Pre-transfusion Testing

UK National External Quality Assessment Scheme for Blood Transfusion Laboratory Practice

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SIMTI Rimini September 2008
Summary

• Role of EQA
• Sources of error and changing practice in pre-transfusion testing
  – Evidence from EQA and haemovigilance
• Reducing errors
  – UK Blood Transfusion Collaborative
What is EQA?

External assessment of results from a group of laboratories, where each laboratory tests identical specimens of ‘known’ but undisclosed content.
Purpose of UK NEQAS

- Monitor performance (in the UK)
- Identify trends in practice
- Provide advice and guidance
- Education through exercises, reports and meetings
- Promote high standards of practice
- Inform national guidelines
- Work with other relevant bodies
- Provides peer data for other countries
Who are the other players?

- NHS
- The Chief Medical Officer’s National Blood Transfusion Committee
- SHOT
- MHRA
- National Patient Safety Agency
- CPA
- BCSH Guidelines
- BBTS
- CPA
Setting the scene

Haemovigilance
Cumulative data 1996 – 2007 (4335 cases)

Total counts:
- IBCT: 2716 (62.7%)
- Anti-D: 396 (9.1%)
- ATR: 534 (12.3%)
- HTR: 342 (7.9%)
- TRALI: 219 (5.1%)
- TA-GVHD: 13 (0.3%)
- PTP: 48 (1.1%)
- TTI: 60 (1.4%)
- Unclassified: 7 (0.2%)
## SHOT and Laboratory Errors

<table>
<thead>
<tr>
<th>Report Year</th>
<th>No of Analysed IBCT Cases</th>
<th>Laboratory as Site of Primary Error</th>
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<tr>
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<td>No</td>
<td>%</td>
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<td>2005</td>
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<td>2006</td>
<td>400</td>
<td>155</td>
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Slide courtesy of Debbie Asher
<table>
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<tr>
<th>Year</th>
<th>Total Errors</th>
<th>Wrong Sample</th>
<th>Transcription</th>
<th>Interpretation</th>
<th>Component Selection</th>
<th>Labelling</th>
<th>Procedural</th>
<th>Testing</th>
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<td>11</td>
<td>55</td>
<td>5</td>
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<tr>
<td>Year</td>
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<td>Wrong Sample Tested</td>
<td>Interpretation Errors</td>
<td>Other</td>
<td>ABO Incompatible Transfusion</td>
<td>Sequalae</td>
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<td>22</td>
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<tr>
<td>2006</td>
<td>6</td>
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<td>1</td>
<td>0</td>
<td>No morbidity</td>
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Manual systems
RhD Typing Errors

2 manual tube tests, incorrectly performed
4 misread or transcription error (manual)
4 errors in manual recording from automated/semi-automated analysers
2 failure to follow protocol following initial weak reactions with anti-D
5 errors analyser/equipment problems
Other Pre-Transfusion Errors

• Testing/Interpretation (n=6):
  – Weak antibodies missed
  – Incorrect phenotype

• Failure to follow SOP (n=22):
  – Inappropriate use of electronic issue
Why so many laboratory errors?

Insight from UK NEQAS
Antibody screening

ABO/D typing

Emergency testing

Crossmatching

Antibody identification

Red cell phenotyping

Practice (through questionnaires)
Changing technology
Routine ABO grouping techniques
Antibody screening IAT technologies
Crossmatching techniques / procedures
Changing technology

• Tubes to CAT
  – Improved standardisation
  – Reduced steps (no washing)
  – Allowed automation

• So, a good thing?
• On the whole yes
• But it brings new risks
New risks

• Six columns so restricted number of reagents for grouping AND expensive
  – Abbreviated testing
  – Not necessarily clear what the reagents are
    • Clones
    • Potentiators
  – Not necessarily having a full understanding of the system
    • Intended use
  – Huge choice of cards/cassettes
EQA errors 2006

• Demonstrate errors in all aspects
Number of errors by category in UK - 2006

64 Ab ID errors
Summary of Causes

- STAFF RESOURCES
- KNOWLEDGE
- TRAINING
- POLICIES AND PROCEDURES
Summary of Causes

• STAFF RESOURCES
  – “Insufficient staff”;
  – “Reliance on agency staff”
  – “Poor skill mix”

• TRAINING
  – “Policy in place, but BMS did not follow it”
  – “More in-house training and competency assessment required”
Summary of Causes

• KNOWLEDGE
  – Interpretation
  – Understanding of reagents and test systems

• UNSAFE POLICIES AND PROCEDURES
  – Manual back-up procedures thought through?
  – Outwith guidelines

  Human Error
Two Examples

RhD grouping of a cde/cde (rr) DAT positive sample

Recognition of a mixed field reaction
Example 1

RhD grouping of a cde/cde (rr)  
DAT positive sample
DAT+ cde/cde (rr) sample – 07R8

• A D negative rr cells coated with anti-c (2-3+ DAT)

• 16 UK participants (3.5%) recorded D positive or D variant (weak or partial D)
DAT+ rr sample – 07R8

• All used BioVue anti-D reagent potentiated with sufficient PEG to give a false positive result

• All recorded a positive reaction with the control reagent at least retrospectively
456 participants

- 16 D grouping errors
  - 10 D positive
    - 6 D variant

7 assigned a result
  - D positive/var
  - No further testing

9 performed confirmatory tests

1 negative result but transcribed as ‘positive’

4 false D positive results

4+1 saline IgM anti-D by tube

5 ABD/ABD cassettes
  - D Pos/var

In many cases the reaction with the control reagents was weaker than that obtained with the anti-D reagent
Incorrect interpretation - causes

• Latent conditions
  – Potentiated reagents giving false positive reactions
  – Reagent control giving weaker or negative reactions
Incorrect interpretation - causes

• Knowledge
  – Significance of pos control
  – Interpretation of D pos based on a wk or MF reaction
  – Understanding of test system

• Training
  – Policy for confirmatory policy not followed

• Policies and procedures
  – Using same/similar reagent for confirmatory testing
  – Editing cell group on automation

• Human error
  – Over-reading of confirmatory tests
Example 2

Recognition of a mixed field reaction
Recognition of mixed field reaction

- 06R9
- 50:50 A/O red cells to mimic group A being transfused group O
- No clinical details given
- Expected result ‘UI’ (unable to interpret)
Reaction grades by country

Figure 1 - Reaction grade recorded
MF by technology (UK)

Figure 3 - UK data by technology

- CAT: 130 (121 Not recording MF, 20 Recording MF)
- Tube: 68
- LPM: 25 (6 Recording MF)

Legend:
- Yellow: Not recording MF
- Brown: Recording MF
MF by automated or manual methods (UK)

Figure 4 - UK data by manual vs automated methods
MF by automated or manual methods (Denmark)

Figure 5 - Recording of MF in Denmark vs technology

- CAT Auto: 16 (4 not recording, 12 recording)
- Cat Manual: 13 (10 not recording, 3 recording)
- LPM Auto: 3 (3 recording)
- Tube: 3 (3 recording)
MF by automated or manual methods (Italy)

Figure 6 – Recording of MF in Italy vs technology

- 5\% not recording MF
- 6\% recording MF
- 100\% recording MF
Interpretation of MF

Figure 2 - Interpretation of MF reaction

UK  | Denmark  | Portugal  | Italy
---|----------|-----------|------
0% | 40%      | 40%       | 20%  
100% | 60%      | 60%       | 80%  
80% | 80%      | 80%       | 100% 
60% | 60%      | 60%       |       
40% | 40%      | 40%       |       
20% | 20%      | 20%       |       
0%  | 0%       | 0%        |       

Group A | UI
---|---
UK      | Denmark  | Portugal  | Italy
0% | 40%      | 40%       | 20%  
100% | 60%      | 60%       | 80%  
80% | 80%      | 80%       |       
60% | 60%      | 60%       |       
40% | 40%      | 40%       |       
20% | 20%      | 20%       |       
0%  | 0%       | 0%        |       

UK NEQAS
Different patterns of recognition

- Better recognition rate in:
  - CAT vs other methods
  - Automation vs manual methods

But - not true in Denmark!

Training and education
UK Transfusion Laboratory Collaborative

- SHOT (Serious Hazards of Transfusion)
- IBMS (Institute of Biomedical Sciences)
- RCPath (Royal College of Pathologists)
- BBTS (British Blood Transfusion Society)
- NBTC (National Blood Transfusion Committee)
Aims of collaborative

• To reduce blood transfusion laboratory errors by 50% by December 2011
Baseline data

- Written questionnaire
- Telephone questionnaire
- Staffing levels
- Qualifications and training
- Workload
- Level of automation
Recommendations

• Drafted and submitted to Collaborators
• To be published by professionals
• Monitoring through CPA and MHRA
Recommendations

• Staffing
  - Levels/skill mix to be set and reviewed annually
  - Lead BMSs excluded from on-call rota

• Technology
  - Full 24/7 automation + electronic issue

• Training & competence
  – Specifies minimum BT qualifications for:
    • Senior staff; lone workers - on-call staff
  – On-going competency assessment
UK NEQAS Error Rates (UK)

Improvement in performance
What do we need

- National guidelines
- Quality management systems
- Haemovigilance
- EQA
- Commitment to reduce laboratory errors
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