Serious Adverse Events 2016-2017

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Serious Adverse Events 2016-2017 – overall data

- Just over 331,000 components and LG octaplas issued from IBTS
- 470 SAE in total submitted from 57 Reporting Establishments
- 437 SAE reports accepted
  - 222 Transfused SAE, (including anti D and factor concentrate SAE) (145 non mandatory, 77 mandatory)
  - 61 Near Miss SAE from HBB
  - 154 SAE from Blood Establishments

Main Findings for SAE involving transfused patients 2016-2017 (n=222)

Nature of incident	2016	2017	Paediatric Reports	Overall % of Total SAE Reports
Other	27	34	10	16%
Incorrect component/product transfused	20	10	10	33%
Transfusion of an incorrectly labeled unit	10	16	1	4%
Failure to give special requirements	13	10	3	13%
Inappropriate/Unnecessary transfusion	13	10	3	13%
Transfusion of other incorrect antigen /incompatible RCC (if no reaction)	3	8	1	9%
Transfusion of incorrectly stored component	3	6	1	11%
Blood or blood product to wrong patient (if no reaction)	2	1	N/A	
Incorrect ABO group transfused (if no reaction)	1	1	1	50%
Incorrect Rh D group transfused (if no reaction)	2	0	1	50%
Transfusion of expired component	0	1	N/A	
Transfusion of incorrectly distributed component	0	1	N/A	
Delay in giving product	9	10	N/A	
Unnecessary administration of Anti-D	0	5	1	20%
Failure to administer Anti-D	2	1	N/A	

Main Findings for SAE near miss reports 2016-2017 (n=61)

Most common SAE Near Miss Reported:

	n
Issue of Incorrectly Labeled Component	40
Incorrect component issued	9
Non-Irradiated / CMV Neg Components Issued	5
Storage	3
Incorrect ABO Group issued	1
Incorrect antigen / incompatible antigen RCC issued	1
Other- Invalid sample processed	1
Other (Specify)	1

Incorrect component/product transfused (N=30)

This category captures incidents where the patient required a blood component/blood product but the most appropriate one was not administered Reviewed by Haemovigilance team and hospital transfusion committee.

- Reported figures decreased in 2017

2016	2017
20	10

Components implicated

- RCC – 21
- Platelets -3
- LG Octaplas – 6

- Most common report effecting paediatric patients (33%)
- Second largest category reported in our near miss events (15%)

- Site of first error – HBB (43%)

- Root causes – Human error in all cases
  - Policies/Procedures (60%)
  - Verification (30%)
  - Miscommunication(27%)

Incorrect component/product transfused (N=30) – Main Findings
Error Discovery

LG octaplas given for emergency reversal of warfarin instead of PCC	6
Unnecessary exposure to another donor	4
Uncrossmatched emergency units transfused due to delay in processing.	3
Apheresis platelet issued instead of pooled platelet	2
Full units suitable for neonatal unit issued instead of an aliqout	2
Incomplete/no antibody identification performed	2
Wrong component issued	2
HLA matched platelet given to the wrong patient.	1

Incorrect components to paediatric patients (n =10)

Error Discovery

- Unnecessary exposure to another donor n=4
  - Full unit issued in error for top up transfusion and further transfusion required a number of days later
  - Failure to irradiate aliquots in a timely manner
  - Aliquot incorrectly returned to supply centre as expired and a further unit requested
  - Decision was made to partially correct patients anaemia pre-op. Theatre delayed. Initial unit used had been discarded.
- Full units suitable for neonatal use transfused instead of aliqout n=2
  - On Call staff member made a mistake initially in the issue of the aliqout and could not undo the error and issued a full unit
  - RGN collecting unit could not see aliquot in fridge and failed to contact MS. Removed a full unit also crossmatched for this patient in error.
- Apheresis platelet issued instead of pooled platelet n=1
  - An apheresis platelet of suitable group was expiring that night. MS wanted to prevent these expiring and did not check patient flags on LIS
- Emergency O RhD Neg CMV Pos unit transfused to a neonate n=1
  - At that time it was not policy to have an emergency O RhD negative unit suitable for paediatric use on site.
- Incorrect neonatal emergency uncrossmatched RCC ordered from supply centre n=1
  - Incorrect component was selected on online ordering system by 1st MS and issued by another MS
- Unit not labeled suitable for neonatal use issued from supply centre n=1
  - Crossmatched unit received out of hours on call - staff member thought unit was suitable as it was crossmatched by supply centre despite LIS flag . Unit in question did meet criteria for a neonatal unit but was not labeled as such by the supply centre.

Incorrect component/product transfused (N=30) due to verification and communication failures.

Case histories

Case 1. A ward clerk took a verbal telephone instruction from the consultant to give 2 units RCC to the patient (ward clerks are not assigned this role). The Consultant stated they thought they were talking to the RGN . RGN took the ward clerks instruction without verifying. NCHD charted the RCC and they were transfused. X ray then contacted the ward and asked if the patient had received the LG Octaplas x 2. The error was then noticed. Consultant was contacted and insisted that the verbal instruction was for LG Octaplas . Patient discharged the following day. Hb:8.9 g/dl

Case 2. Four units RCC had been requested for a patient with a post partum haemorrhage (on call) . On call MS thought that an IAT panel only had to be performed. Enzyme panel not performed. (MS was non core on call staff working in HBB late at night)
Units were not required and were returned to stock following morning. Later in the morning 2 RCC units were requested and re issued to the same patient. Current MS unaware that pre-compatability testing had not been completed.

Case 3. Patient had continued to ooze post surgery and 2 units of LG Octaplas were to be transfused post operatively in the clinical area . RGN misunderstood the post-op handover and did not check the prescription and presumed that RCC were to be transfused as RGN had taken a blood sample for group and crossmatch earlier that day and knew that 2 units of RCC had been requested from the lab.

Findings from Unnecessary Transfusions 2016-2017(n=23)

This category captures events where a patient is transfused with a blood component which was not required. All reports in this category were deemed unnecessary and inappropriate by the reporting hospital.

Inappropriate transfusion				
	2014	2015	2016	2017
	21	24	13	10

Error Occurrence	
Prescription Request	17
Administration	3
Sampling	2
Other	1

Implicated Components	
RCC	17
Platelets	6

Human Error(n=)23	
Classification of human error	n
Failure to adhere to policies/procedures	16
Knowledge	7
Co-ordination/Communication	6
Verification	5

Findings from Unnecessary Transfusions 2016-2017(n=23)

- The majority (48%) 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 (35%)

Prescription related errors leading to unnecessary transfusions (n=17)

SAE
Elderly patient with PR bleed prescribed 3 units of RCC over a two day period. Prescription was completed on the day before either transfusions and Hb result of 9.7g/dl was transcribed instead of 11.0g/dl on day one and 9.7g/dl on day two prior to the third unit RCC instead of the correct result of 13.4g/dl .Hb 13.7g/dl post transfusion
Non bleeding, stable young adult with Hb 8.2g/dl prescribed and transfused with two units RCC given in anticipation of blood loss in future surgery, on indefinite date. Consultant insisted on transfusion despite queries from nursing staff and NCHD. Hb 10.0 g/dl post transfusion.
Adult patient admitted with symptomatic chronic anaemia. Hb on admission 3.8g/dl. Prescribed and transfused 6 units of RCC over 36 Hrs without a check FBC. Consultant had noted in the patients medical notes that 6 units were to be transfused but they also had requested a Hb check. As the 6th unit was in progress – Hb checked -12.0 gd/l. Following day patients Hb 13.5g/dl. On review at least 2 deemed inappropriate by Consultant Haematologist.

NHO Recommendation

- Training large numbers of staff with competing demands, varying skills and educational levels is difficult

However:

- Efforts must be directed towards training and competency assessment of clinical staff involved in the prescription of blood/blood components. Clinical practitioners should be given protected time to attend education sessions on appropriate blood usage and current guidelines. (NHO 2011)

Transfusion/Issue of incorrectly labelled units 2016-2017
Main Findings

- Incorrectly labelled units transfused (n=26)14%
- (no change on 2013-2015)

Transfusion of an incorrectly labeled unit	
2016	2017
10	16

- Issue of incorrectly labelled units (Near Miss n=40)66%
- (significant increase on 2013-2015 figures 28%)

Near Miss SAE	
2016	2017
22	18

Transfusion/Issue of incorrectly labelled units 2016-2017 (n=66) Main Findings

SAE	Transfused Events n=26	Near Miss Events n= 40
Transcription error at initial admission	7	N/A
Transcription errors at sampling	3	N/A
Data discrepancy between sample details and LIS not identified	2	20
Transposition of labels in a single crossmatch	6	8
Data entry error on LIS	5	8
Incorrect batch number assigned to LG Octaplas	2	N/A
Unit issued with incorrect compatibility label	0	1
Incorrect expiry date on hospital label not identified	0	1
Unit of blood issued with unconfirmed group label (Supply Centre error)	1	N/A

Transfusion/Issue of incorrectly labelled units 2016-2017 (n=66)

Reported causes of errors in Transfusion of incorrectly labelled components (n=26)

- Human error in all but one case
- Further seven cases cited system failures
- Failure to adhere to policies/procedures (n=16)
- Failure to verify (n=15)

Reported causes of errors in issue of incorrectly labelled components (n=40)

- Human error in all cases

Most common

- Failure to verify (n=36)
- Inattention to detail (n=32)
- Failure to adhere to policies and procedures (n=25)

Transfusion/Issue of incorrectly labelled units 2016-2017

Data discrepancy between sample details and LIS not identified (n=22)

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)
- Robust policy in place for notifying HBB if patients identifiers are amended

Transposition of labels in a single crossmatch (n=14)

While no patient received/issued the wrong blood in these cases, these errors were either not detected at the final step in the HBB process or in some cases at bedside

The role of the bed side check in safe transfusion practice must continue to be highlighted to staff transfusing blood components

Failure to transfuse CMV negative &/or irradiated components 2016-2017 (n=23) Main Findings

Category of report	Component	2016	2017
Failure to give CMV negative component	RCC	0	1
	Platelet	1	0
Failure to give irradiated component	RCC	7	6
Failure to give CMV negative and irradiated component	RCC	4	3
	RCC & Platelets	1	0
Totals		**13**	**10**
Mandatory SAE		4	3
Non Mandatory SAE		9	7

Comments:

Reduction overall on

- 2014 figures(n=15)
- 2015 figures (n=17)

Error occurrence

- Failure to prescribe &/or request special requirements (70%)

Failure to transfuse CMV negative &/or irradiated components 2016-2017 (n=23)

It is the clinician' responsibility to know the patient's specific transfusion requirements (SHOT 2017)

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.

Reporting to the NHO:
In cases where a hospital policy specifies special requirements outside best practice guidelines,

- *These reports should be managed as non conformances in the hospital quality system, and not reported as mandatory/non mandatory SAE*
- Reports relating failure to transfuse components with special requirements should only be submitted to the NHO where there is clear evidence for this requirement.
- *Hospitals are encouraged to review against expert published guidelines.*

BSH - Use of Irradiated Blood Components – new guideline pending

Overview of root causes of SAE

An adverse event is not necessarily the result of one person making a mistake at the frontline of healthcare; rather conditions in the system often enable the adverse event to occur. The impact of adverse events on healthcare workers is an important consideration with staff often described as the 'second victims' of adverse events. (Rafter et al 2015)

- Staff investigating errors in the transfusion process are advised to examine systems failures so they can identify contributory causes beyond the failure by an individual (SHOT 2017)

Take home message

Haemovigilance is considered to be a part of total healthcare vigilance (along with e.g. pharmacovigilance and vigilance on medical devices).

The information provided by haemovigilance contributes to improving the safety of transfusion by:

- providing the medical community with a reliable source of information about adverse events and reactions associated with transfusion;
- indicating corrective measures required to prevent the recurrence of some incidents or mistakes in the transfusion process;

(**EDQM** 19th Edition 2017)

Take home message

- Education in transfusion practice delivered by the HVO & Consultant Haematologist is critically important to integrate theory with safe transfusion practice.
  - *Training of staff especially medical staff is complex*.
- Initiatives such as audit, provision of feedback, presentations and a “clinical” presence by the hospital HVO & Consultant Haematologist will continue to support transfusion education and raise the profile of safe transfusion practice through out the hospital.

Thank You