THE BENEFITS OF ALERTS FLAGS AND WARNINGS

LESSONS FROM SHOT

DR. MEGAN ROWLEY
CONSULTANT IN TRANSFUSION MEDICINE
SNBTS, EDINBURGH

13th September 2017

BBTS SIG Day, Glasgow

UK Transfusion Laboratory Collaborative: minimum standards for staff qualifications, training, competency and the use of information technology in hospital transfusion laboratories 2014

B. Chaffe,[1] H. Glencross,[2] J. Jones,[3] J. Staves,[4] A. Capps-Jenner,[5] H. Mistry,[6] P. Bolton-Maggs,[6] M. McQuade[7] & D. Asher[8]

Transfusion Medicine 24, 335-340

INFORMATION TECHNOLOGY

It is expected that:

1. All laboratories will have complete walk-away automation which is in use 24/7, with bidirectional interfaces to the LIMS. In the absence of complete automation, documented measures must be taken in order to mitigate procedural laboratory errors
2. Electronic issue of red cells will be introduced when the laboratory infrastructure is robust and supports this procedure
3. Where remote issue of components is being considered as part of service delivery, consideration will also be given to installing complete blood tracking (vein to vein) as an integral feature of this development

Original UKTLC minimum standards
Transfusion Medicine. 2009 Aug;19(4):156-8.

IT in UK Transfusion Practice

NEQAS data for UK BT laboratories (2016)

- All have a Laboratory Information Management System (LIMS)
- 60% are able to issue blood electronically

Data from English Patient Blood Management surveys

- 47% have electronic fridge tracking/release (2011)
  - Further 28% planning to implement
- 16% have bedside administration controlled by IT (2011)
- 73% of Trusts use 4 LIMS providers (2015)
  - WinPath, Telepath, Apex, Labcentre

So what are we worried about?

- Not all hospitals have implemented these systems
- Where systems are implemented they are not being used to full functionality
- Not all systems are interoperable
- Not all systems keep up with developments in BT practice
- Insufficient training means systems are used incorrectly

Lessons from SHOT

- Alerts, Flags and Warnings
- Electronic Issue
- Electronic Blood Management Systems
- Functionality of the LIMS

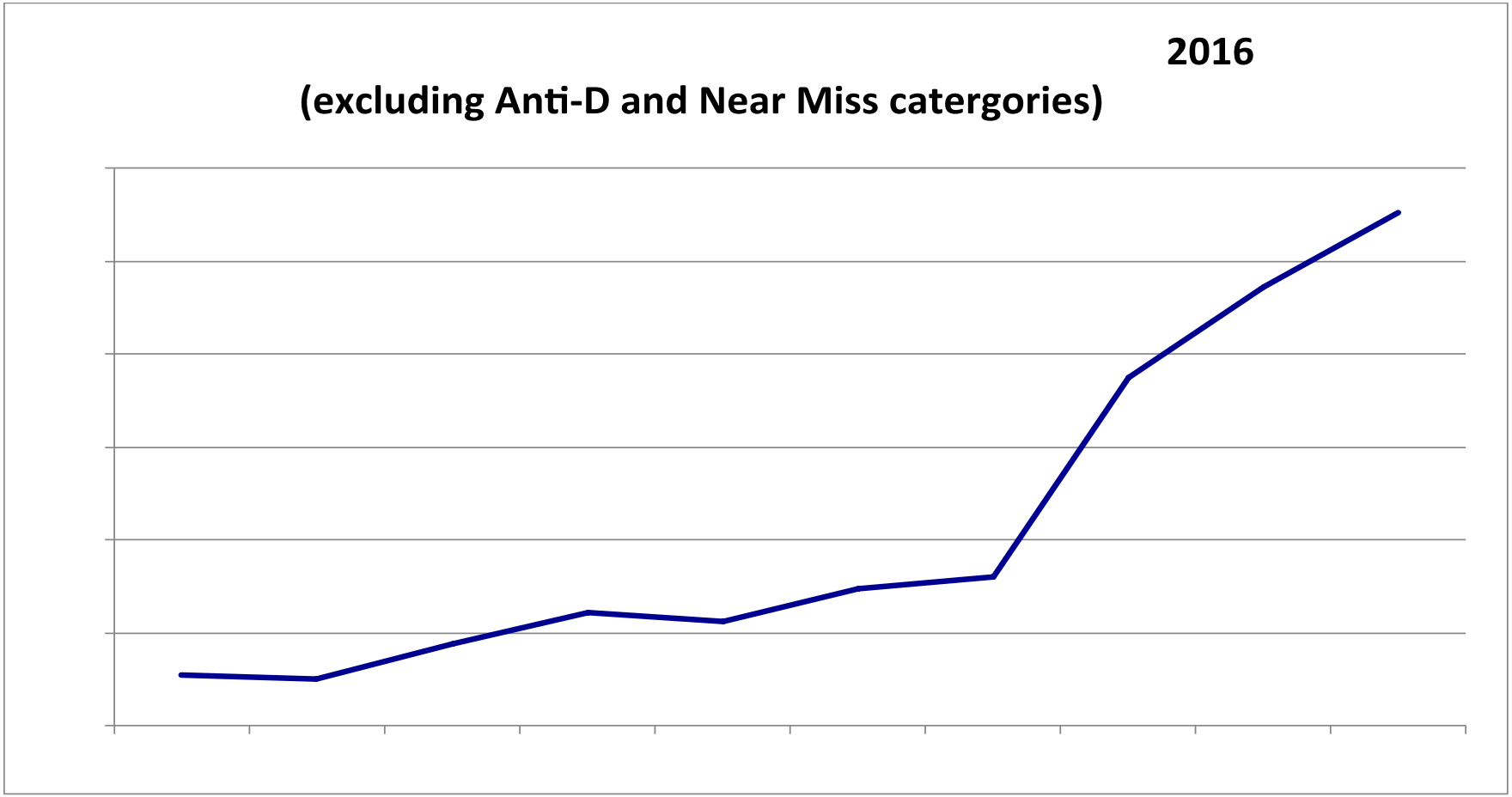
2000

•SHOT IT RECOMMENDATIONS

- SHOT called for the increased allocation of resources to develop electronic "positive identification" systems to control the clinical transfusion process.
- Computer-based systems, employing technology for positive identification, will soon control the clinical transfusion process "from vein to vein"
- It seems essential that as multiple electronic ID systems are introduced to the clinical workplace, they share common standards, hardware and computer-links wherever possible.
- All of those developing systems should communicate effectively and work in collaboration for the benefit of patients and staff alike

Dr Derek Norfolk

SHOT reports included in IT Chapter



Information Technology Errors

Errors caused or contributed to by IT systems

Errors caused by using IT systems incorrectly

Errors where implementation of an IT solution would have/could have prevented the error

Corrective and preventative action in response to an error included an IT solution

SHOT IT Chapter included from 2006 onwards

Alerts, Flags and Warnings

Some are ‘hard wired’ into the LIMS or EBMS

- Preventing ABO incompatible red cell transfusion
- Preventing electronic issue of ineligible patients
- Logic rules based on age, gender for meet specific requirements

Some are ‘set’ on receipt of clinical information

- Specific requirements based on patient/disease characteristics
- Role or competency based access to systems

Wrong Component Transfused and Specific Requirement Not Met

Year	% SRNM	% WCT
2016	58	11
2014	54	9
2013	63	4
2012	39	26
2011	38	41
2010	39	26
2009	30	56
2008	45	40
2007	52	36

A large proportion of IT errors are in the SRNM category

ERROR	SRNM	WCT	**TOTAL**
Warning flag in place but not heeded	11	9	**22**
Warning flag not updated or removed in error	19	1	**20**
Failure to use flags or logic rules	81	7	**91**
Inappropriate EI	17	2	**20**

Failure to use flags, alerts and warnings accounts for many of these failures in 2016

A combination of laboratory and clinical errors result in failure to provide irradiated red cells

- A 5 year old child with DiGeorge syndrome was admitted for cardiac surgery and irradiated red cells were requested by the clinical team and provided by the laboratory
- The surgery was cancelled and the units returned to stock
- When the surgery proceeded 2 days later, irradiated red cells were not requested as the nurse in theatre was unaware they were required
- The laboratory had failed to update the LIMS with this patient's requirement
- The patient was transfused non-irradiated units
- This case shows that communication between laboratory and clinical areas is vital

Inappropriate red cells issued by BMS unfamiliar with the LIMS (1)

- *A 62-year-old female with newly diagnosed acute myeloid leukaemia (AML) required two units of red cells, the request noted these should be CMV-negative. This request was not urgent*
- *The patient grouped as A D-negative; there was no historical record of the blood group on the LIMS*
- *A group-check sample was not obtained*
- *The BMS (working out-of-hours) selected and issued two units of group O D-positive red cells*

(continued)

Inappropriate red cells issued by BMS unfamiliar with the LIMS (2)

- *The error was detected 6 days later when a mixed field blood group pattern was displayed*
- *The BMS undertaking the selection had more than 15 years' experience overseas and was undergoing competency-assessment and had not been signed off to work autonomously*
- *The BMS stated that they must have ignored the warning message on the LIMS as they were used to coloured (red) warnings using their former LIMS*
- *The BMS was being indirectly supervised during component issue, by a BMS2 who was supervising two trainees at the same time, but failed to spot the D-positive selection error*

Two electronic systems fail to prevent D-positive blood being transfused

- *Blood was ordered for an exchange transfusion for a group B D-negative female with sickle cell disease using the OBOS*
- *Group B D-positive blood was ordered in error stating (in the comments box) that O D-negative blood could be substituted if necessary*
- *Six units of O D-positive were provided, crossmatched and transfused*
- *The LIMS did not prevent issue of D-mismatched blood and this error was not detected until the next transfusion was due when an unexplained mixed field was detected in the pre-transfusion sample*

Wrong Component Transfused Errors

Ten 'wrong blood' incidents in haemopoietic stem cell transplant patients and two in renal transplant patients

- Wrong blood errors in transplant centres may arise because of the complexity of information stored on the LIMS
- In some situations the LIMS did not appear to have the functionality to manage the changing requirements before, during and after a transplant
- The key elements requiring some IT control include the ability to
  - Flag the date of the HSCT or SOT
  - Store the recipient and donor blood groups as well as the current blood group
  - Support the issue of each blood component of the correct group and specification

SHOT 2014

Electronic Issue

The computer algorithm needs to have access to all the relevant information on which to base eligibility for EI.

To ensure that those ineligible for EI or remote issue can be determined accurately any change to the LIMS or patient administration system including upgrades, replacements, mergers or hospital number changes should include

- the historical information on blood groups, antibodies and specific requirements
- conditions such as sickle cell disease, haemopoietic stem cell transplant and solid organ transplants

SHOT RECOMMENDATION

Computer algorithm does not control eligibility for EI: still need to set manual flag

- *A patient post HSCT was identified as having received blood by EI on three separate occasions*
- *The laboratory policy is to crossmatch blood serologically for these patients*
- *The error was detected during an audit of specific requirements*
- *The flag relating to the HSCT had been correctly set to ensure the correct group and other specific requirements were met but the additional flag required to prevent EI had not been included*

Inappropriate use of EI excludes essential crossmatch

- *Two units of group A red cells were electronically issued for a group A solid organ transplant patient*
- *Prior to transfusion a full blood count (FBC) sample showed evidence of haemolysis on a blood film and was direct antiglobulin test (DAT)-positive*
- *A recall of blood components issued to the patient was initiated. One unit already being transfused was stopped*
- *Further group A red cell units were crossmatched by indirect antiglobulin test (IAT) and were found to be predominantly incompatible*
- *The Blood Centre reference laboratory testing found no alloantibodies but the patient's eluate demonstrated anti-A as a result of passenger lymphocytes from the group O lung transplant*
- *The SOP was not compliant with the BSH guidelines on pre-transfusion compatibility procedures in blood transfusion laboratories (BSH Milkins et al. 2013)*
- *This patient should have been excluded from EI. A serological IAT crossmatch would have demonstrated the incompatibility and then group O red cells selected as the alternative*

No information in LIMS to identify non-eligibility for EI

- *A shared care patient with HbSC disease was transfused prior to routine surgery.*
- *The current antibody screen was negative so blood was crossmatched by EI and the patient had a preoperative exchange transfusion.*
- *After the transfusion, the details on the patient's condition and history of red cell antibodies detected in the past by another hospital was discovered so the patient should have had a serological crossmatch with antigen-negative blood.*

SHOT CASE 2016

IT Recommendation 2016

Clinicians, laboratory scientists, information technology professionals and IT providers should work together to develop an industry standard for flags, alerts and warnings that prevent harm from wrong blood but still ensure timely and accurate availability of blood components for clinical use

Action: IT/software providers with UK Transfusion Laboratory Collaborative

SHOT RECOMMENDATION

Electronic Blood Management Systems

- Fridge tracking and bedside tracking
- Right blood – right patient
- Cold chain management
- Traceability

Patient identification error

- Using the BloodTrack electronic system a nurse checked the patient's ID band against the compatibility tag on the unit of red cells
- The system alerted the nurse to a wristband compatibility mismatch
- There was a difference in spelling of the surname
- This was the right blood for the right patient and the nurse proceeded with the transfusion ignoring the alert
- The transfusion was stopped because the blood transfusion laboratory staff noticed the alert on BloodTrack and contacted the ward to instruct them not to proceed

WBIT shows a secure electronic labelling system was being used incorrectly

- Two samples were sent for the same patient from the ED
- Sample bottles were electronically labelled and forms and bottles matched
- As the bottles had been electronically labelled, a group-check sample was not required and a single sample would have been deemed safe for transfusion purposes
- The laboratory was alerted by a telephone request for another patient in the ED, from whom no sample had been received
- When the two samples labelled for the same patient were tested, one sample grouped as B D-positive and the other as O D-negative
- The sample taker confirmed when taking the WBIT sample the patient wristband was scanned with the electronic labelling system handheld device without it being on the patient's wrist
- In addition, no verbal confirmation was done of the patient identity and all of the labelling was done away from the patient

Incorrect use of remote issue labelling

- *The transfusion laboratory received a completed traceability tag to confirm transfusion but in the LIMS it appeared that the unit had already been transfused to someone else on a different day*
- *On investigation it was discovered that the patient had been transfused with a different but correct unit of blood and the correct donation number had been entered onto the prescription chart*
- *This unit had been collected using remote issue from a satellite refrigerator where the remote issue label had been printed but not attached to the unit*
- *At the bedside, an old duplicate label for a different unit had been completed and returned to the laboratory*

Blood-tracking system fails to prevent storage of platelets in the refrigerator

- *The theatre porter collected platelets and FFP required for surgery from the transfusion department*
- *On arrival in theatre the FFP was scanned into the theatre refrigerator using the blood-tracking system*
- *The blood-tracking kiosk tried to prevent the platelets being put in the refrigerator by issuing a storage alert when the unit was scanned*
- *Ignoring this, the emergency button was pressed and the platelets were put in the refrigerator*
- *On attempting to scan the platelets to remove them from the refrigerator an alert stating that the unit was not in the location (because they had not been scanned in) was also ignored and the platelets were taken to theatre and transfused to the patient*

Functionality of the LIMS

Providing a new but unnecessary sample causes delay

- *A large number of units of blood were issued electronically to a remote satellite refrigerator for a patient at high risk of bleeding intraoperatively*
- *To be sure a current valid sample was available, a new sample was sent by the anaesthetist at the beginning of the list*
- *The first unit was collected without any problems but on collecting the second unit, access was blocked and no other units could be removed from the refrigerator*
- *This was because the unnecessary sample became the new 'valid sample' and remote electronic issue could not take place until a new result was available on the laboratory information management system (LIMS)*

Auto-validation by laboratory information management system (LIMS) assigns incorrect ABO group to the patient record

- *A blood sample on a patient previously unknown to the transfusion laboratory was tested on the Galileo Echo analyser and, having required no manual editing, the test result was suitable for autovalidation so was exported to the CliniSys WinPath v5 LIMS*
- *The result assigned to the patient record was B D-positive but the result produced and interpreted by the analyser was O D-positive*
- *No blood transfusion was required so the patient came to no harm*
- *This was extensively investigated by the LIMS provider and a notification issued to all users of the same software highlighting the potential, albeit very unlikely, whereby a patient's blood group could be transposed with the results of another patient, under a very specific set of circumstances and that there will shortly be a point upgrade to the software to resolve the issue and mitigate the risk*

Manufacturer's response

- The notification to customers using a specific version of the software stated
  - 'The approved methodology to auto-validate a batch of blood group results from BT Analyser is to click the auto-validate button and wait until the queue is fully processed and the checking has completed'
  - 'should a user scroll down the queue, minimise the screen, or cause the validate grid to refresh in any way while the auto-validate process is still running, a patient's blood group *may* be written against the wrong patient record.
  - 'that this has *only* been seen and recreated when a degradation in network connectivity and/or performance is experienced, hence the rarity of the occurrence'

The SHOT recommendation for software providers to work together with transfusion professionals to learn from errors and provide fit for purpose software is relevant to this case.

What next?

SHOT Key Messages for Transfusion IT for 2016

Knowledge and Training

IT systems can make transfusion safer by supporting and controlling clinical and laboratory tasks but they do not replace knowledge about the supported task and are only safe if timely and accurate training to undertake the role is provided. You can not rely on IT to replace knowledge – you need both

Leadership, supervision and personal responsibility

Although procurement and implementation of new IT systems, or system upgrades, require the leadership of subject matter experts it should be the responsibility of managers and supervisory staff to ensure appropriate role-based training and for individuals to ensure that they are trained and confident in their use of systems, including a clear understanding of the limitations of these systems

Fit for Purpose IT systems

The design and configuration of IT, and other electronic systems, has to meet current requirements and be flexible enough to take account of developments in blood safety and changes in practice, whether they be anticipated or unexpected.

Analysis of SHOT errors has shown weaknesses in some systems and this information should be taken into account for the benefit of all when upgrading existing or developing new systems.

There is a challenge for software and equipment providers to listen to and work with the UK transfusion community so that together we can maximize the promise of IT and electronic systems for patient benefit.

Using alerts, warnings and flags as an example – we need to learn from what works well, share good practice and standardise

Healthcare Professional Responsibilities

- To always remember that the **PATIENT** is the reason we must get this right!
- To be **trained** on IT systems that support their role and demonstrate **competency** in their use
- To use IT systems **as intende**d which includes understanding the **purpose** of the IT system
- To provide their **expert knowledge** of the blood transfusion rules when **procuring** or **updating** IT systems

Manufacturers, Software Developers & Healthcare IT Expert's Responsibilities

- To always remember that the **PATIENT** is the reason we must get this right!
- To **design** and **implement safe systems** that are **fit for purpose**
- To respond to **requests for change** and **BT developments** in a timely way
- To work together to **standardise** IT systems and ensure they are **interoperable**

With many thanks to

- Paula Bolton Maggs and the SHOT Team
- Rashmi Rook and the UK Transfusion Laboratory Collaborative
- Everyone who shares their experiences by reporting to SHOT
- And, in anticipation, all the manufacturers who are going to work with us!