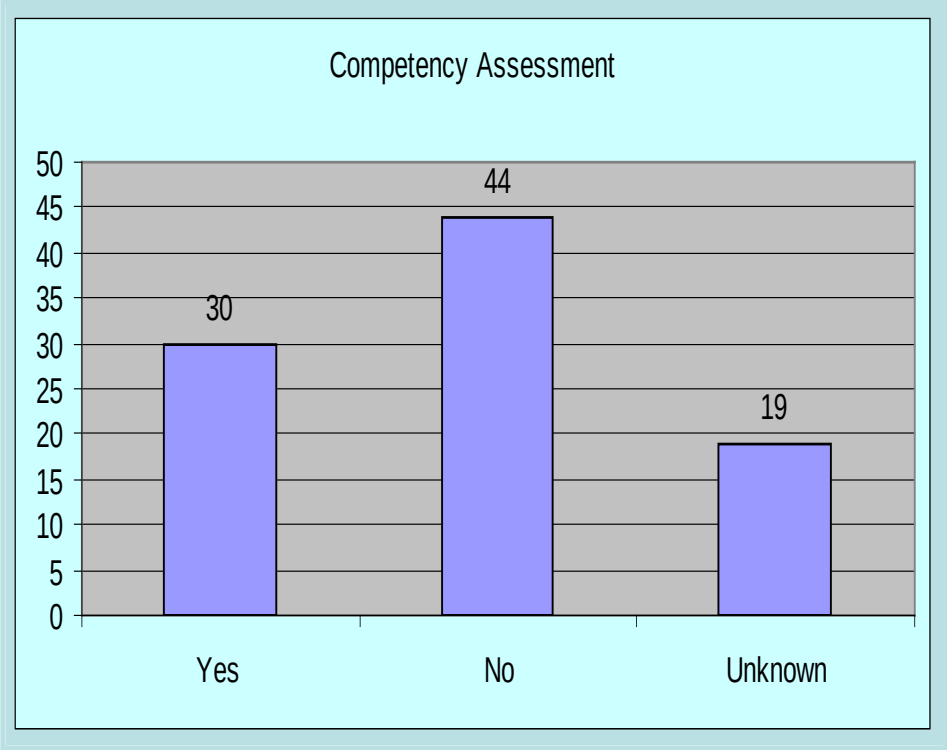


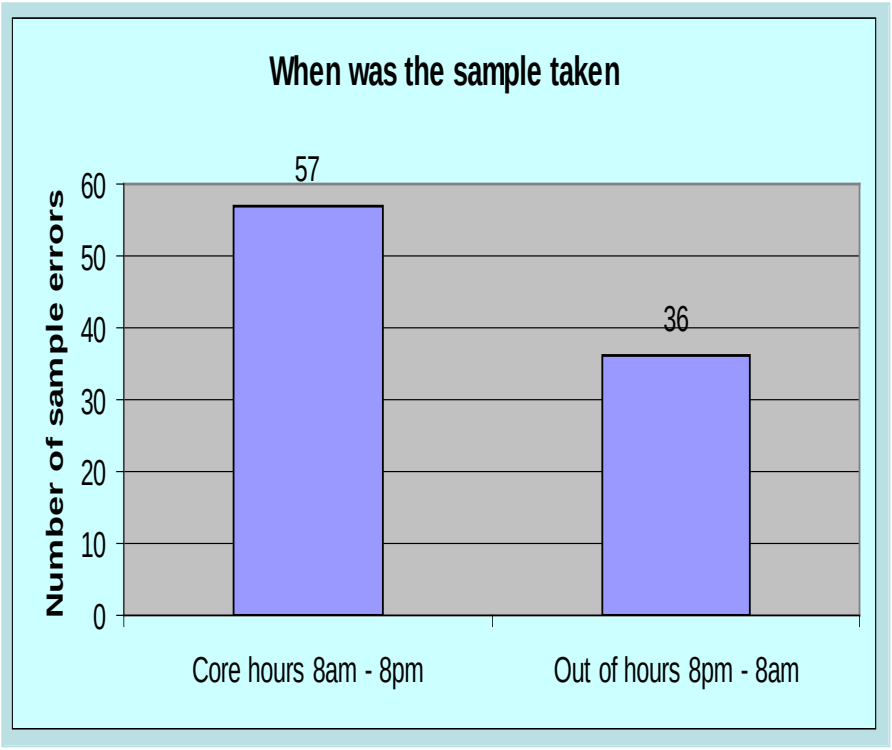
Staff involved in errors not from PAH

6 Agency Nurses & 2 Locum Drs

The Princess Alexandra Hospital
NHS Trust

Findings from In House audit

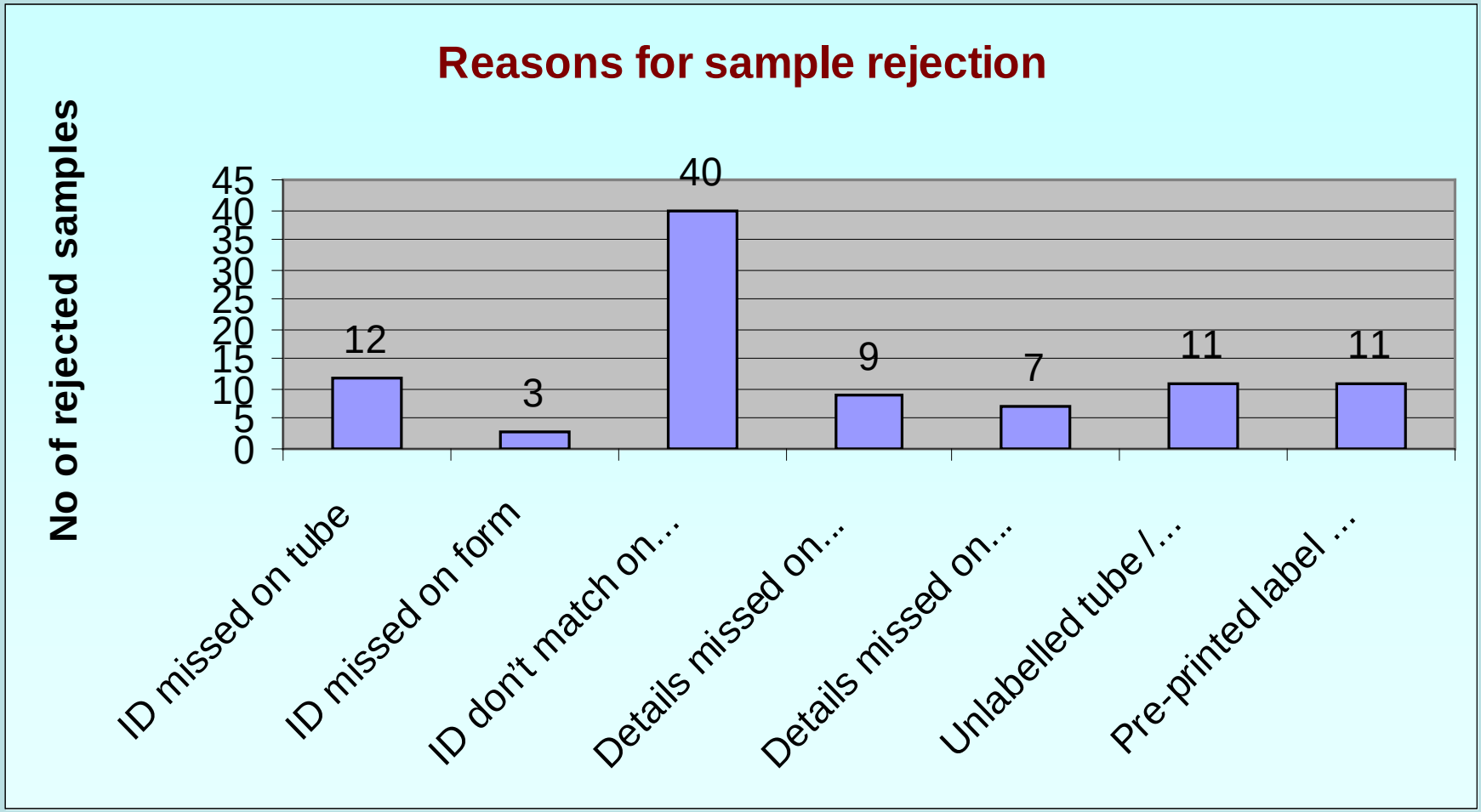




Unknown – staff had left the Trust / long term or mat leave

No – variance in record keeping practice by ward / dept mgrs

The Princess Alexandra Hospital
NHS Trust



☺**Transcription error – 17**
☺**Interrupted / distracted – 24**
☺**Unaware of the procedure – 8**
☺**Other - 38**

The Princess Alexandra Hospital
NHS Trust

In House audit findings

☺**Urgent & Ambulatory Care** - highest incidents in Trust

- Registered Nurses
- Agency / Locum staff no PAH Competency Assessment
- No wristband used for Ambulatory / minor care patients
- HCSW completing G & S request form
- **Lab not informed of updates of patient details

☺**W&CH** – 2nd highest incidents in Trust

- Midwives - Labour Ward
- Wristband not always used for babies / neonates – fragile skin
- Wrong sized bottle used for babies > 4 months
- **Babies should be kept under mums name until discharged home

☺**Surgery & CC** – 3rd highest incidents in Trust

- ITU/HDU – using blood gas competency as blood sampling competency
- ITU/HDU - Agency / Locum staff no PAH Competency Assessment
- POA – HCSW interrupted by Registered Nurses

The Princess Alexandra Hospital
NHS Trust

Recommendations

Communication

☺Continue with Zero Tolerance to incorrectly labelled samples
☺1st August 2012 all errors reported onto DATIX incident reporting system
☺1st August all Off Site/PCT errors reported onto DATIX
☺Continue to report WBIT externally to MHRA
☺Communicate findings to Clinicians, Business Units, Wards & Departments at monthly PSQ, BU & Nursing forums, quarterly to HTC

Training

☺HCSW / Nursing staff / ODP - referred to PDT, follow errors & omission pathway, undergo retraining and reassessed
☺Drs - referred to Medical Skills Facilitator for retraining and reassessment, Clinical Leads informed
☺Ward / Dept Managers must have correct and up to date records of staff blood competencies achieved
☺Training matrix requirements currently under review and training is being updated
☺Key areas – Handout of correct process attached to payslips, Adhoc teaching sessions,
☺Intra net system being developed with BT information, algorithms and training videos

The Princess Alexandra Hospital
NHS Trust

Implementation of recommendations

Laboratory staff

Communication
SOP updates
Training on DATIX
Competency Assessment on new process
Quality control / improvement
Change control Document
Audit
Re-evaluate

Clinical staff

communication
Training
Reinforcement of information
Policy update
Trend analysis
Audit
Re-evaluate

Since implementation venepuncture sample errors is high on the Trusts risk register for the 3 key areas.

The Princess Alexandra Hospital
NHS Trust

Phase 2

Concerns have been expressed that the two samples may be taken at the same time, but one “saved to send to the transfusion laboratory at a later time.

- It is important to have a policy and process in place to assure that the two samples have been taken independently of one another.

- Those taking samples for transfusion, need to understand the reasons for requesting a second sample and the risk of WBIT.

BCSH Guidelines 2012

The Princess Alexandra Hospital
NHS Trust

Initial Assessment

UAC
Most samples requested by ED
**Urgent patients with unknown status

W&CH
Group check performed at booking,
**Out of area patients

Surgery & CC
Elective patients have G&S at POA & XM sample on day of surgery
**Emergency cases in ED with no historic group

Medicine
Most patients would have group check performed in ED
**Some no historic group

CDP
Most patients would have historic group
**New patients without historic group

** key areas of concern

The Princess Alexandra Hospital
NHS Trust

Strike while the iron is hot

- ☺Devised an SOP / Guidance ensure reflect BCSH guidance and key areas
- ☺Review other SOP / Guidelines up to date – Concessionary release
- ☺Contingency plan – system failure
- ☺Step by Step Algorithm of new process for Lab & Clinical staff
- ☺Lab staff competency for new process
- ☺Yellow top sample for group check
- ☺Data collection - 3 monthly audit of new process
- ☺Communication & Training:-
  - Lab Meetings
  - Business Unit meetings – in particular key stakeholders
  - Clinical lead meetings
  - Patient Safety Committees
  - HTC
  - Intranet / global email / laminates in key areas
  - Clinical Update / Induction training sessions / Adhoc training sessions

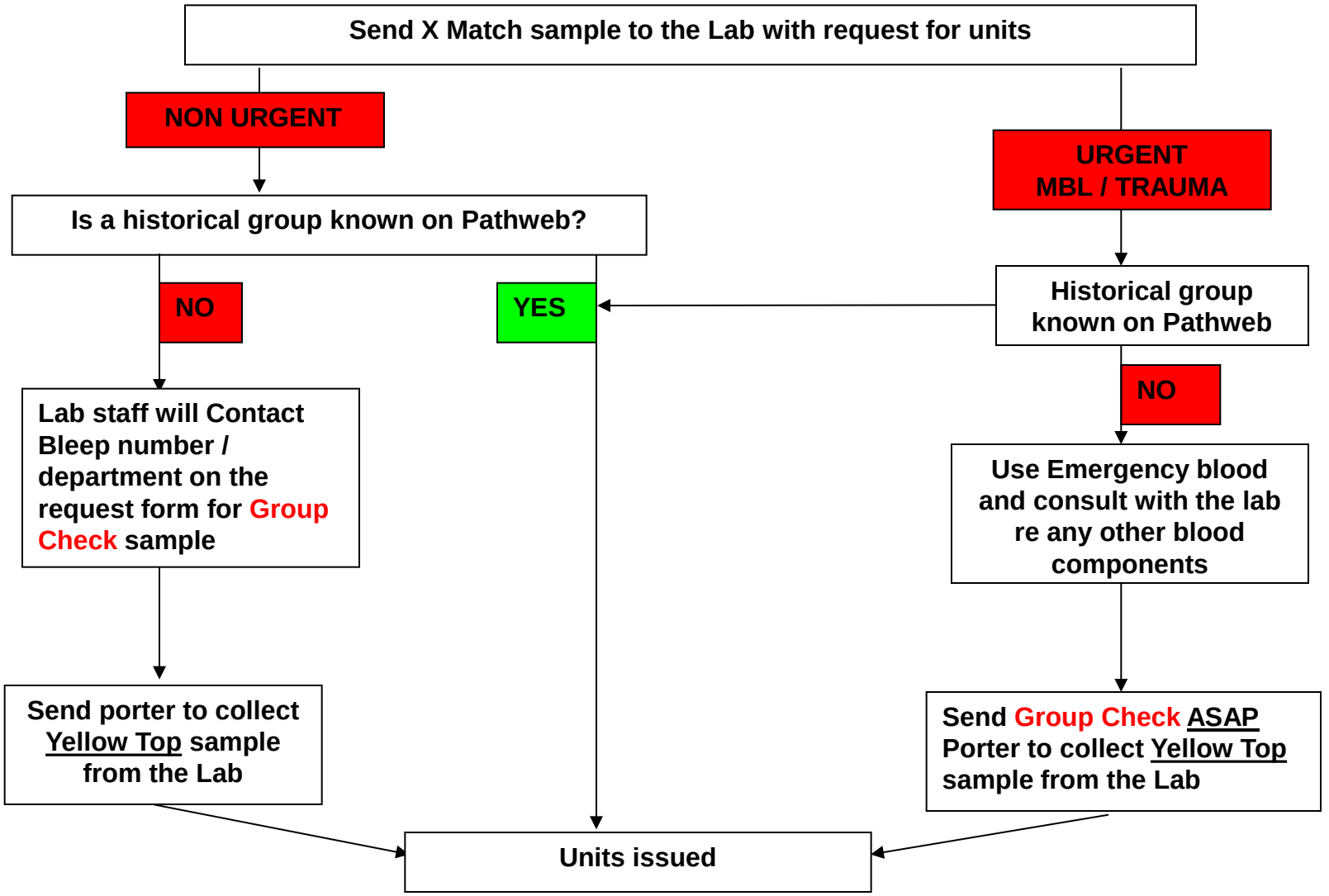
The Princess Alexandra Hospital
NHS Trust

2nd

Group check

sample bottle

The Princess Alexandra Hospital
NHS Trust



The Princess Alexandra Hospital
NHS Trust

Recommended best practice

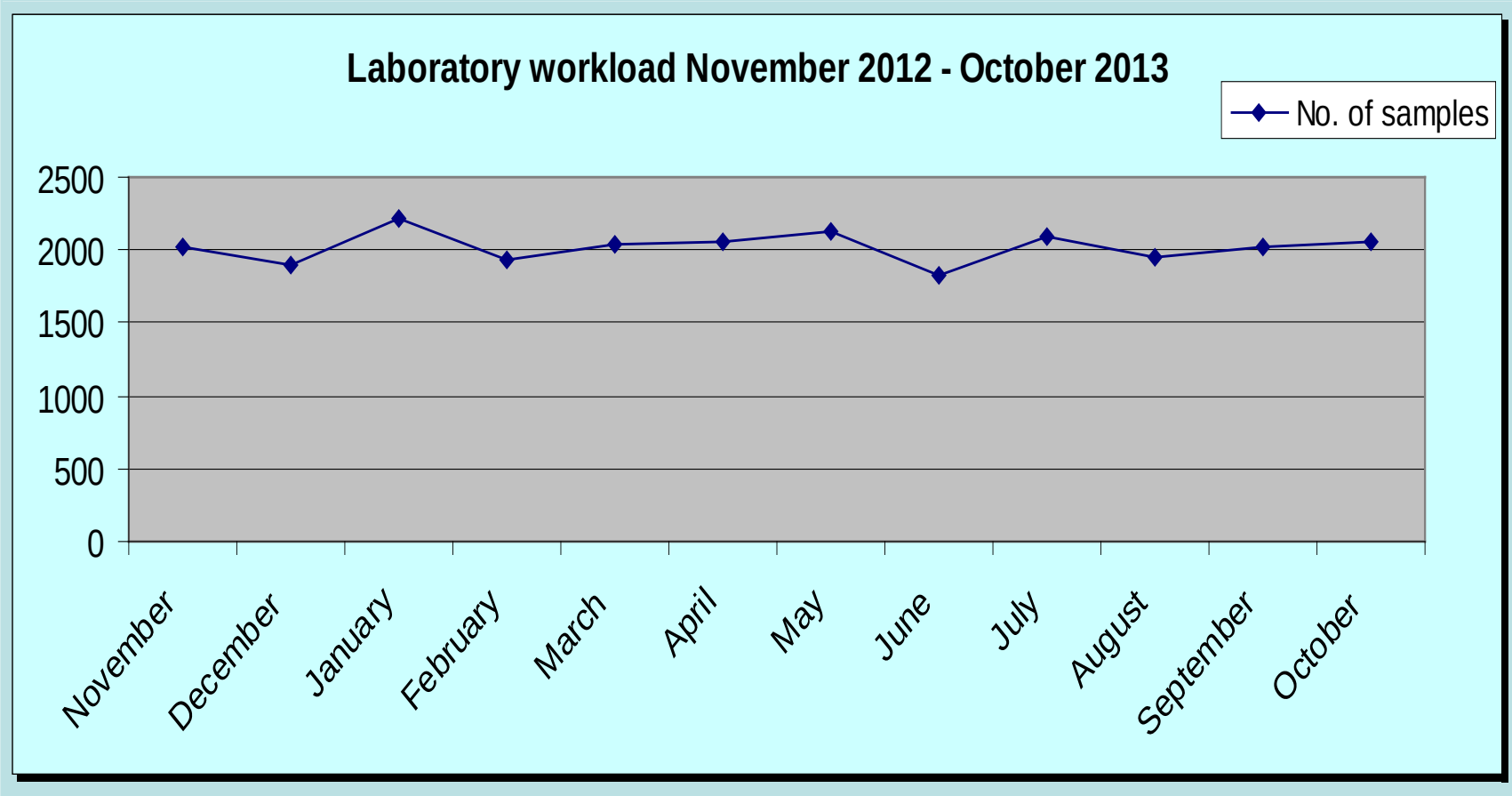
D matched blood is recommended
To preservation supply of O neg O pos can be given to:-

i. Female patients > 50 years.
ii. Adult males who are D negative or whose D status is unknown.
iii. Patients undergoing a large volume transfusion (> 8 units), with the exclusion of children, females of childbearing potential and patients with immune anti-D.

D negative red cells should <u>always</u> be selected for:
i. D negative women of childbearing potential (<51 years).
ii. D negative patients <18 years old.
iii. Patients who have formed immune anti-D, even if not currently detectable.
iv. Transfusion-dependant D negative adults.

Females of child-bearing potential should receive K negative red cells unless they are unavailable in an emergency (concessionary release)

The Princess Alexandra Hospital
NHS Trust



136 extra samples for the 3 months audited = 10 extra samples per week
****New Renal Unit opened in August no historic group for many of the patients**

The Princess Alexandra Hospital
NHS Trust

2 group check audit results

Month	July	August	September
No of errors	8	6	1
Drs	4	4	1
Nurses	4	2	0

Errors

13 = 2 samples taken at same time

1 = 3 samples & forms sent

1 = difficulties getting porter to collect Group check bottle from lab

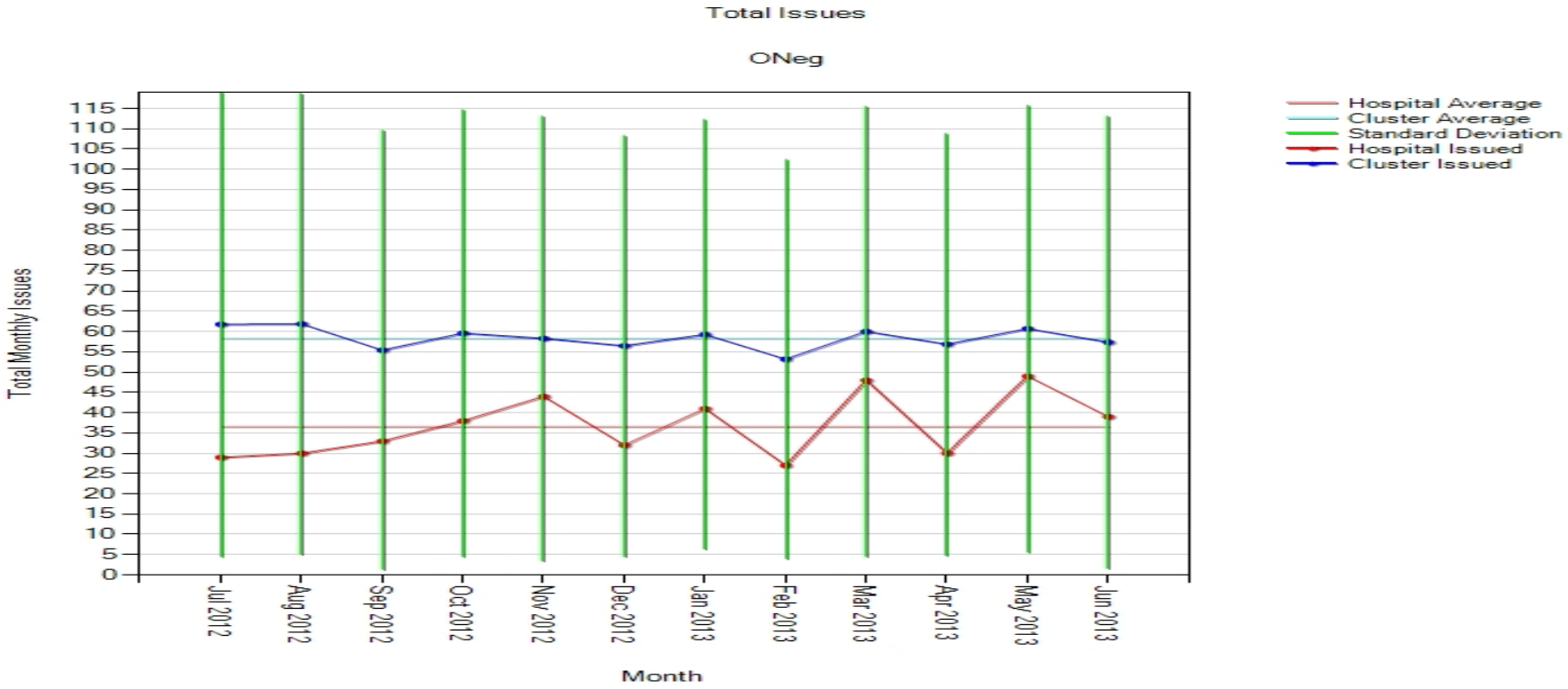
Comments

6 = reason unknown
4 = unaware of new process
1 = lab staff error
1 = patient difficult to bleed
1 = Dr told the nurse to take 2
1 = took 2 in case it was needed
1 = unable to get porter

The Princess Alexandra Hospital
NHS Trust

O Negative usage

Pre roll out of 2 group check July 12 – June 13

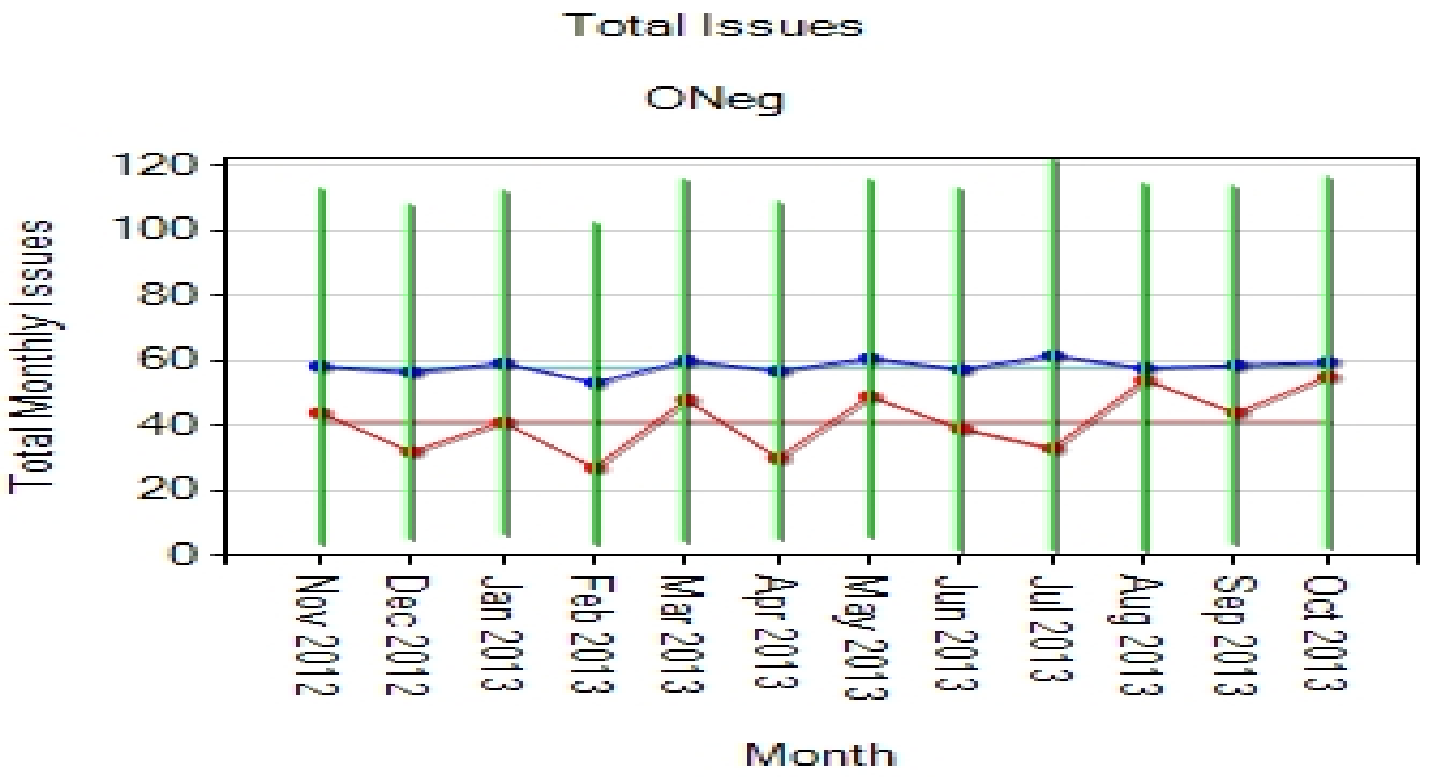


Hospital Average - 36.67 **Cluster Average – 58.4**

The Princess Alexandra Hospital
NHS Trust

O Negative usage

Post roll out of 2 group check NOV 12 – Oct 13



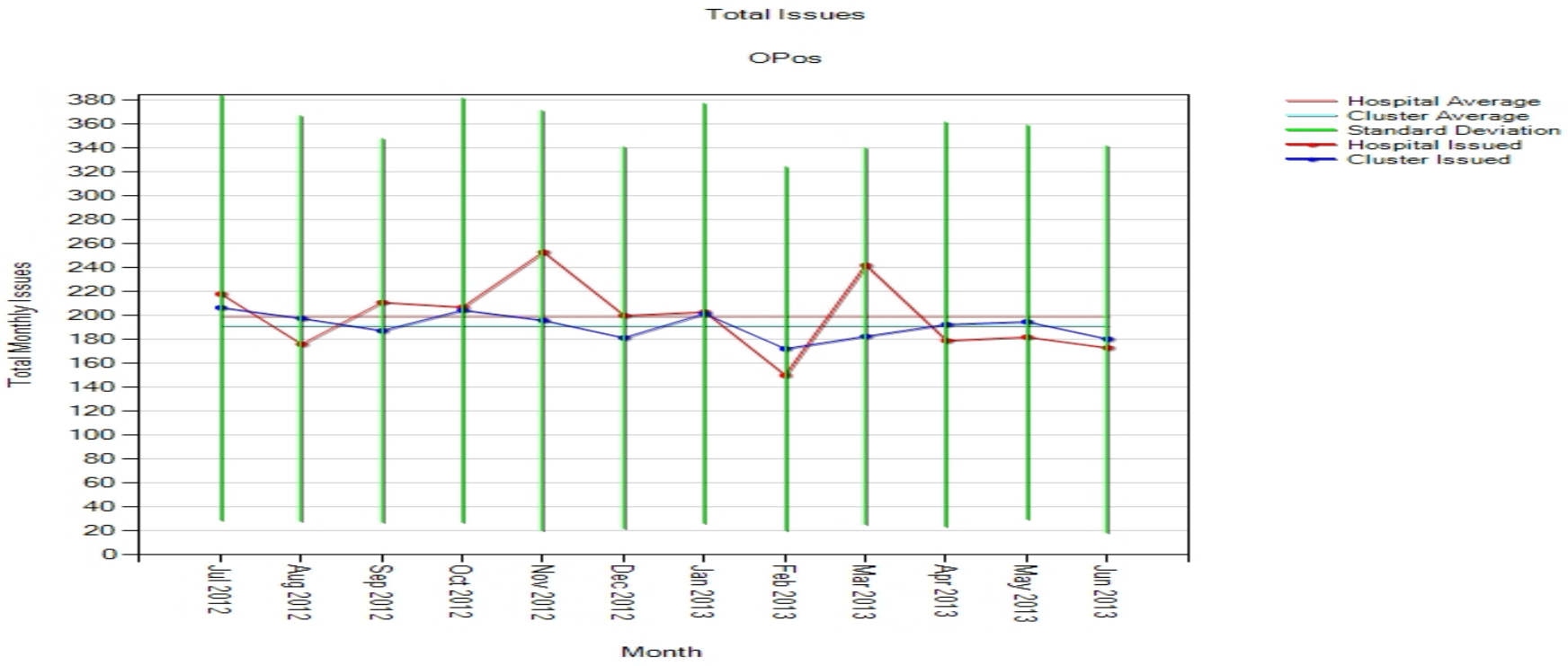
Hospital Average – 41.33

Cluster Average – 58.31

The Princess Alexandra Hospital
NHS Trust

O Positive usage

Pre roll out of 2 group check July 12 – June 13

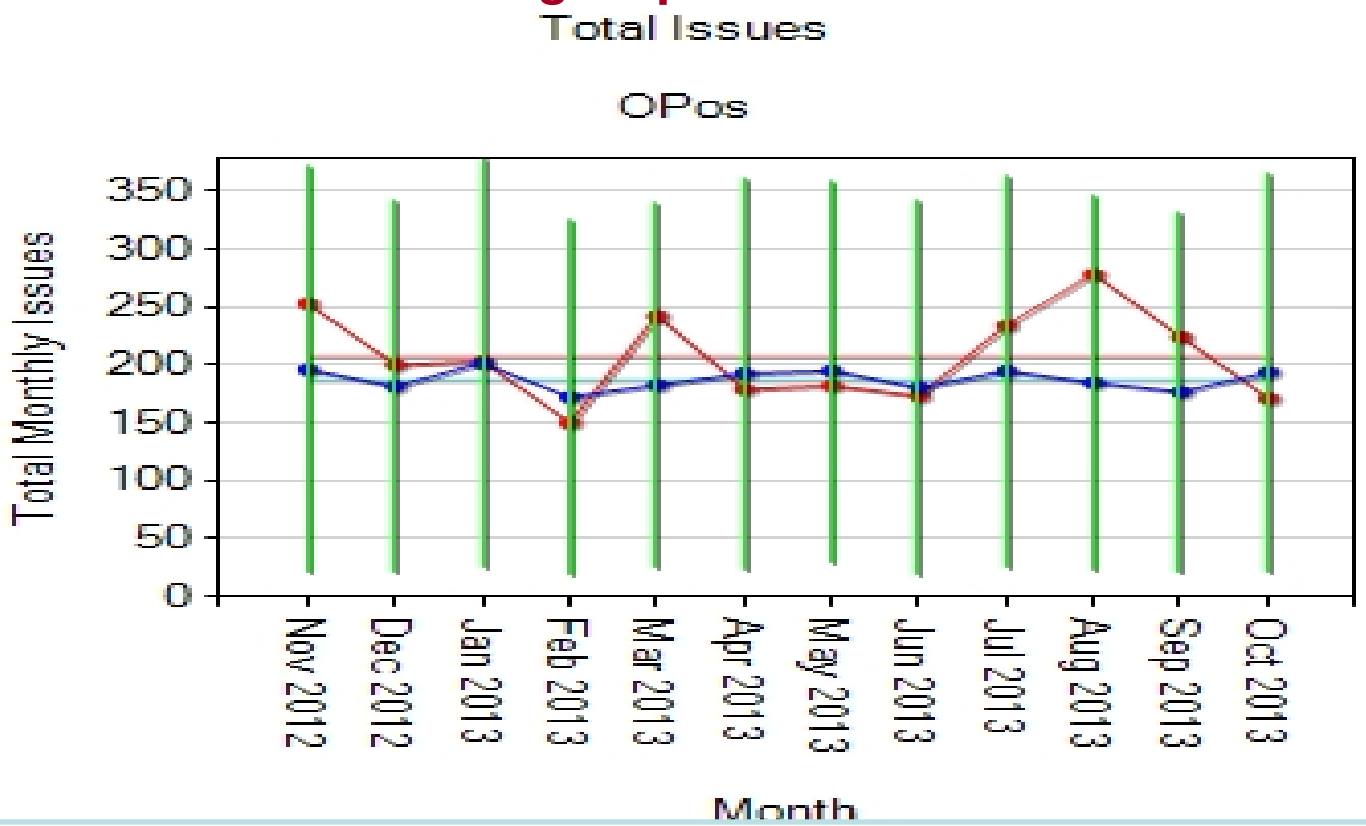


Hospital Average – 199.5 **Cluster Average – 191.39**

The Princess Alexandra Hospital
NHS Trust

O Positive usage

Post roll out of 2 group check NOV 12 – Oct 13



Hospital Average – 207.42 **Cluster Average – 187.51**

The Princess Alexandra Hospital
NHS Trust

WHY? the increase

Transfusion Practitioner away on honeymoon for the month of August

Higher number of Massive Blood Loss Events in the month of August

The Princess Alexandra Hospital
NHS Trust

Things to consider

Prior to rolling out

- ☺Perform audit / NCA results – provide evidence for the need to change
- ☺Have a clear plan of what you would like to implement
- ☺ Devise process with easy step by step stages for staff to follow
- ☺ Risk Assess why the need for 2 group check
- ☺ Update Policies / SOP / Concessionary Release / Contingency plan / Change control and validation standards are met

Roll out

- ☺ In phases if possible so as not to panic staff
- ☺ Engage key stakeholders and service users
- ☺ Communicate as far and wide as possible audit results and your process
- ☺ Develop training for Lab & Clinical staff
- ☺ Ensure lab staff document when they issue group check sample
- ☺ Reinforce process to lab staff / clinical staff – new Drs / lab staff rotating
- ☺ Number the samples before issuing them to clinical area
- ☺ Audit the new process and make amendments according to your findings

The Princess Alexandra Hospital
NHS Trust

Phase 3

PAH supply blood components to
4 off site hospitals

The Princess Alexandra Hospital
NHS Trust

The next dilemma

4 off site Hospitals

- ☺ Referrals from other hospitals – out of district
- ☺ GP referrals for top up transfusion
- ☺ Some Haematology patients who are unable to travel to PAH

Key issues

- ☺CCG / PCT engagement – GPs, District Nurses, off site Hospitals etc
- ☺Area of involvement
- ☺Patient engagement

Where are we at ?

- ☺ Risk Assessment completed for supplying blood with 1 sample

The Princess Alexandra Hospital
NHS Trust

HELP!

The Princess Alexandra Hospital
NHS Trust

YES

WE

DID

IT

TOO