Blood Services reporting to SHOT

Errors related to anti-D Immunoglobulin (Ig)

The questionnaire is not to be used, shared or modified outside the remit of the project

Page 1 – Blood Establishments – Anti-D Ig Incident

Anti-D Ig Incident		
Question	***Answer Options***	**Data Type**
Decision Point – the following question determines which specific pages are generated		
Where in the process did the problem originate	• Taking the blood sample • Request for anti-D Ig • Laboratory procedures • Calculating dose • Prescription • Collection • Administration • Only for Blood Services (diagnostic laboratory)	Multi choice
Data event reported		Date
Was the patient the intended recipient	• Yes • No	Single choice
What are you reporting	• Advised to the wrong patient • Wrong/inadequate dose of anti-D Ig advised • Delayed in testing or provision of results (>72 hours post-natal or post sensitising event) • Dose advised for D-positive mother • Dose advised for D-negative mother with D-negative baby • Anti-D Ig advised to woman with known immune anti-D • Incorrect dosing for D-negative recipients of D-positive platelets/red cells • Incorrect dosing for D-negative recipients of D-positive SOT • Inappropriate route of administration advised • Inadequate advice for follow up of fetal cell clearance • Delays in stock replacemente	Single choice
Was the anti-D Ig error related to	• RAADP • Potentially sensitising event • Post delivery	Single choice
Other comments relating to the anti-D Ig incident		Text
Was there an error in the laboratory	• No • Yes	Single choice

Page 2 – If yes 'was there an error in the laboratory'

Diagnostic Laboratory errors and procedures		
Question	**Answer Options**	**Data Type**
What was the error in the diagnostic laboratory	• Sample receipt and registration • Testing • Misinterpretation of results • Communication of results • Other (please specify)	Multi choice
Other diagnostic laboratory error		Free Text
Was the member of staff lone working at the time of the incident	• No • Yes	Single choice
Does the department have a capacity plan	• No • Yes	Single choice
Was the capacity plan met on the day of the incident	• No • Yes	Single choice
Was a laboratory component labelling and exit check (or equivalent) used	• No • Yes	Single choice
Have the staff received training in Human Factors	• No • Yes	Single choice
Was the competency up to date	• No • Yes	Single choice
Date of assessment		Date
When was the testing carried out	• 09:00 am to 08:00 pm • 08:00 pm to midnight • Midnight to 09:00 am	Single choice
Is this by your local definition	• Within normal working hours • On a shift system • On an on-call system	Single choice
Indicate the professional status of the staff performing the testing	• Laboratory scientist NOT normally working in transfusion laboratory • Laboratory scientist who normally works in transfusion laboratory • Non-HCPC registered staff under supervision • Non-HCPC registered unsupervised • Trainee laboratory scientist • Temporary / locum / agency staff • Redeployed staff • Other (please specify)	
Other staff		Text

Page 3 – if yes 'was there an error in the laboratory'

Diagnostic laboratory errors and procedures (cont…)		
Question	**Answer Options**	**Data Type**
What was the error	• Wrong sample selected for testing • Patient historical record not consulted • D grouping error • Transcription/transposition error • Misinterpretation error • Miscommunication error • Dose calculation error • Other	Multi choice
Other laboratory error		Text
If FMH estimation error – describe error		Text
Does the procedure include an algorithm for calculating anti-D Ig from the quantification of D-positive cell population?	• Yes • No	Single choice
What was the quantification of D-positive cell population?		Text
What was the dose of anti-D Ig advised from the quantification of D-positive cell population?		Text
What was the dose advised of anti-D Ig to the hospital?		Text
What was the patient's blood group	• D-negative • D-positive • Weak D • D-variant • Unknown	Single choice
Was the result correct for the sample being tested	• Yes • No	Single choice
If no, what was the correct group	• D-negative • D-positive • Weak D • D-variant	Single choice
Incorrect result for sample being tested due to	• Reagent defect • Equipment defect • Wrong interpretation • Error in recording result • Failure to follow SOP	Single choice
Further comment		Text

Page 4 – Blood grouping procedure (from current quest.)

Blood grouping procedure		
Question	**Answer Options**	**Data Type**
Was the method used (grouping)	• Manual • Semi-automated • Automated	Single choice
If grouping semi-automated or automated, please name the analyser		Text
Which technology was used for D typing	• Tile • Tube • Microplate • Column agglutination • Other	Single choice
Other D typing technology		Text
What reagents were used	• One • Two • Three • Four • Five	Single choice
Do any of these reagents detect DVI	• Yes • No	Single choice
Are any of these reagents anti-CDE	• Yes • No	Single choice
Was any technique used other than direct agglutination	• Yes • No	Single choice
What controls were performed		Text
Was this method (grouping)	• Routine • Urgent	Single choice
Was the result (grouping)	• Recorded manually • Downloaded electronically	Single choice

Page 4 – Quantification of D-positive cell population procedure

Quantification of D-positive cell population procedure		
Question	**Answer Options**	**Data Type**
Was the method used	• Manual • Semi-automated • Automated	Single choice
If method is semi-automated or automated, please name the analyser		Text
Was flow cytometry used for FMH testing	• Yes • No	Single choice
If no, which other technology was used		Text
Was re-gating required to obtain anti-D Ig dosing?	• Yes • No	Single choice
If yes, did re-gating contribute to the error?	• Yes • No	Single choice
Which were the controls used		Text
Were the controls tested correctly?	• Yes • No	Single choice
Was this method	• Routine • Urgent	Single choice
Was the result	• Recorded manually • Downloaded electronically	Single choice
Did the result required discussion with consultant?	• Yes • No	Single choice
If yes, was the result discussed with consultant	• Yes • No	Single choice
If not, why not		Text
How were the results given to hospital?	• Verbally • Final paper report • Final digital report • Other (please specify)	Multi choice
Other method for provision of results		

Page 5 – Adverse event summary

Adverse event summary		
Question	**Answer Options**	**Data Type**
What was the reason for the error	• Lack of knowledge of staff • Deficiencies in staff training • Advised dosing without checking blood group • Advised dosing without checking if patient had immune anti-D • Patient grouped wrongly • D group wrongly recorded • Inappropriate clinical decision • Other (please specifiy)	Single choice
Other reason for error		Text
What was the inappropriate clinical decision		Text
How was the error discovered	• Detected by ward staff • Detected by hospital laboratory staff • Detected by patient • Detected by patient's relative • Detected by diagnostic laboratory staff • Detected by blood service consultant • Other (please specify)	Single choice

Page 5 - IT

Information Technology		
Question	**Answer Options**	**Data Type**
Did IT contribute to the error	• Yes • No	Single choice
If answered answer 'Yes', all the following questions appear		
Was this primarily due to	• Failure to consult or identify historical record • Failure to link, merge or reconcile computer records • Warning flag in place but not heeded • Warning flag not updated or disabled • Failure to use flags and/or logic rules • Incorrect results entered or accessed manually • Computer or other IT systems failure • Incorrect patient details selected from IT system • Lack of functionality/algorithms in the system to support safe practice • Lack of interfacing/interoperability • System not configured correctly • System not used correctly • Printing error • Other (please specify)	• Single choice
Other IT error		Free Text
What type of IT system was used	• Laboratory information management system (LIMS or LIS) • Ordercomms • Patient administration system • Electronic patient record • Electronic blood management system • Bedside electronic ID system • Electronic prescribing system • Online blood ordering system • Electronic results system (e.g., ICE, SpICE • Temperature monitoring system • Issuing and distribution system in BE • Other (please specify)	Multi choice
Other type of IT system		Free Text
What was the name of the electronic system used		Free Text
Who was the supplier of the system		Free Text
Was the user trained and competent to use the system	• No • Yes	Single choice
If no, please give details		Free Text
Could the error have been prevented by using IT	• No • Yes	Single choice
Was this because the relevant IT was	• Not in place • In place but not used	Single choice
The following questions will appear dependent of the answer to the question above		
Why was not in place	• Lack of funding to purchase • Lack of capacity to implement • Other (please give details)	Single choice
What was the reason for this not being used	• Staff not trained/no access • IT downtime (planner or unplanned) • Other (please give details)	Single choice
Please give further details		Free Text

Page 6 - Handover

Handover		
Question	**Answer Options**	**Data Type**
Did handover between shifts/teams/individuals impact on the error	• No • Yes	Single choice
If answered answer ‘Yes’ all following questions appear		
Was the handover	• Verbal • Written • Electronic	Single choice
Is there a structured handover	• No • Yes	Single choice
Please provide further details of the handover		Free text

Page 7 – Transplant cases

Transplant cases		
Question	**Answer Options**	**Data Type**
Was the patient a transplant recipient	• No • Yes	Single choice
If answered answer 'Yes' the following questions appear		
Was the patient	• Pre-transplant • Post-transplant	Single choice
What was the group of the patient before transplant	• A- • B- • AB- • O- • A+ • B+ • AB+ • O+	Single choice
What was the group of the transplant received	• A- • B- • AB- • O- • A+ • B+ • AB+ • O+	Single choice
What type of transplant did the patient receive	• Solid organ • Haematopoietic stem cell transplant	Single choice
The following questions will appear dependent of the answer to the question above		
Which organ was transplanted	• Heart • Lung • Kidney • Liver • Pancreas • Other (please specify)	Multi choice
Please specific transplanted organ		Free Text
Which type of HSCT?	• Autologous • Allogeneic - haploidentical • Allogeneic - sibling donor • Allogeneic - unrelated donor	Single choice

Page 8 (Human Factors I)

Human Factors

As three quarters of all incidents reported to SHOT are related to errors, we would like to understand more about why these occur. Errors in transfusion practice may be related to workplace features, communication, and IT systems, and organisational pressures.

It is important to answer every question as this will allow SHOT to interpret practices, and gain understanding of all the factors involved.
SHOT has recognised how difficult it can be for reporters to score the human factors aspects of an incident, so we have prepared some self-learning material. You may want to save this incident report first if you are planning to access any training material now.
The Human Factors Tuition Package includes case studies and there are 2 short videos produced by SHOT for more information about Human Factors.

These resources can be accessed if you copy and paste this link to the Human Factors page on the SHOT website www.shotuk.org/human-factors-tuition-package/ into your internet browser.

By placing your curser over each question in the subsequent tabs, you will be able to access tooltips which are pop up examples to assist you to complete the questions.

Question	Answer Options	Data Type
When investigating incidents do you apply any Human Factors principles or use a Human Factors framework or model?	• Yes • No; but we are planning to • No	Single choice
If answered answer 'Yes' the following questions appear		
Which framework or model do you use	• Fishbone • In house Human Factors tool • In house Root Cause Analysis tool • SHOT Human Factors resources • PSIRF (Patient Safety Incident Response Framework) • SEIPS (Systems Engineering Initiative for Patient Safety) • HFACS (Human Factors Analysis and Classification System) • AcciMap • SHELL (Software, Hardware, Environment, Liveware) • SHEEP (Systems, Human Interaction, Environment, Equipment, Personal) • PEAR (People, Environment, Actions, Resources) • London Protocol • YCFF (Yorkshire Contributory Factors Framework) • Bowtie • Other (Please specify)	Single choice
Please specify other HF framework or model		Free Text
Please give any additional relevant information		Free Text

Page 9 (Human Factors II)

Human Factors		
Question	**Answer Options**	**Data Type**
Section 1 – Situational Factors		
Does the cause of this incident include any failures in team function	• No • Yes	Single choice
Were there any reasons this incident was more likely to occur with the particular staff involved	• No • Yes	Single choice
Did task features make the incident more likely	• No • Yes	Single choice
Were there reasons that this incident was more likely to occur to this particular patient	• No • Yes	Single choice
Please give any additional relevant information for situational factors		Free Text

Page 10 (Human Factors III)

Human Factors		
Question	**Answer Options**	**Data Type**
Section 2 – Local Working Conditions		
Was there a mismatch between workload and staff provision around the time of the incident	• No • Yes	Single choice
Was there any failure of team function in relation to leadership, supervision and roles	• No • Yes	Single choice
Were there any difficulties obtaining the correct equipment and/or supplies	• No • Yes	Single choice
Please give any additional relevant information for local working conditions		Free Text

Page 11 (Human Factors IV)

Human Factors		
Question	**Answer Options**	**Data Type**
Section 3 – Organisational Factors		
Did the environment hinder work in any way	• No • Yes	Single choice
Were there problems in other departments that contributed	• No • Yes	Single choice
Did organisational pressures play a role in the incident	• No • Yes	Single choice
Were there issues or gaps with staff skill or knowledge	• No • Yes	Single choice
Please give any additional relevant information for organisational factors		Free Text

Page 12 (Human Factors V)

Human Factors		
Question	**Answer Options**	**Data Type**
Section 4 – External Factors		
Were there any characteristics about the equipment that were unhelpful	• No • Yes	Single choice
Have any national policies or high-level regulatory issues influenced this incident	• No • Yes	Single choice
Please give any additional relevant information for external factors		Free Text

Page 13 (Human Factors VI)

Human Factors		
Question	**Answer Options**	**Data Type**
Section 5 – Communication and culture		
Did a lack of safety culture in your area contribute to this incident	• No • Yes	Single choice
Did poor written, or verbal communication worsen the situation	• No • Yes	Single choice
Please give any additional relevant information for communication and culture		Free Text

Page 14 (Human Factors VII)

Human Factors		
Question	**Answer Options**	**Data Type**
Section 6 - Summary		
Which of these options do you consider to be the most important contributory factor for this incident	• Situational • Local working • Organisational • External • Communication and culture	Single choice
If you could change one thing to make this incident less likely to happen again, what would it be?		Free Text

Page 15 - Outcome

Outcome		
Question	**Answer Options**	**Data Type**
If not already on ITU/HDU, did the patient require admission to ITU/HDU	• Yes • No • Not known	Single choice
The next question will be dependent on the answer above		
If yes, did the adverse transfusion event contribute to the admission to ITU/HDU	• Yes • No	Single choice
If not already on dialysis, did the patient required dialysis	• Yes • No	Single choice
If answered yes, the following question will appear		
If yes, how many days did the patient spend on dialysis		Integer
Did the patient required admission to the ward from outpatients/day care	• Yes • No	Single choice
If answered yes, the following question will appear		
If yes, how many days did the patient spend on a ward		Integer
Other consequences/patient requirements		Free Text
Clinical outcome in relation to the transfusion episode	• Complete recovery • Minor sequelae • Serious sequelae • Death related to the transfusion • Not known • None (Eg SAE with no adverse • reaction in the patient)	Single choice Mandatory question
If minor or serious sequelae, please give details and time to resolution		Free Text
What is the likelihood of the blood component being the cause of the reaction (imputability)	Not assessable 0 - Excluded or Unlikely 1 - Possible 2 - Likely / probable 3 - Certain	Single choice Mandatory question
If 0 – Excluded or Unlikely what was the reaction considered to have been caused by?		Free Text
If the patient died, please give the time and date of death		Data/Time

Page 16 – Procedural review

Procedural review		
Question	**Answer Options**	**Data Type**
Has this case been reviewed	• Yes • No	Single choice
The next questions will be dependent on the answer above		
If no, why has this case not been reviewed?		Free Text
If yes, which group has reviewed this case (please tick all that apply)	• Hospital Transfusion Team • Hospital Transfusion Committee • Regional body (please specify) • Senior clinical group (SMG/SMT) or equivalent (blood establishments) • National body (please specify) • Other group (please specify)	Multi choice
Please give details of any regional, national or other review body		Free Text
Please give details of the outcome of the review		Free Text
As a result, have there been recommended changes to transfusion procedures or policy	• Yes • No	Single choice
If answered yes, the following question will appear		
Please specific changes to transfusion procedures or policy		Free Text
Has a Root Cause Analysis, or other equivalent formal investigation, been carried out?	• Yes • No	Single choice
The next questions will be dependent of the answer above		
Why was no RCA or formal investigation carried out		Free Text
Has the anonymised RCA/Investigation been share by	• Upload to SABRE (MHRA) • Upload to Dendrite (below) • E-mail to SHOT	Multi choice
SHOT's primary focus is on improving patient safety, so additional information from your local investigation and root cause analysis may have important general lessons to share with others If you have any problems in uploading your anonymised RCA or investigations, then please contact the SHOT office for assistance		
Please upload any relevant document e.g., Root Cause Analysis		Multimedia
Was any specific 'good practice' identified as a result of this incident? If so, please provide details		Free Text
Please give any other additional information which you think is relevant		Free Text
Is the questionnaire complete? Click 'Yes' to close the report	• Yes • No	Single choice