The Leeds Teaching Hospitals NHS
NHS Trust
Leeds and Bradford Pathology CMT
Department of Blood Transfusion

VALIDATION OF ELECTRONIC ISSUE ON THE LTH BLOOD BANK TELEPATH SYSTEM

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Contents

1 Introduction

1.1 Validation must be performed on all automated systems that are considered critical. In transfusion an automated system is considered critical:

> If its use is directly linked to the decision made for blood or blood product manufacturing, testing (donor/patient), labelling and release for transfusion.

And/or

> If it is used to manipulate the related information.

1.2 A validation plan is a well planned set of test cases that:-

Evaluate the performance of a system with regard to its effectiveness based on the intended purpose.

Establish documented evidence providing a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.

2 Electronic Issue

2.1 The department of Blood Transfusion at Leeds Teaching Hospitals intends to move to a system of electronic issue of red cells in Early 2005.

2.2 The use of electronic issue procedures without serological testing requires that a number of criteria must be satisfied before electronic selection and issue is permitted. These criteria are base on the current BCSH/BBTS guidelines for blood bank computing[1]. The criteria form the basis of the validation test cases, and are laid out in the system requirements (section 3).

3 System Requirements

3.1 The Blood bank system for a patient to be suitable for electronic issue must meet the following criteria:-

3.1.1 The ABO and RhD group of the patient must be determined twice. This will be either:-

a. Two identical groups on the same sample
b. Or One group on this sample matching a previous historic group

3.1.2 Blood groups on the current sample and any historic blood group must be identical

3.1.3 The blood grouping and antibody screening on the latest sample must have been done using full automation.

3.1.4 No editing of the ABO front group or RhD group must have occurred on the automated grouping system.

3.1.5 The patient's serum / plasma must not contain or have ever been known to contain a clinically significant allo antibody reactive at 37^{o}C. Excluding anti-D immunoglobulin administered to the patient which is now no longer detectable.

3.1.6 The following antibodies are not considered clinically significant

a. anti-Le^{a}
b. anti-Le^{b}
c. anti-HI
d. anti-H
e. anti-I
f. anti-P_1
g. HTLA antibodies (e.g. anti-Ch, anti-Rg, anti-Yk^{a} etc) which are no longer detectable

3.1.7 The latest sample must have a negative antibody screen. The antibody screening cells used must conform to minimum recommendations contained in the current BCSH/BBTS compatibility guidelines[2].

3.1.8 A facility to flag individual patients as unsuitable for electronic issue must be available. The patient's excluded will be:-

a. Sickle cell disease patients. *These patients are often very good antibody responder, and can often form unusual antibodies.* Excluded for life.
b. Post allo bone marrow/stem cell transplant patients who have received an ABO incompatible transplant. Excluded for 1 year
c. Post solid organ transplant patients who have received an ABO incompatible transplant. Excluded for 1 year
d. Patients with a positive direct antiglobulin test. Exclude until DAT is negative

3.1.9 The computer system must not allow the selection of ABO incompatible red cells.

3.1.10 The system should demand authorisation of suitable but non identical ABO group red cells

3.1.11 The system should demand authorisation of RhD incompatibility.

4 Risk Assessment and Management

4.1 Using electronic issue in place of serological crossmatching is associated with a number of risks mainly linked to the accurate determination of the ABO and RhD group of the patient and the subsequent reservation, authorisation and issue of red cells.

4.2 Risk 1 – Incorrect determination of ABO & Rh D group

4.2.1 The risk of incorrectly determination of ABO group can be categorized as **high** this is because if it occurs the consequences are intolerable.

4.2.2 Serological crossmatching is normally the last chance of determining and ABO grouping error as incompatibility would lead to non-authorisation of the crossmatch and non-issue of units of blood

4.2.3 **Possible causes**

4.2.3.1 Incorrect interpretation of blood group
4.2.3.2 Incorrect editing of blood group
4.2.3.3 Wrong lab number barcode on sample resulting in results going to wrong patient's sample
4.2.3.4 Phlebotomy errors

4.2.4 Risk reduction /removal

4.2.4.1 Tests must be automated and the automated system fully validated

The system currently being used for automated grouping and antibody screening (Ortho AutoVue) has been serologically validated using BB LTH Validation AutoVue Serology 2004

4.2.4.2 The sample number barcode must refer to the sample on which it is labelled. This must be checked at the sample labelling and upon completion of the tests. This will avoid results being uploaded to the wrong patient

This is covered by the following standard operating procedures
BBSOP Sample reception, handling, storage and disposal
BBSOP Automation – checking off samples after completion of automated testing

4.2.4.3 It is vital that information transferred between the AutoVue and the LIS is done so reliably and accurately.

This has been previously validated using BB LTH Validation AutoVue LIS link 2004 (1)

4.2.4.4 The system must not allow electronic issue where the current blood group disagrees with a previous blood group (potential phlebotomy error).

All discrepant blood group matches are currently held in the REVUQ program on TelePath. This has been previously validated using BB LTH Validation AutoVue LIS link 2004 (1)

4.2.4.5 Any editing of an automated blood group result must invalidate that sample from electronic issue.

Although there is no system in the computer software to prevent this from occurring, the standard operating procedures used will require a user entered flag to be used to stop EI.

4.3 Risk 2 - Patients with clinically significant allo antibodies

4.3.1 The risks associated with an incompatible transfusion occurring in a patient with previously detectable clinically significant antibodies varies depending on antibody specificity and potency and on the individual patient's own immune system.

4.3.2 In cases where a reaction occurs symptoms can vary from mild reaction through to major morbidity and in some rare cases fatality. For this reason this risk is categorized as **high**

4.3.3 Risk reduction /removal

4.3.4 All positive antibody screens will be excluded from electronic issue

4.3.5 All antibodies will be flagged as unsuitable for electronic issue except for those know to be clinically benign (anti-Le^a, anti-Le^b, anti-HI, anti-H, anti-I, anti-P_1 and HTLA antibodies)

4.4 Risk 3 – At risk patient groups

4.4.1 The following are defined as at risk patient groups

4.4.1.1 Pregnant patients. These patients are always at risk of producing antibodies through iso immunization.

4.4.1.2 Sickle cell disease patients. These patients are often very good antibody responder, and can often form unusual antibodies. **Risk low** as patients with a positive antibody screen will automatically be excluded.

4.4.1.3 Post allo bone marrow/stem cell transplant patients who have received an ABO incompatible transplant. Here the risk comes from the fact that as a consequence of the transplant the patient will be undergoing a blood group change. Blood needs to be both compatible with both patient and donor(BM) groups. **Risk high** as there is a potential for serious reaction

4.4.1.4 Post solid organ transplant patients who have received an ABO incompatible transplant. Here the risk is associated with passenger lymphocytes contained in the transplanted organ. The passenger lymphocytes can produce potent ABO antibodies which can only be detected by crossmatch. **Risk high** as there is a potential for serious reaction

4.4.1.5 Patients with auto-immune haemolytic anaemia. These patients may have strong auto antibodies which may react with transfused red cells. These patients are characterized as having a positive direct antiglobulin test. **Risk low** as patients with a positive antibody screen will automatically be excluded and those who do not have a positive antibody screen are unlikely to have any transfusion problems

4.4.1.6 Patients who have received a transfusion within the last 3 months. These patients are at risk of being in the process of forming allo antibodies

4.4.2 Risk reduction /removal

4.4.2.1 Pregnant patients will not be excluded from electronic issue but samples will only be valid for seven days as per compatibility guidelines[2].

4.4.2.2 Recently transfused patients will not be excluded from electronic issue but patients will only be valid for electronic issue while the laboratory has a valid sample as per compatibility guidelines[2]

The TelePath system allows for an algorithm to determine recent transfusions

4.4.2.3 RhD negative patients who have been transfused RhD positive blood are at particular risk of allo immunization to form anti-D. Procedures will be written to ensure special treatment of these patients

4.4.2.4 All the other patient groups will be excluded manually using a flag system on the TelePath computer.

4.5 Risk 4 – Stock Entry

4.5.1 The entry of red cell stock with the correct details (i.e. correct blood group with correct donation number) is essential for EI.

4.5.2 Incorrect blood group entry could result in potentially incompatible units being reserved for a patient; and with no serological crossmatch being performed the incompatibility would go undetected.

4.5.3 Risk reduction / removal

4.5.3.1 Using concatenated barcode reading would prevent incorrect entry of blood group (i.e. Donation number and group are read together using a scanner or light pen). This however is not currently available on TelePath

4.5.3.2 Stock entry SOP will indicate that blood group must only be entered using the barcode on that bag. This must apply to **all** products as TelePath automatically enters the group if it has previously received a product with that donation number.

4.5.3.3 Any bag where the group barcode cannot be read must be returned to the NBS Leeds as a defective product

5 Validation Tests Cases

5.1 Stock Reservation (ABO and RhD compatibility)

5.1.1 These test cases ensure that it is not possible to reserve ABO incompatible red cells for all ABO blood groups and that there is a warning of ABO and RhD mismatched but suitable red cells at reservation.

5.1.2 See appendix A for reservation test cases

5.2 Patient's with antibodies

5.2.1 These test cases ensure that all patients with clinically significant antibodies are flagged as not suitable for electronic issue.

5.2.2 The test goes through each antibody currently in the Telepath system to ascertain whether EI is allowed

5.2.3 The cases include antibodies flagged as suitable for EI.

5.2.4 The cases include combinations of flagged and none flagged antibodies.

5.2.5 See appendix B for antibody test cases

5.3 Recently Transfused patients

5.3.1 Current guidelines (BCSH).

Patient transfused	Age of sample used for crossmatch
3 to 14 days previously	Less than 24 hours old
15 to 28 days previously	Less than 72 hours old
29days to 3 months previously	Less than 7 days old

Situations where a patient is being repeatedly transfused a daily sample is not required. These patients should be screened for antibodies at least every 72 hours

Pregnant patients should have samples no more that 7 days old when used for crossmatching

Current situation

SJH and LGI operate a 72 hour rule for all recently transfused patients whereas BRI operate a 48 hour rule

Possible ways forward

1. Stick rigidly to guidelines.

2. Adopt a more lenient approach
E.g. Transfused 1-28 days samples less than 72 (or 48 hours) old
Transfused 29 days to 3 months samples less than 7 days old

3. Follow our current system and use either 72 or 48 hour rule

5.3.2 Test cases will be designed to cover all the rule bases for recent transfusions.

5.3.3 Patients currently active on the Blood Bank system will be selected to provide the test cases

5.3.4 Decision of Transfusion Co-ordinators (meeting 31st January 2005)

- Patient transfused last 1 to 28 days ago – sample less than 3 days (72 hours) old at time of transfusion
- Patient transfused last 29 to 90 days ago – sample less than 7 days (168 hours) old at time of transfusion

- BRI to be allowed to continue its 48 hour policy for all recently transfused patients

5.4 Sample no longer available

5.5 The flag for maximum age of sample will be set at 90 days. Any patient's where the last sample is greater than 90 days old will be unsuitable for EI

5.6 Patients with a positive antibody screen

5.6.1 A test case will be created with a positive antibody screen

5.7 Patients with a positive DAT

5.7.1 This will fit into the manually flagging of patients

5.8 Manually flagged not eligible for EI

5.8.1 A test case will be created which covers this

6 Continuing Maintenance of Validation of EI

6.1 Any changes or updates to the telepath system will mean that the EI system will need re validating

6.2 Any changes to the EI policy will mean that those parts of the system affected will need re validating

6.3 Any incidents resulting from the EI system will be fully investigated under the current transfusion incident investigating system.

7 References

7.1 Requirements for the Electronic Crossmatch. *Vox sanguinis* 1998; 74 (suppl. 2): 409-417

7.2 Guidelines for blood bank computing. *Transfusion Medicine*, 2000, 10, 307-314

7.3 Guidelines for compatibility procedures in blood transfusion laboratories. *Transfusion Medicine*, 2004, 14, 59-73

7.4 Electronic Issue. *UK NEQAS* 30.10.02

7.5 ISBT – guidelines for Validation and Maintaining the Validation State of Automated Systems in Blood Banking. *Vox sanguinis* 2003; 85 (suppl. 1): S1-S14

7.6 BB LTH Validation AutoVue LIS link 2004 (1)

7.7 BB LTH Validation AutoVue Serology 2004

Appendix A – Reservation Test cases (ABO and D)

Expected results should be recorded as:-
R = Reservation allowed (no warnings)
WF = Warning flag given – reservation allowed
Ex = Reservation Excluded / Impossible

Patients group	Group of blood reserved	Expected result
O Neg	O Neg	R
O Neg	O Pos	WF
O Neg	A Neg	Ex
O Neg	A Pos	Ex
O Neg	B Neg	Ex
O Neg	B Pos	Ex
O Neg	AB Neg	Ex
O Neg	AB Pos	Ex
O Pos	O Neg	WF
O Pos	O Pos	R
O Pos	A Neg	Ex
O Pos	A Pos	Ex
O Pos	B Neg	Ex
O Pos	B Pos	Ex
O Pos	AB Neg	Ex
O Pos	AB Pos	Ex
A Neg	O Neg	WF
A Neg	O Pos	WF
A Neg	A Neg	R
A Neg	A Pos	WF
A Neg	B Neg	Ex
A Neg	B Pos	Ex
A Neg	AB Neg	Ex
A Neg	AB Pos	Ex
A Pos	O Neg	WF
A Pos	O Pos	WF
A Pos	A Neg	WF
A Pos	A Pos	R
A Pos	B Neg	Ex
A Pos	B Pos	Ex
A Pos	AB Neg	Ex
A Pos	AB Pos	Ex

Patients group	Group of blood reserved	Expected result
B Neg	O Neg	WF
B Neg	O Pos	WF
B Neg	A Neg	Ex
B Neg	A Pos	Ex
B Neg	B Neg	R
B Neg	B Pos	WF
B Neg	AB Neg	Ex
B Neg	AB Pos	Ex
B Pos	O Neg	WF
B Pos	O Pos	WF
B Pos	A Neg	Ex
B Pos	A Pos	Ex
B Pos	B Neg	WF
B Pos	B Pos	R
B Pos	AB Neg	Ex
B Pos	AB Pos	Ex
AB Neg	O Neg	WF
AB Neg	O Pos	WF
AB Neg	A Neg	WF
AB Neg	A Pos	WF
AB Neg	B Neg	WF
AB Neg	B Pos	WF
AB Neg	AB Neg	R
AB Neg	AB Pos	WF
AB Pos	O Neg	WF
AB Pos	O Pos	WF
AB Pos	A Neg	WF
AB Pos	A Pos	WF
AB Pos	B Neg	WF
AB Pos	B Pos	WF
AB Pos	AB Neg	WF
AB Pos	AB Pos	R

Appendix B

Leeds Teaching Hospital Blood Transfusion Department Validation of Electronic Issue					
Stock reservation Test cases: antibody status					
		Was EI allowed			
Antibody	EI allowable (Policy)	at reservation (yes or no)	Tested by	Signature	Date
A1	No				
Bga	Yes				
Bgb	Yes				
C	No				
C+D	No				
C+D+E	No				
Cha	Yes				
Cw	No				
D	No				
D+E	No				
E	No				
Fya	No				
Fyb	No				
Gya	No				
H	Yes				
HI	Yes				
HLA	Yes				
HTLA	Yes				
I	Yes				
JMH	Yes				
Jka	No				
Jkb	No				
Jsa	No				
Jsb	No				
K	No				
Kna	Yes				
Kpa	No				
Kpb	No				
Lea	Yes				
Leb	Yes				
Lua	No				
Lub	No				
M	No				
N	No				
P	No				
P1	Yes				
PP1Pk	No				
Rga	Yes				
S	No				
U	No				
wra	No				
Yta	No				
Ytb	No				
c	No				
cE	No				
ce	No				
e	No				
f	No				
i	No				
k	No				
s	No				
combinations					
K+Fya	No				
K+Lea	No				
Lea+Fya	No				
Lea+Leb	Yes				

Appendix C

Leeds Teaching Hospital Blood Transfusion Department Validation of Electronic Issue						
Stock reservation Test cases: Recently transfused patients						
		EI allowable	**Was EI allowed**			
Days since transfusion	**Age of sample (Days)**	**Policy**	**at reservation (yes or no)**	**Tested by**	**Signature**	**Date**
1 to 28	0 to 3	Yes				
1 to 28	4 to 7	No				
1 to 28	8 to 90	No				
29 to 90	0 to 3	Yes				
29 to 90	4 to 7	Yes				
29 to 90	8 to 90	No				

Appendix D

Leeds Teaching Hospital Blood Transfusion Department Validation of Electronic Issue					
Stock reservation Test cases: Sample age					
	EI allowable	Was EI allowed			
Age of sample (days)	Policy	at reservation (yes or no)	Tested by	Signature	Date
0 to 7 days	Yes				
7 to 14 days	Yes				
14 to 28 days	Yes				
28 to 90 days	Yes				

Appendix E

Leeds Teaching Hospital Blood Transfusion Department Validation of Electronic Issue						
Stock reservation Test cases: Other cases						
	EI allowable	Was EI allowed				
Test case	Policy	at reservation (yes or no)	Tested by	Signature	Date	
Positive antibody screen	No					
Positive DAT	No					
Manually flagged not suitable	No					