

SHOT Toolkit

Acknowledgements

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Introduction to Haemovigilance in the UK

Haemovigilance may be defined as the systematic surveillance of adverse reactions and adverse events related to transfusion, and is aimed at improving safety throughout the transfusion chain from donor to patient.

Across the European Union, there is a legal commitment to submit data on Serious Adverse Reactions (SAR) and Serious Adverse Events (SAE) to the EU Commission, under the terms of the European Union Directive 2002/98/EC and Commission Directive 2005/61/EC. These directives have been transposed into UK law as the Blood Safety and Quality Regulations (SI50, 2005)

Within the UK, the **Medicines and Healthcare products Regulatory Agency (MHRA)** have been appointed as the 'Competent Authority' to oversee the regulations on behalf of the Secretary of State. In its regulatory role, the MHRA emphasis is upon the quality management system (QMS) in place in blood establishments and hospital transfusion laboratories, and its legislative remit extends to the point where the transfusion laboratory responsibility ends.

To make the reporting of adverse reactions and events more streamlined, the MHRA have developed a web-based reporting portal, called SABRE (Serious Adverse Blood Reactions and Events). Hospitals can notify and confirm incidents that have occurred, and provide the MHRA with evidence that the incidents have been discussed within risk management structures and 'corrective and preventative actions' have been put in place to lessen the likelihood of recurrence.

This portal is also used to submit reports to the Serious Hazards Of Transfusion (SHOT) scheme, and hospitals can print a summary of reports submitted to use as evidence of participation for compliance with NHSLA (NHS Litigation Authority) standards.

The MHRA has produced 2 guidance documents to help you decide what incidents require reporting and information and guidance on how to submit reports. These are:

- 'Background and Guidance on reporting Serious Adverse Events and Serious Adverse Reactions'
- 'SABRE – a User Guide'

These documents are available to download from www.shotuk.org or <http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Blood/index.htm>

Further information on the EU Directives, the MHRA, and the Operational Impact Group, an advisory panel set up to provide expert advice relating to interpretation of the BSQR by hospital transfusion laboratories may be found at;

<http://www.transfusionguidelines.org/index.aspx?Publication=REGS>

The **Serious Hazards of Transfusion (SHOT)** confidential reporting scheme was launched in 1996 following growing concern amongst UK transfusion specialists, haematologists and other clinicians that there was little information on the safety of the transfusion process (SHOT Report 1996-1997). It collects a wider scope of data than that of the MHRA, extending into the professional and clinical areas of transfusion practice.

SHOT is a professionally led, confidential, voluntary organisation that aims to collect anonymised reports from across the UK on adverse events related to transfusion of blood and blood components (red cells, platelets, fresh frozen plasma, cryoprecipitate, granulocytes), and more recently anti-D Immunoglobulin and cell salvage. All cases reported to SHOT are subject to expert scrutiny, to ensure that the data reported is accurate and comprehensive.

How does SHOT publish its results?

An annual report and a separate summary leaflet have been published each year by SHOT, in which several general and specific recommendations are made with the aim of improving transfusion safety. Recommendations are targeted at all relevant professional groups, including the Department of Health, through to each and every member of hospital staff involved in transfusion, as there is evidence of errors at all stages of the process. SHOT findings are used to:

- inform policy within transfusion services
- improve standards of hospital transfusion practice
- aid the production of clinical guidelines for the use of blood
- educate users on the hazards of transfusion and their prevention

Paper copies of reports and summaries are sent to key personnel within hospitals, but may also be downloaded as pdf files from the SHOT website www.shotuk.org

The website is an invaluable resource, containing useful material such as;

- access to previous years' reports
- Presentations given at National Events
- Current reporting criteria
- A toolkit of files and educational material
- Links to the MHRA, other countries' haemovigilance schemes and transfusion-related websites.

In addition, Tony Davies, SHOT Transfusion Liaison Practitioner and other SHOT staff are available to present at local hospital and regional meetings or to discuss specific aspects of SHOT reporting.

How is SHOT organised and run?

The strategic direction of SHOT is provided by a Steering Group with wide representation from Royal Colleges and professional bodies representing medical, nursing and laboratory staff as well as Health Service Managers.

The operational aspects of the scheme are the responsibility of a Standing Working Group, composed of transfusion specialists, and which is accountable to the Steering Group.

Funding for SHOT is provided by the four United Kingdom Blood Services (England, Wales, Scotland and N. Ireland) on a pro-rata basis according to the number of red cell units issued by each service.

Is participation in SHOT compulsory?

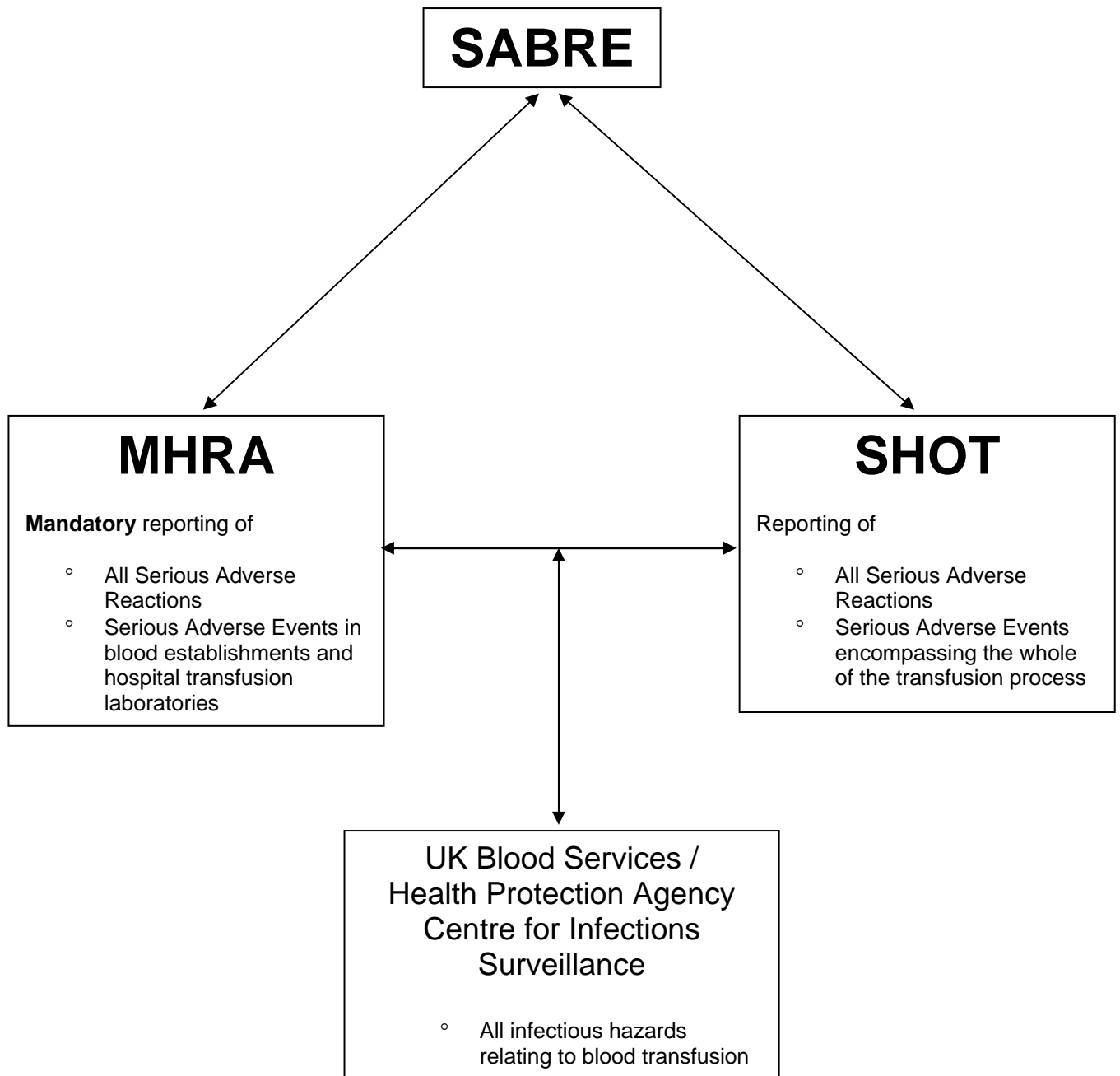
Participation in SHOT is currently not a statutory requirement. As it is not mandatory to report clinically based adverse incidents to the MHRA, there is some concern that these events may not be reported at all.

However, the Health Service Circular HSC 2007/001 Better Blood Transfusion requires participation in SHOT as one of its action points, and the NHSLA (NHS Litigation Authority, *previously CNST; Clinical Negligence Scheme for Trusts*) requires evidence of participation in SHOT as one of its standards. Clinical adverse events are mandatory to report under the Clinical Governance Framework and for Clinical Pathology Accreditation.

Perhaps more important than these imperatives is the professional and moral responsibility to gather the data and continue to learn and improve practice.

It is therefore vital that all hospitals, whatever their size, continue to report events to SHOT, in order to maintain the safety culture that we have established in the UK and to provide continuity of data for monitoring of important on-going blood safety initiatives.

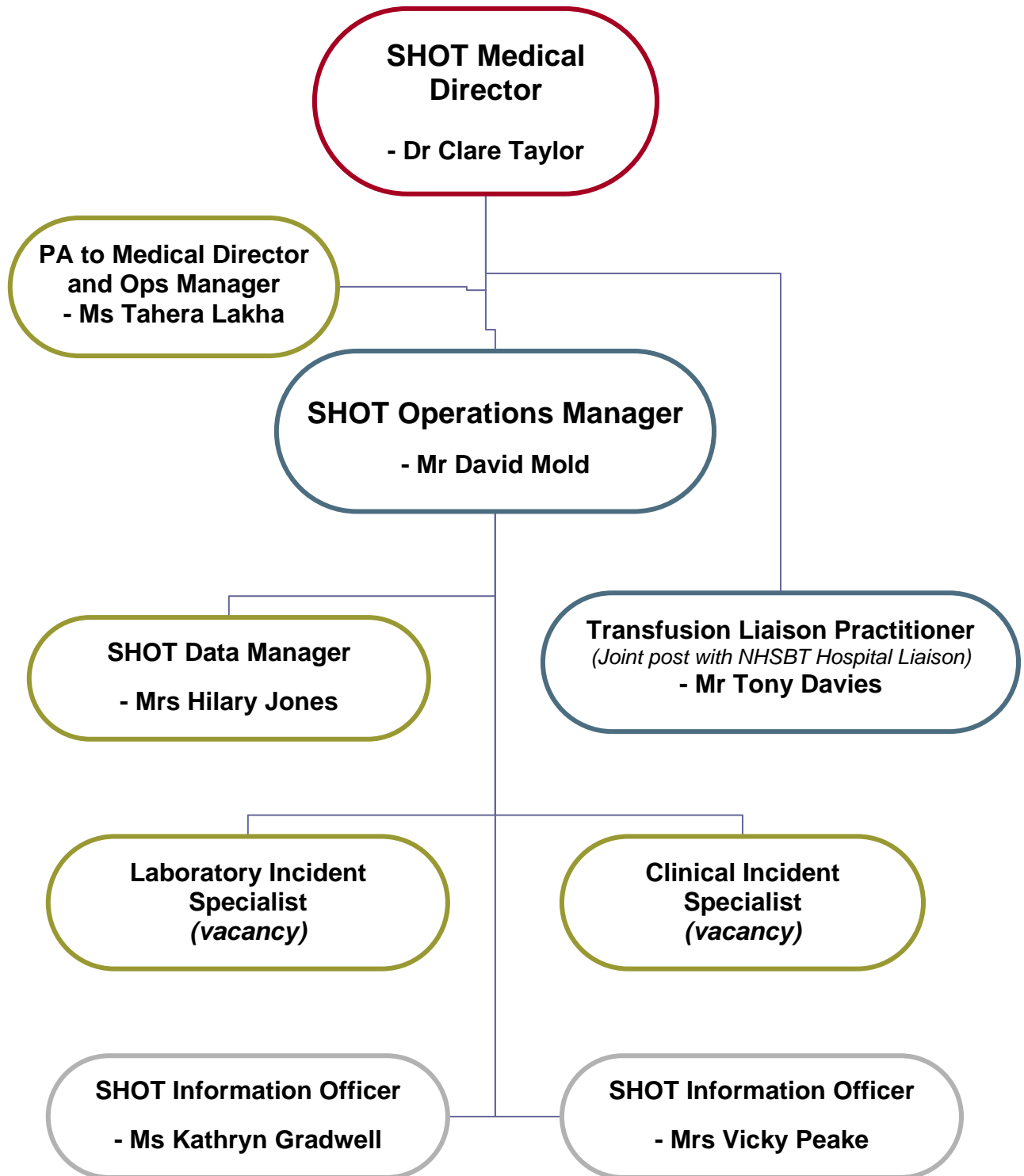
Overview of Haemovigilance reporting in the UK



Who can report incidents ?

At hospital level, adverse events should be reported to the Hospital Transfusion Team (HTT), usually comprising the Consultant Haematologist, Transfusion Laboratory Manager and Transfusion Practitioner. A designated member of the HTT will be registered with the MHRA as a reporter, and they will access the on-line SABRE reporting system at <https://aic.mhra.gov.uk/mda/sabresystem.nsf/Login?Open>

SHOT Structure
(as at August 2008)



Registration to SABRE

The SABRE log-in page is at; <https://aic.mhra.gov.uk/mda/sabresystem.nsf/Login?Open>

Registration is a simple process requiring only the completion of a straightforward online form on which you are asked to provide basic details of who you are, the name and type of organisation that you work for, and how you can be contacted. In this and the other sections of the form, there are certain fields that you must complete prior to submission. These **mandatory fields** are marked with a red asterisk.

Prior to registration there are several areas that hospital transfusion teams should consider:

1. For this system to work efficiently and allow review of reports sent to SABRE by members of the Hospital Transfusion Team, it is suggested that you approach your IT department to set up a group email i.e. htt@stelsewhere.nhs.uk. This will need to be an active email for receiving notification of registration. Should you find that this is not what your IT department would normally do, the Operational Impact Group has a letter to support Hospitals in their request to the IT Department - see <http://www.transfusionguidelines.org/index.asp?Publication=REGS&Section=23&pageid=791>
2. MHRA anticipate that many reporters will operate as part of a haemovigilance team and may therefore choose to register using a shared email address. For obvious reasons of security and confidentiality, we recommend that you take care to ensure that your chosen password is carefully guarded within your team.
It is vitally important that these mailboxes are checked regularly, as it has become apparent that important communications from the MHRA have not been read and actioned.
 - When registering you will need to submit one name as the primary reporter, but this does not prevent other members of the team reporting adverse reactions/events on behalf of the team, and when this occurs you will have the opportunity to enter your own name on the report submission.
 - If you are responsible for reporting incidents from more than one hospital you will need to either register with SABRE for each site separately (to do this you will need a separate email address for each) or register once for the main site and then each time you report something you must specify which hospital the incident occurred in, in the 'incident location' field – (do not enter ward names or clinical areas here).
3. When you have completed the Registration form, just click the *Submit* button to send your details to the Adverse Incident Centre (AIC). The AIC staff will then validate your request and send you an email containing your **Registration Number**. In certain circumstances the AIC may wish to speak to you in person as part of the validation process.
4. There are three pieces of information required for successful "Log In" to SABRE:
 - an **email address** (the one submitted on your registration request)
 - a **registration number** (notified to you by the MHRA Adverse Incident Centre)
 - your **Password** (chosen by you when registering)

It is important that these details are kept up to date to enable timely communications from the MHRA. If staff who are registered reporters leave, for example, it is easy to change details via the SABRE site.

Tips for completing the on-line forms

The MHRA has produced 2 guidance documents to help you determine what incidents need to be reported and information and guidance on how to submit reports. These are:

- 'Background and Guidance on reporting Serious Adverse Events and Serious Adverse Reactions'
- 'SABRE – a User Guide'

These documents are available to download either from www.shotuk.org or <http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Blood/index.htm>

- The "local reference number" is simply a number compiled by your hospital to identify the report in future i.e. St Elsewhere may set up their local number as SE (hospital initials) 05 (Year 2005) 001 (1st incident).
- Remember you can use 'cut and paste' techniques while on-line, to save having to re-write text.
- When reporting an incident do not try to 'Submit' it until you have completed all the necessary pages i.e. when you 'Create a new report', you will be led to complete a page called 'Report Source' asking for details on what type of incident it is. You then need to carry on and click on SAR, SAE and/or SHOT and complete these pages, before you can submit it.
- **For the sake of completeness of reporting, please always tick the 'report to SHOT' box if you are reporting a reaction or event to the MHRA**
- Do report the incident as soon as possible
- Do not 'confirm' SARs or SAEs until the investigation is complete.
- Do not click on the icons more than once as this causes duplication of records on the database. Please allow time for the system to load as you have requested.
- Help text is available throughout SABRE and can be accessed by clicking on the '?' in the relevant box/section/page.
- Two separate incident reports need to be completed if two patients are transfused following one error.
- In the box titled 'Description of incident' on the SHOT page, please give enough detail to enable the SHOT staff to decide which questionnaire to send for you to complete, including if the transfusion is given or not and if there was ABO incompatibility. Guidance on minimum datasets required may be found on pages 12 – 22.
- Completion of the information as requested will save valuable time in unnecessary follow-up calls

Please contact the SHOT Office or the MHRA if you require help or have any questions.

Some definitions

Serious Adverse Reaction (SAR)

“An unintended response in a donor or in a patient that is associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling or incapacitating, or which results in, or prolongs, hospitalisation or morbidity.”

Reportable to both MHRA and SHOT, regardless of where the error originated.

Serious Adverse Event (SAE)

“Any untoward occurrence associated with the collection, testing, processing, storage and distribution, of blood or blood components that **might** lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.”

Reportable to MHRA if within the responsibility of the blood establishment or hospital blood bank quality system – always copy to SHOT as well.

Adverse events involving only clinical staff, or involving a blood product such as anti-D Ig, are not reportable to MHRA, but are reportable to SHOT.

Major Morbidity – 2008 definitions

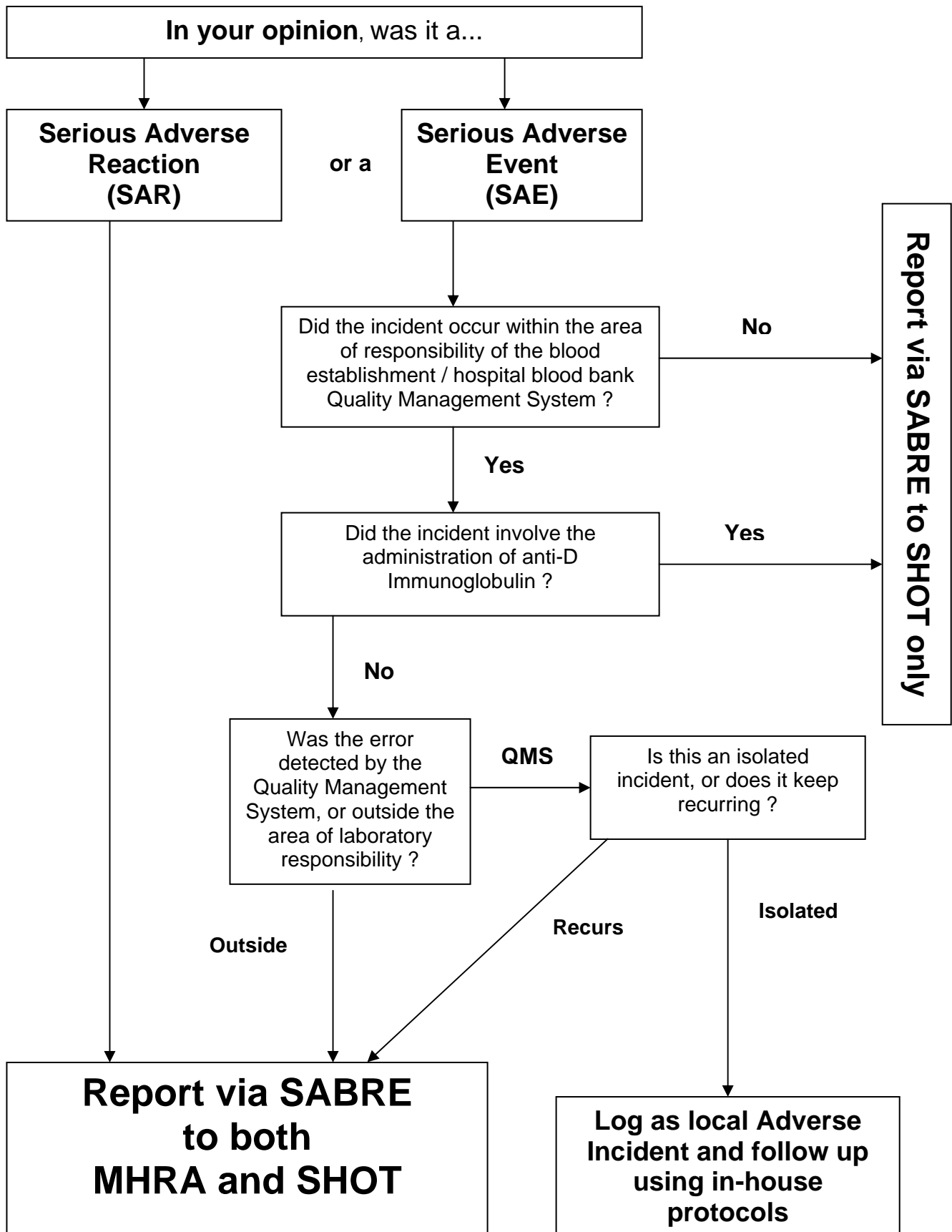
- Intensive care admission and / or ventilation
- Dialysis and / or renal impairment
- Major haemorrhage from transfusion-induced coagulopathy
- Evidence of Intravascular haemolysis
- Potential risk of anti-D sensitisation in a female of childbearing potential
- Persistent viral infection
- Acute symptomatic confirmed infection
- Reaction resulting in a low or high haemoglobin level of a degree sufficient to cause risk to life without immediate medical intervention

Imputability

MHRA defines imputability as ‘the **likelihood** that a serious adverse reaction in a recipient can be attributed to the blood component transfused’. (Not to be confused with severity of reaction)

- | | | |
|---|---|---|
| 0 | = | excluded / unlikely - the evidence is clearly in favour of attributing the reaction to other causes. |
| 1 | = | possible – the evidence is indeterminate for attributing the reaction to the blood or to alternative causes. |
| 2 | = | likely / probable – the evidence is clearly in favour of attributing the adverse reaction to the blood or the blood component. |
| 3 | = | certain – there is conclusive evidence beyond reasonable doubts attributing the adverse reaction to the blood or blood component. |

Is it reportable ?



Current SHOT Categories and What to Report

Incidents are classified under the following headings:

- Incorrect blood component transfused (IBCT)
- Anti-D administration
- Acute non-haemolytic transfusion reaction (ATR)
- Haemolytic transfusion reaction: acute and delayed (HTR)
- Transfusion associated graft-versus-host-disease (TA-GVHD)
- Transfusion-related acute lung injury (TRALI)
- Post-transfusion purpura (PTP)
- Transfusion transmitted infection (TTI)
- Transfusion associated circulatory overload
- 'Near miss' events
- "Right blood to right patient" (RBRP) events are included in the annual report for interest, but are not counted in the total number of cases.

The UK Cell Salvage Action Group has recently started to work with SHOT to develop a reporting questionnaire for adverse incidents relating to cell salvage. More information about the reporting pilot may be obtained from the SHOT Office.

The UK Cell Salvage Action Group was established in 2006 to help support the wider implementation of Intra-operative Cell Salvage as an alternative to donor blood, and to facilitate a UK approach to its use. Further information can be found within the Better Blood Transfusion Toolkit at;

<http://www.transfusionguidelines.org/?Publication=BBT&Section=22&pageid=1353>

The tables on the following pages show the active categories for reporting to SHOT during 2008.

1. IBCT – Incorrect blood component transfused

Category	Definition	What to report
IBCT (Incorrect or Inappropriate blood component transfused)	All reported episodes where a patient was transfused with a blood component or plasma product that did not meet the appropriate requirements or which was intended for another patient	This category currently includes: ‘Wrong Blood’ events where a patient received a blood component intended for a different patient, or of an incorrect group, including components of an incorrect group given to BMT/SCT or solid organ transplant patients Transfusion of blood of inappropriate specification or that did not meet the patient’s special requirements.
Inappropriate or unnecessary transfusions	These are cases in which the intended transfusion is carried out, and the component itself is suitable for transfusion and for the patient, but where the decision making is faulty	Prescription of components that are not required, or where another component or therapy would have been more clinically appropriate, or prescription at an incorrect dose or rate, or for an inappropriate indication
Handling and Storage errors	Transfusion of a correct component to an intended patient, when handling or storage errors may have rendered the component less safe for transfusion	‘Unsafe’ transfusion where there were handling or storage errors such as a component out of temperature control, or delay in completion of transfusion

Minimum Dataset for IBCT reports
Age and sex of patient
Where did the transfusion occur (E/D, Theatre, ICU, Ward, Community)
What time did the transfusion occur – is this in core hours / non-core hours
Was it an emergency or routine
What pre-transfusion testing methodology was used
What was the diagnosis / reason for the transfusion
What blood component did the patient receive
How many units / what volume of the component did the patient receive
Did the patient have a reaction – if so what happened
What laboratory investigations have been carried out in response to the incident
Did the patient require any further clinical intervention / medication
What was the outcome for the patient
Has the incident been discussed at risk management / HTC
Was there a policy / SOP in place to cover the process, and was it adhered to
What was the cause of the incident
Who was involved in the incident – profession / grade of staff
Did the staff involved normally work in the area where the incident occurred
Have there been any changes put in place as a result of this incident

1(b). RBRP – Right blood right patient

Category	Definition	What to report
RBRP (Right blood right patient)	Incidents where the right blood was transfused to the right patient despite one or more errors that should have led to the unit being rejected.	These incidents do not fit the definition for IBCT, but are nevertheless instructive and merit a sub-chapter in the annual report. They are not included in the overall numbers of IBCT cases

Minimum Dataset for RBRP reports
Age and sex of patient
Where did the transfusion occur (E/D, Theatre, ICU, Ward, Community)
What time did the transfusion occur – is this in Core hours / Non-core hours
Was it an emergency or routine
What pre-transfusion testing methodology was used
What was the diagnosis / reason for the transfusion
What blood component did the patient receive
How many units / what volume of the component did the patient receive
What was the outcome for the patient
Has the incident been discussed at risk management / HTC
Was there a policy / SOP in place to cover the process, and was it adhered to
What was the error
What check procedures failed in the detection of the error
Who was involved in the incident – profession / grade of staff
Did the staff involved normally work in the area where the incident occurred
Have there been any changes put in place as a result of this incident

2. ATR – Acute transfusion reaction

Category	Definition	What to report
ATR (Acute transfusion reaction)	<p>Reactions occurring at any time up to 24 hours following a transfusion of blood or components, excluding cases of acute reactions due to incorrect component being transfused, haemolytic reactions, transfusion-related acute lung injury (TRALI), transfusion-related circulatory overload (TACO) or those due to bacterial contamination of the component.</p> <p><i>N.B. It is very much a local clinical decision whether a simple febrile or allergic reaction is serious enough to report to SHOT (or MHRA). Factors that should be taken into account include whether supportive therapy beyond simple antipyretics or antihistamines was required, whether the transfusion was discontinued, or whether the reaction resulted in extended hospital stay for the patient.</i></p>	<p>Isolated febrile – a rise in temperature of > 1°C +/- minor rigors and chills. (see note)</p> <p>Minor allergic – skin +/- rash (see note)</p> <p>Anaphylactic/anaphylactoid – hypotension with one or more of: urticaria, rash, dyspnoea, angioedema, stridor, wheeze, pruritus, within 24 hours of transfusion.</p> <p>Severe allergic reaction – Severe allergic reaction with risk to life occurring within 24 hours of transfusion, characterised by bronchospasm causing hypoxia, or angioedema causing respiratory distress.</p> <p>Hypotension – a drop in systolic and/or diastolic pressure of >30mm Hg occurring within one hour of completing transfusion, provided all other adverse reactions have been excluded together with underlying conditions that could explain hypotension.</p> <p>Febrile with other symptoms/signs – rise in temperature of >1°C, with no features of an allergic reaction, but with one or more of myalgia, nausea, change in blood pressure or hypoxia.</p>

Minimum Dataset for ATR reports
Age and sex of patient
Where did the transfusion occur (E/D, Theatre, ICU, Ward, Community)
What time did the transfusion occur – is this in Core hours / Non-core hours
Was it an emergency or routine
What pre-transfusion testing methodology / materials were used
What was the diagnosis / reason for the transfusion
Had the patient been transfused / pregnant before this event
What blood component did the patient receive
How many units / what volume of the component did the patient receive
How long after commencement of the transfusion did symptoms / signs develop
What were the signs and symptoms of the reaction
What laboratory investigations have been carried out in response to the incident – what were the results
Did the patient require any further clinical intervention / medication
Was bacterial culture of the patient / pack performed
What was the outcome for the patient
Has the incident been discussed at risk management / HTC
Was there a policy / SOP in place to cover the process, and was it adhered to
What was the cause of the incident
Who was involved in the incident – profession / grade of staff
Did the staff involved normally work in the area where the incident occurred
Have there been any changes put in place as a result of this incident

3. HTR – Haemolytic transfusion reaction (acute or delayed)

Category	Definition	What to report
HTR (Haemolytic transfusion reaction) Acute	Acute HTRs are defined as fever and other symptoms / signs of haemolysis within 24 hours of transfusion; confirmed by a fall in Hb, rise in LDH, positive DAT and positive crossmatch.	Cases with relevant features (see definition) should be reported together with results of all laboratory investigations and antibody identification results if available.
HTR (Haemolytic transfusion reaction) Delayed	Delayed HTRs are defined as fever and other symptoms / signs of haemolysis more than 24 hours after transfusion; confirmed by one or more of: a fall in Hb or failure of increment, rise in bilirubin, positive DAT and positive crossmatch not detectable pre-transfusion. Simple serological reactions (development of antibody without positive DAT or development of haemolysis) are excluded.	Cases with relevant features (see definition) should be reported together with results of all laboratory investigations and antibody identification results if available. Cases will be included with no clinical or laboratory features as long as DAT is positive.

Minimum Dataset for HTR reports
Age and sex of patient
Where did the transfusion occur (E/D, Theatre, ICU, Ward, Community)
What time did the transfusion occur – is this in Core hours / Non-core hours
Was it an emergency or routine
What pre-transfusion testing methodology / materials were used
What was the diagnosis / reason for the transfusion
Had the patient been transfused / pregnant before this event
What blood component did the patient receive
How many units / what volume of the component did the patient receive
How long after commencement of the transfusion did symptoms / signs develop
What were the details of the reaction
What laboratory investigations have been carried out in response to the incident – what were the results
Have samples been sent to a reference centre – what was the outcome
Did the patient require any further clinical intervention / medication
What was the outcome for the patient
Has the incident been discussed at risk management / HTC
Was there a policy / SOP in place to cover the process, and was it adhered to
What was the cause of the incident
Who was involved in the incident – profession / grade of staff
Did the staff involved normally work in the area where the incident occurred
Have there been any changes put in place as a result of this incident

4. TRALI – Transfusion related acute lung injury

Category	Definition	What to report
TRALI (Transfusion related acute lung injury)	Acute dyspnoea with hypoxia and bilateral pulmonary infiltrates during or within six hours of transfusion, not due to circulatory overload or other likely cause.	Suspected cases should be discussed with a Blood Service Consultant, and reported if there is a high index of suspicion, even if serological investigation is inconclusive.

Minimum Dataset for TRALI reports
Age and sex of patient
Where did the transfusion occur (E/D, Theatre, ICU, Ward, Community)
What time did the transfusion occur – is this in Core hours / Non-core hours
Was it an emergency or routine
What pre-transfusion testing methodology was used
What was the diagnosis / reason for the transfusion
Had the patient been transfused / pregnant before this event
What blood component did the patient receive
How many units / what volume of the component did the patient receive
How long after commencement of the transfusion did symptoms / signs of TRALI develop
What were the details of the reaction
Did the patient have pre-existing acute lung injury or concomitant medical conditions
Did the patient require clinical intervention / medication
What was the outcome for the patient
What local investigations have been carried out in response to the incident – what were the results
Have samples been sent to a reference centre – what was the outcome
Has the incident been discussed at risk management / HTC
Was there a policy / SOP in place to cover the process, and was it adhered to
Have there been any changes put in place as a result of this incident

5. PTP – Post transfusion purpura

Category	Definition	What to report
PTP (Post transfusion purpura)	Thrombocytopenia arising 5 – 12 days following transfusion of red cells, associated with the presence in the patient of alloantibodies directed against the HPA (Human Platelet Antigen) systems.	Cases where the platelet count drops more than 50% following transfusion should be investigated and reported if complete or partial serological evidence is available.

Minimum Dataset for PTP reports
Age and sex of patient
Where did the transfusion occur (E/D, Theatre, ICU, Ward, Community)
What time did the transfusion occur – is this in Core hours / Non-core hours
Was it an emergency or routine
What pre-transfusion testing methodology was used
What was the diagnosis / reason for the transfusion
Had the patient been transfused / pregnant before this event – give details
What blood component did the patient receive
How many units / what volume of the component did the patient receive
How long was it since the implicated transfusion did symptoms / signs of PTP develop
What were the clinical features
Were there any other reasons for a low platelet count
Did the patient require clinical intervention / medication
What was the outcome for the patient
What local investigations have been carried out in response to the incident – what were the results
Have samples been sent to a reference centre – what was the outcome
Has the incident been discussed at risk management / HTC
Was there a policy / SOP in place to cover the process, and was it adhered to
Have there been any changes put in place as a result of this incident

6. TA-GvHD – Transfusion associated graft versus host disease

Category	Definition	What to report
TA-GvHD (Transfusion associated graft-versus-host disease)	Characterised by fever, rash, liver dysfunction, diarrhoea, pancytopenia and bone marrow hypoplasia occurring less than 30 days after transfusion. The condition is due to engraftment and clonal expansion of viable donor lymphocytes in a susceptible host.	All cases where diagnosis is supported by skin / bone marrow biopsy appearance or confirmed by the identification of donor-derived cells, chromosomes or DNA in the blood and/or affected tissues. Cases with a very high index of clinical suspicion.

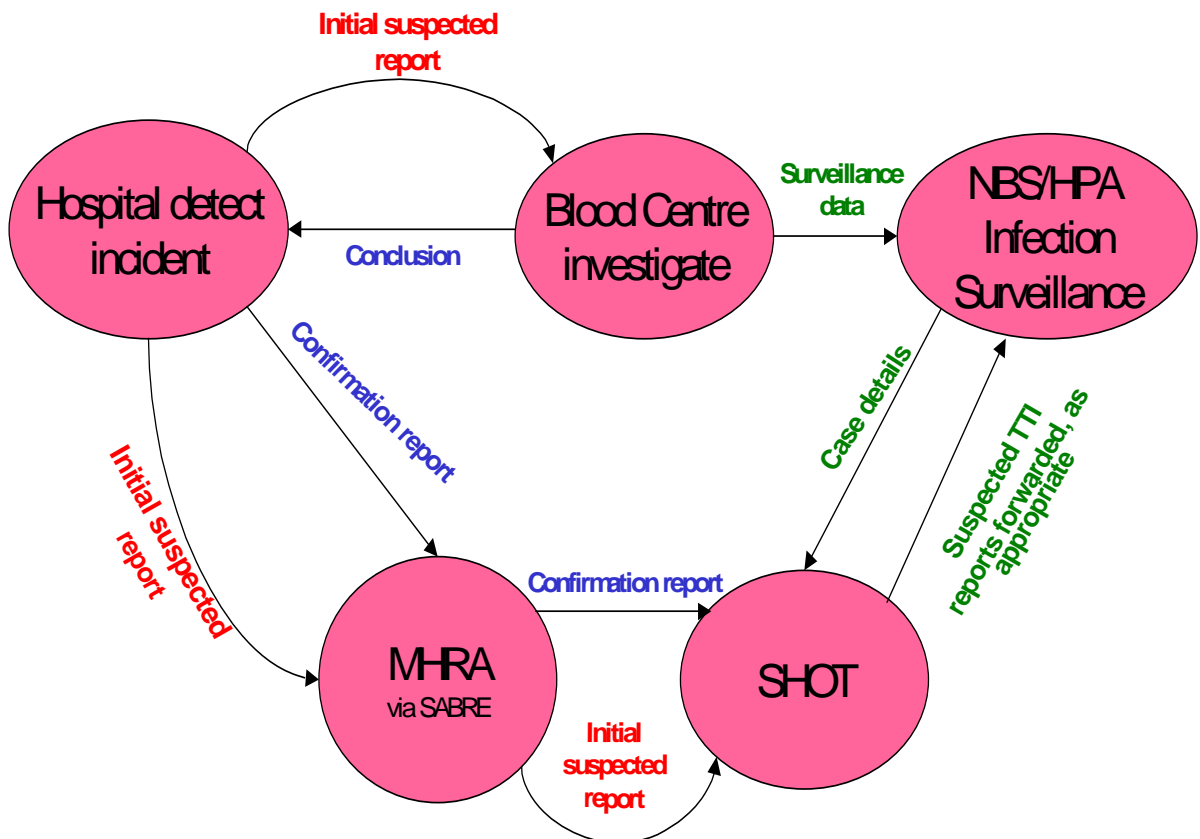
Minimum Dataset for TA-GvHD reports
Age and sex of patient
Where did the transfusion occur (E/D, Theatre, ICU, Ward, Community)
What time did the transfusion occur – is this in Core hours / Non-core hours
Was it an emergency or routine
What pre-transfusion testing methodology was used
What was the underlying diagnosis / reason for the transfusion
Does this diagnosis require irradiated components according to your protocol
Had the patient been transfused / pregnant before this event – give details
What blood component did the patient receive
Did the patient receive gamma-irradiated blood components
How many units / what volume of the component did the patient receive
How long was it since the implicated transfusion did symptoms / signs of TA-GvHD develop
What were the clinical features
Did the patient require clinical intervention / medication
What was the outcome for the patient
What local investigations have been carried out in response to the incident – what were the results
Have samples been sent to a reference centre – what was the outcome
Has the incident been discussed at risk management / HTC
Was there a policy / SOP in place to cover the process, and was it adhered to
Have there been any changes put in place as a result of this incident

7. TTI – Transfusion Transmitted Infection

Category	Definition	What to report
TTI (Transfusion-transmitted infections)	<p>Include as a TTI if, following investigation, the recipient had evidence of infection post-transfusion, and there was no evidence of infection prior to transfusion and no evidence of an alternative source of infection.</p> <p>Plus; Either at least one component received by the infected recipient was donated by a donor who had evidence of the same transmissible infection.</p> <p>Or at least one component received by the infected recipient was shown to contain the agent of infection.</p>	<p>Cases of bacterial transmission from blood components, where cultures from the patient's blood match cultures from the component bag and/or from the donor.</p> <p>Transmissions of viruses, whether routinely tested for by the blood services or not.</p> <p>Transmissions of other agents such as prions, protozoa and filaria.</p>

- As soon as transfusion transmitted infection is suspected, it **must** be reported to the issuing blood establishment so that the donor and any related blood components may be investigated.
- Report to the MHRA and SHOT.
- Do not confirm the report to the MHRA until the investigation is complete – it may turn out not to be a TTI, and a confirmed report can not be withdrawn.

The diagram below illustrates the mechanism for reporting suspected transfusion transmitted infections:



8. Events associated with administration of anti-D Ig

Category	Definition	What to report
Anti-D	Events relating to the administration of anti-D immunoglobulin.	<p>Reports in this section include:</p> <ul style="list-style-type: none"> ◦ Omission or late administration. ◦ Anti-D given to a D Positive patient or a patient with immune anti-D. ◦ Anti-D given to mother of a D Negative infant. ◦ Anti-D given to wrong patient. ◦ Incorrect dose of anti-D given. ◦ Anti-D given that was expired or out of temperature control.

Minimum Dataset for anti-D reports
Age and sex of patient
What category of event (<i>see table above</i>) occurred
Where did the administration (or failure to administer) occur (E/D, Theatre, Clinic, Ward, Community)
What time did the administration occur – is this in Core hours / Non-core hours
Was it an emergency or routine
What laboratory testing methodology was used – what were the results
What was the diagnosis / reason for the administration of anti-D Ig
How many weeks gestation was the patient
What dose of anti-D Ig did the patient receive / should the patient have received
Who issued the anti-D Ig
Was the anti-D Ig issued from the laboratory or kept as stock in the clinical area
Who prescribed and/or administered the anti-D Ig
Was the anti-D Ig issued in response to a sensitising event, post-natal, or routine ante-natal prophylaxis
Was the anti-D Ig administered after taking a sample for group & screen
Did the patient require clinical intervention
What was the outcome for the patient
What laboratory investigations have been carried out in response to the incident – what were the results
Have samples been sent to a reference centre – what was the outcome
Has the incident been discussed at risk management / HTC
What was the cause of the incident
Who was involved in the incident – profession / grade of staff
Did the staff involved normally work in the area where the incident occurred
Was there a policy / SOP in place to cover the process, and was it adhered to
Have there been any changes put in place as a result of this incident

9. TACO – Transfusion associated circulatory overload

Category	Definition	What to report
TACO (Transfusion associated circulatory overload)	Any four of the following occurring within six hours of transfusion: <ul style="list-style-type: none"> ◦ Acute respiratory distress. ◦ Tachycardia. ◦ Increased blood pressure. ◦ Acute or worsening pulmonary oedema. ◦ Evidence of positive fluid balance. 	A new questionnaire has been developed, which is not yet available on-line, but may be utilised in paper form for 2008. This will be sent out from the SHOT Office on receipt of a SABRE notification which fits the definition

Minimum Dataset for TACO reports
Age and sex of patient
Where did the transfusion occur (E/D, Theatre, ICU, Ward, Community)
What time did the transfusion occur – is this in Core hours / Non-core hours
Was it an emergency or routine
What was the underlying diagnosis / reason for the transfusion
Did the patient have any concomitant medical conditions
Had the patient been transfused in the 24 hours prior to onset of symptoms – give details
What blood component(s) / fluids did the patient receive
Who prescribed the transfusion
What was the prescribed rate / amount of transfusion
How many units / what volume of the component did the patient receive
How long from commencement of transfusion did symptoms / signs of TACO develop
What were the clinical features of the reaction
Did the patient require clinical intervention / medication
What was the outcome for the patient
What local investigations have been carried out in response to the incident – what were the results
Have samples been sent to a reference centre – what was the outcome
Has the incident been discussed at risk management / HTC
What was the cause of the incident
Who was involved in the incident – profession / grade of staff
Did the staff involved normally work in the area where the incident occurred
Was there a policy / SOP in place to cover the process, and was it adhered to
Have there been any changes put in place as a result of this incident

10. Near miss events

Category	Definition	What to report
Near miss events	Any event which, if undetected, could result in the determination of a wrong blood group, or issue, collection or administration of an incorrect, inappropriate or unsuitable component, but which was recognised before transfusion took place.	The first phase of the 2008 pilot has now been completed, with a further phase due in September, 2008. Results will be published once analysis is complete. Always ticking 'report to SHOT' on the SABRE reporting page ensures laboratory collection of Near Miss data as well as full reports

- SHOT are not analysing Near Miss reports during the current year, but will continue to accept reports submitted for future analysis.
- It is clear that many of the SAE reports submitted to MHRA would also be classified as SHOT Near Miss reports, so it is important that the 'Report to SHOT' box is ticked as well.
- Sample errors that are detected and rejected prior to testing by the laboratory are not classed as near misses and are not reportable.

Minimum Dataset for Near Miss reports
Age and sex of patient
Where did the error occur (E/D, Theatre, ICU, Ward, Community)
What time did the error occur – is this in Core hours / Non-core hours
Was the request an emergency or routine
What was the diagnosis / reason for the request
What blood component was involved
What testing methodology was used
How was the error detected
Who detected the error
What was the immediate impact of the error
Has the incident been discussed at risk management / HTC
Was there a policy / SOP in place to cover the process, and was it adhered to
What was the cause of the error
Who was involved in the incident – profession / grade of staff
Did the staff involved normally work in the area where the incident occurred
Have there been any changes put in place as a result of this incident

SABRE scenarios

	Scenario	Reportable as
1.	<p>Any component which has been issued from the laboratory and for whatever reason is available for collection even if it is not collected and any of the following are identified these should be reported as SAEs:</p> <ul style="list-style-type: none"> ▪ Expired units available for collection ▪ Labels transposed between units ▪ Incorrect component e.g. irradiated unit not supplied but known to the laboratory ▪ If the units above are transfused 	<p>SAE</p> <p>SAE</p> <p>SAE</p> <p>SAE + SHOT (IBCT)</p>
2.	Porter picks up blood for the wrong patient but has the correct details written down	SAE
3.	Porter picks up the right unit but for the wrong patient (ie clinical area supplied incorrect details)	Internal incident report
4.	<p>Blood issued correctly, packed in a transport box but left in the clinical area past the boxes validation time as stated in the protocol.</p> <p>If these units are administered and started after the time the box is validated for</p>	<p>SAE</p> <p>SAE + SHOT (IBCT)</p>
5.	Two patients on an oncology ward required transfusion. Patient 1 was Group O, Patient 2 was group A. Both units of blood were collected from the blood bank and checked on the ward away from the bedside. The units were inadvertently transposed by the nurse and transfused to the wrong patients. Patient 1, who was group O, and received group A blood, suffered a severe acute haemolytic transfusion reaction and required admission to ICU. Patient 2, who was group A and received group O blood, was unharmed.	<p>Patient 1 = SAR + SHOT (IBCT)</p> <p>Patient 2 = SHOT only (IBCT)</p>
6.	<p>A young woman was admitted through A&E with gastro-intestinal bleeding. An on-call BMS grouped her as D positive when, in fact, she was D negative. She had been grouped previously but because she was allocated an A&E number the previous record was unavailable.</p> <p>If she was transfused on the basis of this result</p> <p>If she was not transfused, but the incorrect result left the laboratory</p> <p>If the error was captured by the laboratory quality system</p>	<p>SAE + SHOT (IBCT)</p> <p>SAE</p> <p>Internal incident</p>

7.	<p>Blood was cross-matched for a patient undergoing liver transplantation on Friday 7th October and was placed in a satellite refrigerator in the liver unit. One of the units expired at midnight on Saturday 8th and the ICU had been warned by the lab that it was near expiry and should be used first. This blood was not used peri-operatively, but on Sunday 9th the patient's Hb had fallen to 6.5 g/dl and transfusion was prescribed. The expired unit was collected from the refrigerator and transfused. The patient did not suffer harm. If the laboratory is responsible for the remote storage facility</p> <p>If the clinical area is responsible for the remote storage facility</p>	<p>SAE + SHOT (IBCT)</p> <p>SHOT only (IBCT)</p>
8.	<p>A patient is admitted with a ruptured abdominal aortic aneurysm. A blood sample for crossmatch is sent to the lab. The on-call BMS uses a manual grouping technique and incorrectly groups the patient as AB instead of the correct group, O. He has no group AB blood available, so instead issues 4 units of group A, which are all transfused in theatre. During the operation the patient becomes hypotensive and develops Disseminated Intravascular Coagulation.</p>	<p>SAR + SHOT (IBCT)</p>
9.	<p>A patient is admitted to A&E from a hospice with gastro-intestinal bleeding. He is terminally ill with oesophageal cancer. The MO requests blood but takes the sample for crossmatch from the wrong patient. After the first 100 mL of blood the patient complains of loin pain, develops a fever and passes dark urine. The transfusion is stopped and on investigation the blood is found to be ABO incompatible. The patient develops renal failure and dies 3 days later – the certified cause of death was metastatic carcinoma.</p>	<p>SAR + SHOT (IBCT)</p>
10.	<p>A patient with acute leukaemia is admitted from the clinic for a platelet transfusion. During the transfusion she becomes acutely dyspnoeic and a chest X-ray shows a complete white-out. She is admitted to ICU and ventilated for 48 hours. She makes a complete recovery.</p>	<p>SAR + Blood Service + SHOT (TRALI?) <i>Do not send confirmation to MHRA until investigations complete</i></p>
11.	<p>Request made for 2 units of red cells for a patient on Fludarabine. The request is made for the units to be irradiated. The lab computer has marked against this patient the need for irradiated components. Two units issued but not irradiated. The patient received the 2 units with no apparent ill effect.</p> <p>Six weeks later the patient develops TA-GvHD confirmed by skin biopsy.</p>	<p>SAE + SHOT (IBCT)</p> <p>SAR + SHOT (TA-GvHD)</p>
12.	<p>Two units requested for patient with Non Hodgkins Lymphoma who is on oral Fludarabine. Information on request form = anaemia. No request for irradiated components, patient not known to the Laboratory Information Management System. Two units issued, transfused no ill effect. Two days post transfusion the consultant informed lab the patient should have received irradiated components. Marked for future on LIMS.</p>	<p>SHOT only (IBCT)</p>
13.	<p>A group received on a 28 year old female who is 26 weeks pregnant and admitted with Ante Partum Haemorrhage. The laboratory groups the sample as group O D negative, no irregular antibodies – 500 iu anti-D issued. The following day a repeat group received and grouped as O, D positive. A further sample was requested and confirmed as O positive. The original sample had been taken from the wrong patient.</p>	<p>SHOT only (anti-D)</p>

14.	Patient undergoing THR, post-op significant blood loss and unstable. Two units of blood requested and stored in theatre. One given in recovery, the 2 nd unit of blood up and running. When checked on handover – patient details found to be incorrect. Blood groups compatible. Patient wrongly identified from addressograph label.	SHOT only <i>BUT SHOT would need further detail before deciding whether this is IBCT or right blood to right patient.</i>
15.	Patient admitted for Coronary Artery Bypass Graft, orthopaedic operation 2 years previously and received transfusion elsewhere. No historical transfusion records. Two G+S samples Antibody screen negative. Blood issued by Electronic Issue. No immediate problems. Ten days post-op patient haemolysing with Hb 7 g/dL. Antibody screen and DAT now positive.	SAR + SHOT (HTR)
16.	Two units of blood requested for Ann Jones, date of birth 14/12/52. Lab used sample labelled Annie Jones, 14/12/02. The sample used was group A positive, the patient was O positive and received 2 units A positive with no apparent adverse outcome.	SAE + SHOT (IBCT)
17.	Unit of platelets required for prophylactic management in oncology patient thrombocytopenia. Platelets given, immediate fever, hypotension and shock. Blood and platelets cultured and were positive for <i>Staphylococcus aureus</i> .	SAR + Blood Service + SHOT (TTI)
18.	A patient is admitted with a ruptured abdominal aortic aneurysm. A blood sample for crossmatch is sent to the lab. The on-call BMS uses a manual grouping technique and incorrectly groups the patient as AB instead of the correct group, O. He has no group AB blood available, so instead issues 4 units of group A, which are all transfused in theatre. During the operation the patient becomes hypotensive. Massive bleeding is uncontrolled and he dies in the recovery room.	Consider symptoms to decide whether SAR or SAE Consider imputability level After full investigation of case review report type and imputability SAR or SAE + SHOT (IBCT)
19.	Unit of platelets given to day case patient for insertion of Hickman line. Platelets transfused and patient suffered a febrile reaction which required treatment and overnight stay. Platelets and patient sample cultured but no growth observed in either.	Estimation of seriousness of reaction is needed. If transfusion was not stopped and reaction cleared quickly with minimum treatment – Not reportable to either MHRA or SHOT If transfusion stopped and aggressive treatment given or if patient stayed in overnight for further treatment SAR + SHOT (ATR)

Contact Details

SHOT contact details

The SHOT office is based at the Manchester Blood Centre. Please contact them if you have any queries or questions and they will be happy to help if they can.

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- Further contact details for members of both the Steering Group and Standing Working Group may be found on the website at; www.shot-uk.org

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