Serious Adverse Events
2018
2019 Wrong Blood in Tube
&
Rejected Sample Survey Results

Róisín Brady
National Haemovigilance Office
March 2020

Serious Adverse Events 2018

Overall data

- Just under 162,000 components and SD Plasma issued from IBTS
- 221 SAE reports in total received comprising of transfused events near miss events and omission of anti D Ig events . These reports were submitted from 46 reporting establishments
- 195 SAE reports both mandatory and non mandatory were accepted. ⬇10% 2017 figures
  - 105 Transfused SAE, (including anti D and factor concentrate SAE) (67 non mandatory, 38 mandatory)
    - 14 Transfused SAE involved Paediatric Patients (13%)
  - 30 Near Miss SAE from HBB
  - 60 SAE from Blood Establishments

Main Findings for SAE involving transfused patients 2018 n=105 (n=105)

	n	Paediatric Reports
Other	26	6
Failure to give special requirements	17	1
Inappropriate/Unnecessary transfusion	17	1
Transfusion of an incorrectly labelled unit	11	1
Incorrect component/product transfused	7	2
Transfusion of other antigen incompatible RCC (if no reaction)	3	1
Transfusion of incorrectly stored component	3	1
Transfusion of expired component	2	N/A
Blood or blood product to wrong patient (if no reaction)	2	1
Incorrect ABO group transfused (if no reaction)	1	N/A
Anti D Ig and plasma derived medicinal products events	n	
Delay in giving product	6	N/A
Failure to administer product	5	N/A
Unnecessary administration of Anti D.	4	N/A
Incorrect dose of PCC prescribed and administered	1	N/A

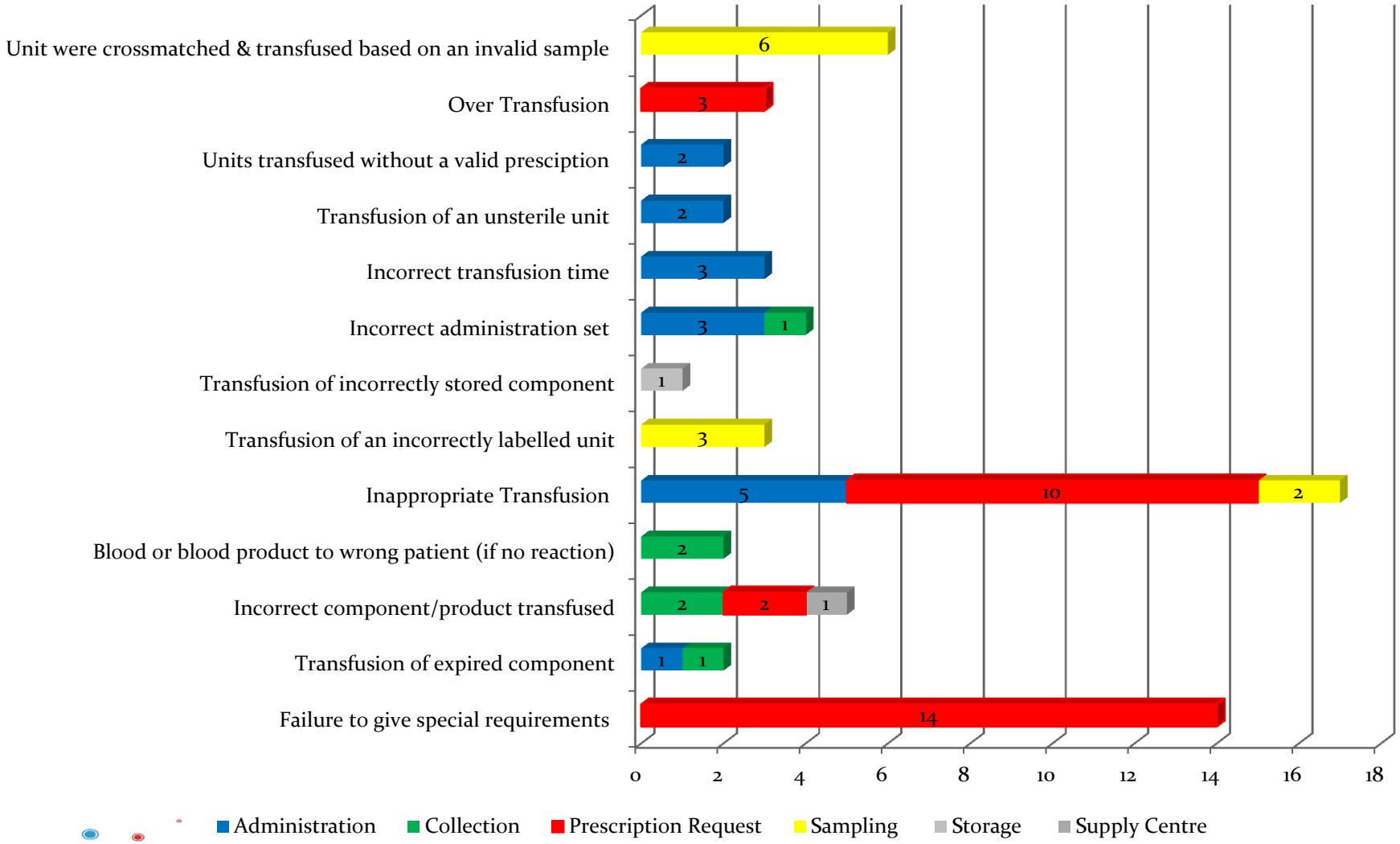
Breakdown of accepted transfused events reported under the category "Other" n=26

		Paediatric Reports
Testing of an invalid sample	7	N/A
Incorrect administration set used	4	N/A
Incorrect transfusion time (RCC > 6hrs following removal from controlled storage)	3	1
Over transfusion	3	3
Transfusion of an unsterile unit	2	N/A
Units transfused without a valid prescription	2	1
Incomplete compatibility testing	2	N/A
Inappropriate use of electronic crossmatch	1	N/A
Blood group incorrectly documented on LIS however group compatible units transfused	1	1
Alerts on LIS not followed	1	N/A

Main Findings for SAE near miss reports 2018 n=30

Issue of Incorrectly labelled Component	12
Incorrect components issued	6
Incorrect storage of units	3
Unit issued with incomplete testing	2
Blood issued to wrong patient	1
Inappropriate neonatal RCC unit available for emergency use	1
Units remained available following a transfusion reaction	1
Incorrect Rh Group Issued	1
Expired unit remained available	1
Special requirements not issued	1
Units issued on an invalid sample	1
Total	30

Outcome to patient as a result of site of first error – clinical area– transfused events – n=64



Failure to transfuse CMV negative &/or irradiated components 2018 (n=17)
Main Findings

Category of report	Component	2017	2018
Failure to give CMV negative component	RCC	1	4
	Platelet	0	0
Failure to give irradiated component	RCC	6	9
Failure to give CMV negative and irradiated component	RCC	3	4
Totals		**10**	**17**
Mandatory SAE		3	8
Non Mandatory SAE		7	9

Comments:

Error occurrence

- Failure to prescribe &/or request special requirements (82%)

Human Error n=17	
Classification of Human Error	n
Co-ordination/Communication	11
Failure to adhere to policies/procedures	9
Knowledge	5
Verification	5

Failure to transfuse CMV negative &/or irradiated components due to prescription errors &communication failures

Case History

Case 1

- Patient had been previously treated with purine analogue drugs.
- Prescription was marked as not requiring CMV Neg/ Irradiated Components
- Over the phone the CNM requesting the blood said it was not required as the Haematologist had instructed her.
- Special requirements were removed from LIS in error. Procedure was not followed Consultant Haematologist was not contacted to ensure special requirements could be removed.
- It is possible that CNM confused this patient with another case as the Haematologist did not apparently request removal of the special requirements.
- Error was identified when another Medical Scientist noticed on IT system that special requirements were removed in error

Failure to transfuse CMV negative &/or irradiated components due to prescription errors communication failures

Case 2

- Patient who was approximately 9/52 weeks gestation presented to a general hospital with an underlying GI condition and required a transfusion.
- The request form asks if the patient had any pregnancies in the last 3 months? The doctor ticked yes and wrote 6 weeks and 5 days, however CMV negative components were not specifically requested.
- MS interpreted this as the patient had been pregnant and no flag was placed on the system.
- Hospital policy suggests that it is the doctors responsibility to order special requirements.

Case 3. No communication with HBB.

- Patient with a history of Hodgkin lymphoma received 13 units RCC over a three month period which were not irradiated.
- Patient admitted under surgical team. No review by Haematology team.
- At no time was the HBB informed of the patients special requirements so no electronic marker had been placed on the patients record.
- Prescribing Doctors failed to recognise the need for irradiated components when prescribing the units.

Failure to transfuse CMV negative &/or irradiated components

Comment:

Hospital and laboratory policies are very often broader than the published guidelines for transfusing CMV negative or irradiated components. Very often these special requirements are linked to ensure that at risk patients receive blood meeting their specific requirements.

There must be an agreement and a consistent approach to the interpretation and indication for patients special requirements

IHS SIG in collaboration with NTAG – Irish Guidelines for special requirements – Q4 2020

The group may also considered the implementation of a patient alert card that could be issued at point of diagnosis.

Inappropriate/Unnecessary transfusion n=17 Main Findings

- The majority (47%) of unnecessary transfusions were attributable to errors in clinical decision-making not in conformity with best practice guidelines

Or

- Transfusion Based on Incorrect or Absent Haematology Result (29%)

Implicated Components	
RCC	12
Platelets	4
SD Plasma	1
Error Occurrence	
Prescription Request	10
Administration	5
Sampling	2

Human Error n=17	
Classification of Human Error	n
Failure to adhere to policies/procedures	10
Knowledge	6
Co-ordination/Communication	5

Inappropriate Transfusions		
2016	2017	2018
13	10	17

Unnecessary transfusions not in conformity with best practice guidelines

Culture of prescribing two units:
Case 1
Two units of RCC prescribed for 88 years old patient with asymptomatic iron deficiency anaemia - Hb 7.3 g/dl MCV 70 Ferritin 19. 2 units were transfused overnight consecutively No check Hb or review in between units. Doctor decided to proceed as patient has history of CVA in the last four years. HVO requested that patient be reviewed after one unit / check Hb to see if second unit was required. This did not occur
Case 2
Two units of RCC prescribed for 89 year old patient low weight (34kgs) who had 1-2 episodes of hemoptysis but was not actively bleeding .Hb was 7.7g/dl pre transfusion. Patient Hb was checked prior to Transfusion of 2nd unit of RCC . Hb was 10.1g/dl. Medical Scientist noted patients Hb however, 2nd unit of RCC had been removed from issue fridge. Haemovigilance Officer was informed and went to investigate. The blood results were not checked prior to transfusion of the 2nd unit of RCC.

Inappropriate Transfusion based on Incorrect or Absent Haematology result.

Case History

Oncology patient on an initial FBC gave platelet count of 6 x 10^9/l

Repeat sample requested as Hb of 19.6 g/dl was out of character for patient.

Platelets transfused before repeat FBC result available. Repeat Platelet count = 21 x 10^9/l

Patient would not normally receive platelets at this count.

Comments on Unnecessary Transfusion

All patients receiving transfusions should have regular clinical review

and assessment of their needs.

Every clinician who signs a transfusion prescription should be satisfied that the reason for every transfusion

- is known, and evidence-based,
- documented in the case notes.
- Before transfusion consider underlying risk factors (age, comorbidity particularly ischaemic heart disease)
- Transfuse the minimum amount; if really necessary, give one unit and review

Paediatric Events n =14

SAE	n
Over transfusion	3
Incorrect component/product transfused	2
Failure to give special requirements	1
Inappropriate/Unnecessary transfusion	1
Transfusion of an incorrectly labelled unit	1
Transfusion of other antigen incompatible RCC (if no reaction)	1
Transfusion of incorrectly stored component	1
Blood or blood product to wrong patient (if no reaction)	1
Incorrect transfusion time	1
Transfusion of an unsterile unit	1
Blood group incorrectly documented on LIS however group compatible units transfused	1

Over transfusion in Paediatric patients n= 3 due to prescription request errors

Case 1

Doctor was on call and was asked to prescribe 1 Pool of Platelets for a 14 year old boy in one single room and RCC for this particular patient in the room next door. One unit of RCC prescribed instead of using formula to calculate the correct volume per Kg bodyweight. The child received 73 mls more than should have with no ill effects.

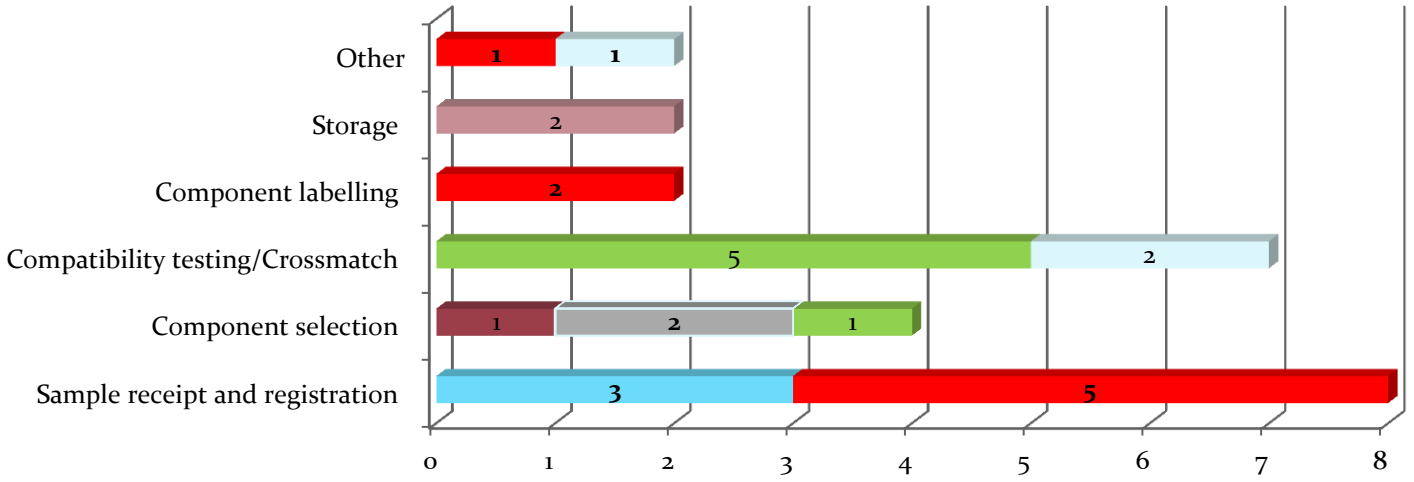
Case 2

The doctor who prescribed the RCC, although was aware of the guidelines for sickle cell top ups, prescribed a larger volume than what was required. The volume prescribed and transfused was in excess of Sickle Cell Guidelines for pre-op patient. The pt should have received enough red cells to bring his Hb to 10.0g/dl as per guidelines. His pre Hb was 8.6 g/dl. He received 387mls, with post Hb 12.4g/dl

Case 3

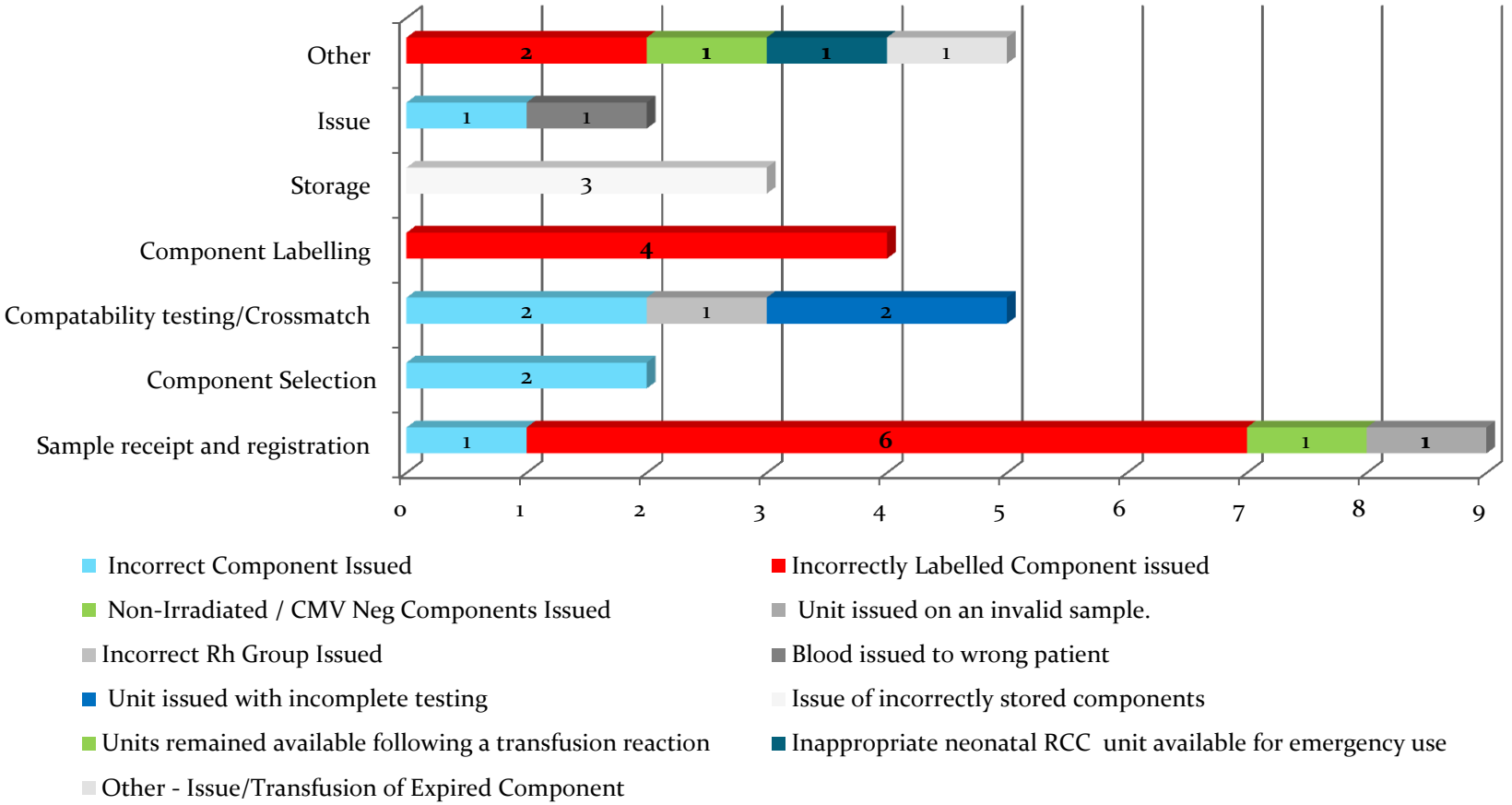
Patient in OT for management of post tonsillectomy bleed. Third bleed post procedure. Haemocue read as 8.2g/dl prior to first unit. Haemocue still reading 8.2g/dl post transfusion. Team requested second unit. MS advised confirming Hb with FBC. No FBC taken and second unit administered. Hb 15.1g/dl post transfusion. Nursing staff on ward had also discussed with Doctor prior to transfusion.
Contributing Factor: Senior NCHD was new to Paediatrics (first week). Had attended the Haemovigilance talk at induction however did not want to question decision from Consultant Anaesthetist to transfuse 2nd unit despite advice from MS and Nurses on ward.
Note: Hemocue not validated for use in theatre

Outcome to patient as a result of site of first error – HBB – transfused events – n=25



- Failure to give special requirements
- Transfusion of an incorrectly labelled unit
- Incorrect ABO group transfused (if no reaction)
- Incorrect component/product transfused
- Other
- Transfusion of other antigen incompatible RCC (if no reaction)
- Transfusion of incorrectly stored component

Potential outcome to patient as a result of site of first error – HBB – Near Miss Events n=30



Transfusion/Issue of incorrectly labelled units 2018
Main Findings

	Transfused Events n=11 (10%)		Near Miss Events n= 12 (40%)
SAE	Clinical Error	HBB error	
Transcription errors at sampling	3	Subsequent error in the HBB 1	N/A
Data discrepancy between sample details and LIS not identified		1	5
Data entry error on LIS		4	1
Transposition of labels in a single crossmatch			3
Transposition of patients name on unit label (manual process on this occasion IT system down)		1	N/A
Two Units issued with the same compatibility label - same label had printed twice		N/A	1
Changed DOB on LIMS without requesting a new sample.		1	N/A
Data discrepancy between collection slip and unit not identified.			2

Transfusion/Issue of incorrectly labelled units 2018
Main Findings

Recommendation:

- Laboratory staff must make sure the patient record selected on the LIMS when booking in samples matches the details exactly on the request form and the sample received (SHOT 2017)

PDA Alarms at the bedside

SAE
Patient DOB registered incorrectly when originally admitted. Sample sent to HBB for crossmatch. Error subsequently identified and corrected on hospital information system. Patient's ID band changed. HBB not notified at this time. On checking availability of RCC Nurse identified the error and alerted MS who changed DOB on LIMS without requesting a new sample.. Unit collected from HBB and at pretransfusion check wrist band and unit compatibility label matched but blood track still had wrong DOB on system - so PDA alerted the mismatch. HBB contacted again. Clinical staff were advised to override alert.
Patient registered on this admission under Irish spelling of their name. Patient was known under English & Irish version of their name. However always used English version in hospital in past. Sample was sent to HBB had Irish spelling of name, MS did not change Patients existing record with spelling change. At the pretransfusion check PDA alerted a mismatch. Clinical staff proceeded with the transfusion.
Patients forename Details entered on the LIS did not match details on sample and request form. Clinical used PDA for pre-tx checks & mismatch was notified. HBB staff were then notified. MS did not notice discrepancy in spelling of forename & erroneously advised to proceed as mismatch was due to discrepancy between lower case & higher case between label & ID Band.
Patient forename entered incorrectly on LIS. Unit compatibility label and patient ID band did not match. At pretransfusion check PDA alerted the mismatch. HBB staff were contacted and advised clinical staff to proceed with transfusion
Patients forename incorrectly in to LIS. RCC issued with incorrect spelling. Ward rang HBB to advise of the PDA mismatch .HBB and clinical staff checked details over the phone but did not detect error. HBB advised clinical area to continue with transfusion and check the blood manually. Also this error occurred out of hours during major bleed and MS was new to doing on call in Transfusion Lab.
Introduction of PDA in the clinical area identified this error. Error in spelling of patients name on the unit label was noted when PDA alerted that details on unit did not match patients ID Band .Incorrectly spelling of patient's surname on LIS. Not identified on four previous transfusion episodes. Request form and sample had correct spelling on each occasion.

Incorrect ABO group transfused n = 1

Case 1 – Component Selection & Administration error

Group specific B Rh positive RCC were issued and transfused to an adult patient instead of Group O Rh positive RCC following ABO incompatible bone marrow transplant from a group A Rh D positive donor.

Medical scientist failed to check patient's special requirements and clinical staff failed to check post BMT transfusion policy on the ward.

Checking post BMT policy in Lab and on Ward is a manual step as the patients own blood Group B Rh positive RCC was issued instead of universal Donor Group O Red cells. The IT System in the Lab and Blood Track System on Ward used for pre transfusion checks would not detect this error.

The error was discovered by the medical scientist when the next crossmatch sample was received.

Case highlighted both Human and System failures

Overview of root causes of SAE

- Reports to the NHO highlight human error year on year as a predominant feature contributing to these SAE in the transfusion process
- SAE - Transfused events 142 human errors were reported across 87 reports (n=89). System failures = 23
- SAE – near miss events 61 human errors were reported across 29 reports (n=30) System failures = 10

Classification of human error	Transfused events	Near Miss events
Failure to adhere to policies/procedures	58	19
Carrying out task incorrectly	22	1
Co-ordination/Communication	20	2
Knowledge deficit	17	N/A
Verification	15	22
Slip	9	6
Monitoring	1	N/A
Insufficient attention to detail	N/A	11

Overview of root causes of SAE

- If the investigation of incidents places too much emphasis on human error, the opportunity to resolve underlying system problems may be lost (SHOT 2018)
- SOP need to be simple, clear, easy to follow and explain the rationale for each step. This will then ensure staff are more engaged and more likely to follow the SOP (Key Message SHOT 2018)

2019 Wrong Blood in Tube & Rejected Sample Survey Results

- Rejected sample survey came out of the collection of WBIT so the survey was on mislabelled samples as apposed other reasons for rejection i.e. haemolysed sample, expired sample tubes, incorrect samples or samples too old to test.

- Object of the survey:To evaluate incorrectly labelled samples submitted to Hospital Blood Banks in Ireland over a twelve month period and to compare this with the number of wrong blood in tube reports submitted to the National Haemovigilance Office in Ireland for 2019

- Included all samples that underwent ABO typing or grouping – type and screen, type and crossmatch, cord blood samples, infant group and DCT samples, second confirmatory groups samples)

- 45 hospital Blood Banks with IBTS acting as HBB for a number of facilities in Dublin and the Cork area
- Data from 40 HBB was submitted for the survey
- 20 Hospitals submitted WBIT reports in 2019

National Haemovigilance Office - Survey of Rejected Samples in the Hospital Blood Bank 2019

Main findings

- Is an electronic system for patient ID/Sample labelling at the bedside in use in your hospital?
  - Yes- 71.4% No-28.6%
- Is the use of the electronic system for patient ID/Sample labelling at the bedside mandatory ?
  - Yes –26.7% NO –73.3%
- Is there a written policy with explicit criteria for acceptance/rejection of blood bank samples ?
  - 100% - yes
- When a sample does not meet the requirements for sample labelling information, does your blood bank permit corrections?
  - Yes partial/minor amendments – 45.2% No - 54.8%

Do you record the specific reason why a blood transfusion sample was rejected?

Reason for rejection	Totals	
Sample taken from the intended patient but missing / incorrect identifiers	2781	21% of all samples rejected
A mismatch between paperwork request and specimen (in clinical area)	618	
A mismatch between paperwork request, specimen and laboratory information system	109	
Addressograph label used to label tube (This does not include an electronic generated label from a bed-side scanning system)	1468	11% of all samples rejected
Sample tube and/or requested form not clearly signed	857	
Unlabelled sample	166	

92% of HBB record data

80% HBB identified the reasons in this survey

National Haemovigilance Office - Survey of Rejected Samples in the Hospital Blood Bank 2019

- Do you record who was involved in the blood transfusion sample error?

Staff role	n
Medical Staff	1045
Nursing/Midwifery Staff	632
Phlebotomy Staff	106
Medical and Nursing/Midwifery Staff	66
Medical and Phlebotomy Staff	0
Nursing/Midwifery and Phlebotomy Staff	0
Unknown Staff	214

46% HBB record figures
34% HBB identified staff role involved in the survey

National Haemovigilance Office - Survey of Rejected Samples in the Hospital Blood Bank 2019

Clinical Area where error occurred	n
Pre Assessment Clinic /OPD	462
Emergency Department	1409
Day Ward/Ward	2247
Maternity/Labour Ward	1001
Theatre	145
ICU/CCU	240
Neonatal Unit	91
Unable to determine	71
None of the above	394

80% HBB record figures
68% HBB identified clinical area where error occurred.

WBIT Main findings

In total – 57 reports were received

48 reports considered.

9 further reports related to a mismatch between paperwork request and specimen

- Sample taken from the intended patient but labelled with another patient details n = 36
- Sample taken from the wrong patient but labelled as per intended patient details n = 12

Who was involved in the WBIT event	n
Nurse/Midwife	21
Doctor	20
Phlebotomist	5
Nurse and Administration Staff	1
Nurse and Doctor	1

Patient age category	n
Neonate (< 28 days)	7
Adult (18-30 years)	2
Adult (31-50 years)	13
Adult (51 - 70 years)	12
Elderly (70+)	14

WBIT Main findings

- Is an electronic system for patient ID/Sample labelling at the bedside in use in your hospital? N = 42

- *Was the electronic system in use when collecting or labelling the sample on this occasion?- Yes - 27*

Was the electronic system in use when collecting or labeling the sample on this occasion ?

- Yes(n=27)– so what happened ?

Patient not identified correctly at phlebotomy	12
Label not verified prior to application to sample bottle	5
Sample remotely labelled	4
Sample not labelled by person taking the sample	4
Prelabelling of sample	2

- No(n= 21)– so what happened ?

Patient not identified correctly at phlebotomy	8
Sample remotely labelled	5
Details on sample not transcribed from ID Band	4
Patient not identified correctly on admission	2
Unknown	2

WBIT Main findings

Considering the groups of the patient/component(s) involved,

- *19(40%) *WBIT events from 15 sites would have led to an ABO incompatible transfusion if the error had not been detected*

Reduction on 2017 survey (n=22)

9 (47%) WBIT occurred when an electronic system was in use when collecting or labeling the sample

- **one sample came from a GP practice to the HBB*

WBIT which would have led to ABO Incompatible Transfusions n=19

EBTS used at collection and sampling n=9	n
Patient not identified correctly at phlebotomy	5
Sample not labelled by person taking the sample	2
Sample remotely labelled	2

EBTS - not used at collection and sampling n=10	n
Patient not identified correctly at phlebotomy	5
Details on sample not transcribed from ID Band	2
Sample remotely labelled	2

What did we learn from the survey and WBIT ?

- Total number of samples received in the HBB – 413,542
- Total number of samples processed – 394,982
- Total No. of samples rejected – 18,560 – 4.4% overall rejection rate (1:22 samples rejected)
  - 2011 (1:24 samples rejected)
  - 2017 figures (1: 23 samples are rejected)
- **Based on WBIT reports submitted -The current incidence of WBIT events in Ireland is (1:8615)**
  - 2017 figure ((1:7,294 samples)

Failure to identify the patient at when collecting and labelling the sample continues to occur

Patient identification

- “Technology alone cannot ensure accurate patient identification,” says Gerard M. Castro, PhD, MPH, project director, Patient Safety Initiatives, The Joint Commission. “We must consider not only the technology, but also the people involved and their processes.
- Accurate patient identification involves shared responsibility and involvement of all stakeholders.” (JCI 2018)

Take home message

- If it is your role to take samples for pre transfusion testing – it is your responsibility to follow the procedure correctly
- It should be one uninterrupted process from start to finish - correctly linking the sample to the patient from whom it was taken remains fundamental - whether using electronic systems for labelling, or hand writing the label.

Acknowledgements

Thank you

- Hospital HVO's
- Hospital Blood Bank Staff
- Hospital Medical Staff
- Hospital Quality/Risk Managers
- Dr Stephen Field IBTS
- Dr Kieran Morris IBTS
- Dr Joan Power IBTS
- Shonagh Ward IBTS
- Maria Kane IBTS
- Catherine Keating IBTS