Serious Adverse Blood Reactions and Events (SABRE)

User guide for mandatory haemovigilance reporting in the UK

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Contents

Overview ................................................................................................................................. 4

1 WHY – the legal framework in the UK ................................................................. 4
  1.1 UK legislation and the EU blood safety and quality directives .......... 4
  1.2 Reporting to the MHRA .............................................................................. 4
  1.3 Annual summary reports ......................................................................... 5
  1.4 Annual haemovigilance fees ................................................................. 6
  1.5 Confidentiality ....................................................................................... 6
  1.6 Reporting to SHOT (Serious Hazards Of Transfusion) ......................... 7

2 WHAT – legal definitions and guidance ....................................................... 7
  2.1 Serious adverse reactions (SAR) .......................................................... 7
  2.2 Serious adverse events (SAE) ............................................................... 8

3 HOW – using the SABRE online reporting system .................................... 12
  3.1 Help ..................................................................................................... 12
  3.2 Registration ......................................................................................... 12
    3.2.1 Updating registration details ......................................................... 12
  3.3 Log in .................................................................................................... 13
  3.4 Workspace ............................................................................................ 13
    3.4.1 Folder management .................................................................... 13
    3.4.2 Searching .................................................................................... 14
    3.4.3 Printing ....................................................................................... 14
  3.5 Report source ..................................................................................... 14
    3.5.1 Local incident reporting ............................................................. 14
    3.5.2 SHOT accessibility ..................................................................... 14
    3.5.3 Blood establishment notification ................................................. 15
    3.5.4 Reporting adverse incidents involving medical devices .......... 15
    3.5.5 Reporting adverse incidents relating to a licensed medicinal product 15
  3.6 Serious adverse reactions .................................................................. 16
    3.6.1 Notification report ......................................................................... 16
    3.6.2 Reaction types ............................................................................... 17
    3.6.3 Patient/donor information ........................................................... 17
    3.6.4 Confirmation report ..................................................................... 17
    3.6.5 Imputability levels ....................................................................... 18
  3.7 Serious adverse events .......................................................................... 18
    3.7.1 Notification report ......................................................................... 18
    3.7.2 Event categorisation ..................................................................... 19
    3.7.3 Confirmation report ..................................................................... 20
    3.7.4 Root causes .................................................................................. 20
    3.7.5 Corrective measures .................................................................... 20
    3.7.6 Referral to the MHRA inspectors and the haemovigilance expert panel 20
  3.8 Footnotes .............................................................................................. 21
    3.8.1 Attaching files ............................................................................... 21
  3.9 Saving/submitting reports .................................................................... 21
    3.9.1 Acknowledgements and reference numbers ......................... 21
  3.10 Logging out .......................................................................................... 21

4 Additional information .................................................................................. 22
  4.1 Troubleshooting .................................................................................... 22
Overview

The Department of Health has designated the Medicines and Healthcare products Regulatory Agency (MHRA) as the UK Competent Authority for blood safety. It is, therefore, the MHRA’s responsibility to ensure there is an accessible mechanism for the reporting and recording of serious adverse blood reactions and events. To facilitate this reporting requirement the MHRA has developed SABRE, an online system that allows the drafting, editing, saving and submission of notifications and subsequent confirmations of blood related adverse events and adverse reactions.

1 WHY – the legal framework in the UK

1.1 UK legislation and the EU blood safety and quality directives

The Blood Safety and Quality Regulations 2005 No. 50 [1] and the Blood Safety and Quality (Amendment) (No.2) Regulations 2005 No. 2898 [2] became effective for the purposes of regulation in the United Kingdom (UK) on 08 November 2005. These regulations implement the requirements of the following European Union (EU) directives:


Two further technical directives were adopted by the European Commission on 30 September 2005. These are:


These directives were transposed into UK legislation by the Blood Safety and Quality (Amendment) Regulations 2006 No. 2013 [7], which came into force on 31 August 2006.

The Blood Safety and Quality Regulations [7] apply to blood establishments and to hospital blood banks. The 2006 Amendment Regulations [7] introduce requirements for a quality system in blood establishments and hospital blood banks. They also extend traceability and record-keeping requirements to ‘facilities’ which may receive blood and blood components (care homes, independent clinics, hospitals and other NHS facilities and services, manufacturers of medicines and medical devices and biomedical research.)

1.2 Reporting to the MHRA

Directive 2005/61/EC [5] introduces the legal requirement for serious adverse reactions (SARs) and serious adverse events (SAEs) occurring within EU member states to be reported to the relevant Competent Authority. The Department of Health has designated the MHRA as the UK Competent Authority. It is, therefore, the MHRA’s responsibility to provide a mechanism for the reporting and recording of
these incidents. For this purpose the MHRA has developed the fully accessible online reporting system: SABRE (Serious Adverse Blood Reactions & Events).

Haemovigilance comprises organised surveillance procedures relating to serious adverse or unexpected events or reactions in blood donors or recipients, and the epidemiological follow-up of donors. The overall aim of this is to improve transfusion safety. The UK was one of the first countries to implement such a system and since 1996 the Serious Hazards of Transfusion (SHOT) scheme has successfully undertaken those aspects of haemovigilance relating to recipients. Implementation of the Directive 2005/61/EC [5] with the mandatory requirement for reporting to the MHRA has provided an opportunity to strengthen and further develop haemovigilance in the UK.

This document describes the requirements of the directives and also, in order to assist reporters of adverse events and reactions, includes guidance and flow charts to help identify what constitutes a serious adverse reaction and a serious adverse event and, therefore, what is or is not reportable to the Competent Authority (MHRA) under the Directive 2005/61/EC [5] and UK legislation [7]. However, this does not provide a definitive list of what does and what does not constitute a reportable incident. You may also need to contact the MHRA for advice. As a general rule, in cases of doubt, a report should be submitted.

1.3 Annual summary reports

Article 8 of Directive 2005/61/EC [5] and UK legislation [7] requires the Competent Authority to submit an annual report to the Commission, by 30 June of each year. The MHRA SABRE team will therefore ask each reporter to review and verify a summary of their reports for the preceding calendar year by the end of March the following year. For example, we will ask you to verify the summary of your 2010 reports by the end of March 2011. In order to provide an accurate record of overall transfusion activity in the UK you will be asked to submit data in the format shown in the table below.

<table>
<thead>
<tr>
<th>Report related to</th>
<th>SABRE summary report confirmed as accurate</th>
<th>Number of units issued</th>
<th>Number of recipients</th>
<th>Number of units transfused</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole blood</td>
<td>Yes/No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Red blood cells</td>
<td>Yes/No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Platelets</td>
<td>Yes/No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plasma (Including cryo precipitate)</td>
<td>Yes/No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (include granulocytes and buffy coats, but not blood products such as anti-D etc)</td>
<td>Yes/No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Events</td>
<td>Yes/No</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Notes**

Number of units issued = units distributed by blood establishments to the hospital blood banks + units issued by blood establishments directly for transfusion.

Number of recipients transfused = overall number of recipients transfused at least once over a period of one year.
Number of units transfused = the total number of individual units transfused over the reporting period independent of the number of hospitalisation episodes but including home transfusions.

1.4 Annual haemovigilance fees

Under the terms of The UK Blood Safety and Quality (Amendment) (No. 2) Regulations 2005 [2], paragraph (3B), the person who is responsible for the management of a hospital blood bank is required by law to ensure that the annual haemovigilance fee is paid to the Finance Division of the MHRA (acting on behalf of the Secretary of State).

Invoices are raised by the Finance Division of the MHRA and payment is required within 30 days.

The fee payable is reviewed annually.

Please note that a fee is payable for every blood bank within a trust. Where services are merged onto one central site it is important to advise us of this in writing so that we can ensure correct invoicing.

1.5 Confidentiality

Directive 2005/61/EC [5] traceability requirements and consequent UK legislation [7] also require that identifying information on donors and recipients should be recorded by blood establishments and by those to whom the blood or blood components may be delivered. However, this information is not required to be submitted to the MHRA as part of a notification or confirmation of a SAE or SAR. The link between any submitted report and the traceability records held by the reporting organisation will be made through a local incident reference number that you associate with your report and that you record on the report source section of the SABRE form. The local incident reference number can be any reference used to identify a report locally but must not be the patient ID number, NHS number, donation number, donor number or any other reference that can be linked directly to personal details.

Although SABRE provides a single starting point for reporting to both the MHRA and SHOT, the reporter is also able to choose to submit a report to only one organisation. Reports can be made in confidence i.e. a SHOT only report cannot be viewed by the MHRA. Similarly, the user must specify if MHRA reports are to be made available to SHOT for review.

Any personal data that has been supplied in your registration or in your submitted reports of adverse events or reactions will be held on our database and will be used in accordance with the Data Protection Act [8]. This could be for statistical analysis, management, planning or in the provision of services by the Agency. The MHRA will treat all personal information as confidential. Whilst details of reported events or reactions may be disclosed, personal identifying details of patients and/or reporters will not.

Since 01 January 2005 the Freedom of Information Act [9] obliged the MHRA to respond to requests for information which it holds and is recorded in any form, and creates a right of access to that information. The Agency will carefully consider its obligations to SABRE reporters under the Act prior to any release or non-release of information.
If you are concerned that, as a result of having disclosed information, you may be penalised by your employer or that your actions may lead to your dismissal you may wish to consider whether the provisions of The Public Interest Disclosure Act (‘PIDA’) [10] will protect your employment position.

PIDA protects workers who make a protected disclosure of information, concerning certain types of matters relating to their employment, from being dismissed or penalised by their employers as a result of the disclosure. The Act also has the effect of making confidentiality clauses unenforceable where there is a protected disclosure.

1.6 Reporting to SHOT (Serious Hazards Of Transfusion)


Active participation in SABRE and SHOT by all hospitals was recommended by the chief medical officer for England in his 2007 annual report. A number of blood safety initiatives depend on continuity of SHOT data for monitoring and evaluation and it is therefore important that reporters use the SABRE system to initiate a report to SHOT at the notification stage. Reporters should select either ‘Share this report with SHOT’ or select the ‘SHOT only report’ box. SABRE will then prompt the SHOT Dendrite database to create a record for you and to send you an automated email link to the database. You will then be asked to log in separately to the SHOT Dendrite system and complete their online form.

Please refer to the SHOT Dendrite database user manual for details of how and what to report to SHOT. Alternatively, contact the SHOT office on 0161 423 4208.

2 WHAT – legal definitions and guidance

2.1 Serious adverse reactions (SAR)

Definitions
All italicised quotes are from the UK legislation [7].
A serious adverse reaction (SAR) is:

‘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’

‘blood establishments and the person responsible for the management of a hospital blood bank shall notify the Secretary of State (Competent Authority) of any serious adverse reactions observed during or after transfusion which may be attributable to the quality or safety of blood or blood components –

(i) collected, tested, processed, stored or distributed by the blood establishment, or (ii) issued for transfusion by the hospital blood bank’
International Society of Blood Transfusion (ISBT) definitions, clinical and laboratory features of reaction types.

The table in Annex A reproduces the ISBT’s internationally agreed definitions of the serious adverse reactions terms listed in annex II, part D (annual notification format for serious adverse reactions) of Directive 2005/61/EC [5]. The use of ISBT terms has been agreed by a working party of the EU Commission and aims to facilitate the comparison of the information sent to the Commission from all EU Competent Authorities.

2.2 Serious adverse events (SAE)

Definitions
All italicised quotes are from the UK legislation [7].
A serious adverse event (SAE) is:

‘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.’

Reporting requirements
‘Blood establishments shall notify… any serious adverse events related to the collection, testing, processing, storage and distribution of blood or blood components by the blood establishment which may have an influence on their quality and safety, and;

‘the person responsible for the management of a hospital blood bank shall notify… any serious adverse events related to the collection, testing, processing, storage and distribution of blood or blood components by the hospital blood bank which may have an influence on their quality and safety,’

Distribution
‘the act of delivery of blood and blood components to other blood establishments, hospital blood banks and manufacturers of blood and plasma derived products. It does not include the issuing of blood or blood components for transfusion’

The following terms, though used, are not defined in the Directive 2005/61/EC [5]. Reporters in the UK should be guided by the following definitions to help in determining the need to report an SAE.

‘Collection’ means the collection of whole blood or apheresis components from the donor.

‘Testing’ means the mandatory or discretionary testing of the donation by the blood establishment. It also includes tests done by the blood bank on processed components or the recipient sample to determine compatibility. Note: for SABRE reporting the event category ‘testing of donations’ should only be used by blood establishments. For laboratory testing errors use the event category ‘other’.

‘Processing’ means manipulation of the blood donation or other blood components for further manufacturing or subsequent administration to humans.
Note: for SABRE reporting the event category ‘processing’ should only be used by blood establishments. For laboratory processing errors use the event category ‘other’.

‘Storage’ means safe management of the blood at all stages of the cold chain and is undertaken by blood establishments and also by hospital transfusion laboratories. Blood leaves the control of the hospital transfusion laboratory at the point where it is issued for transfusion or transferred to a satellite refrigerator that is not within the control of the laboratory (it is arguable that all blood storage refrigerators should be within laboratory control).

**EU Commission definitions of reportable SAEs**
The table in Annex B [link] provides examples of serious adverse events and how they should be classified according to the proposed format in annex III, part C (Annual notification format for serious adverse events) of the Directive 2005/61/EC [5]. The use of these examples has been agreed by a working party of the EU Commission and aims to facilitate the comparison of the information sent to the Commission from all 28 Competent Authorities.

The table in Annex C provides some worked examples of what is and is not reportable to the MHRA as an SAE.
Has there been a reaction in a recipient whilst receiving blood or blood components?

Yes

Might the reaction have been related to the quality and safety of the blood/blood component transfused?

No → No report required

Yes

Was the reaction serious? i.e. fatal/life-threatening/disabling/incapacitating, resulting in or prolonging hospitalisation or morbidity?

No → Report to SHOT only

Yes

Submit notification report via SABRE as soon as known
- Include components involved
- Details of symptoms (in 'Further Detail')
- Suspected reaction type (select from pick list)
- Imputability (likelihood that the transfused component was the cause of the reaction)
  Indicate whether the blood establishment has been informed if suspected TTI or TRALI

Yes

Undertake and complete local investigation (ideally within 30 days of notification)

Yes

Submit confirmation report
- Verify details already submitted or amend as required
- Specify clinical outcome of the reaction (not the outcome for the patient)
  Provide brief details of reasons for selection of imputability level.

Note: Reports which are not confirmed and closed by the MHRA within 3 months of initial notification are likely to be referred to MHRA inspectors. If investigations are likely to take more than 3 months then please ensure this is indicated via a footnote.
Figure 2 SABRE reporting flow chart for serious adverse events (SAE)

Has there been an adverse event which occurred within the organisation’s scope of responsibility as monitored by their quality management system?

- Was the adverse event associated with the collection, testing, processing, storage or distribution of blood or blood components, or might it result in the provision of inappropriate components for clinical use?
  - No → Not an SAE—local incident report
  - Yes → Did the quality system highlight the adverse event at the time it was made?
    - Yes → Is this an isolated adverse event?
      - No → Is this a repeated adverse event which shows a significant weakness in the quality system?
        - Yes → SAE – report to MHRA via SABRE
          - i) Might the adverse event have lead to death or life-threatening, disabling or incapacitating conditions or result in, or prolong hospitalisation or morbidity (even those not directly involved in the event)?
          - ii) Did the adverse event result in the loss of rare or irreplaceable components, or the loss of a significant quantity of unmatched components?
          - iii) Could the event seriously jeopardise the blood transfusion system?
            - No → SAE – report to MHRA via SABRE
              - Submit a Notification report via SABRE as soon as known
                - select the event type - where within the system the adverse event occurred
                - specify the type of error
                - state the implicated component
                - provide ‘further details’ as appropriate
              - Undertake and complete local investigations and implement corrective measures (ideally within 30 days of notification)
              - Submit confirmation report with details of root cause analysis and corrective measures
              - NOTE: Reports which are not confirmed and closed out by the MHRA within 3 months of initial Notification are likely to be referred to MHRA Inspectors. If investigations are likely to take more than 3 months then please ensure this is indicated via a Footnote.
            - Yes → SAE – report to MHRA via SABRE
          - Yes → SAE – report to MHRA via SABRE
            - i) Might the adverse event have lead to death or life-threatening, disabling or incapacitating conditions or result in, or prolong hospitalisation or morbidity (even those not directly involved in the event)?
            - ii) Did the adverse event result in the loss of rare or irreplaceable components, or the loss of a significant quantity of unmatched components?
            - iii) Could the event seriously jeopardise the blood transfusion system?
              - No → SAE – report to MHRA via SABRE
            - Yes → SAE – report to MHRA via SABRE
              - i) Might the adverse event have lead to death or life-threatening, disabling or incapacitating conditions or result in, or prolong hospitalisation or morbidity (even those not directly involved in the event)?
              - ii) Did the adverse event result in the loss of rare or irreplaceable components, or the loss of a significant quantity of unmatched components?
              - iii) Could the event seriously jeopardise the blood transfusion system?
                - No → SAE – report to MHRA via SABRE
                - Yes → SAE – report to MHRA via SABRE

MHRA SABRE user guide December 2010
3 HOW – using the SABRE online reporting system

SABRE can be accessed via the MHRA website: www.mhra.gov.uk. The system is secure and provides access only to registered users. Once registered, users have access to an electronic report form and to a workspace containing a library of their previously drafted and/or submitted reports. Draft reports can be edited online and may have electronic files (e.g. images, documents) attached for submission.

3.1 Help

Online help is available at every stage and every level when using SABRE. Not only does every page (registration, log in etc) and every section of the report form have general help text (accessed via a button at the top of the page), but each individual item on those pages has its own help information (accessed by clicking the help icon adjacent to that item).

Practical advice on the use of SABRE is available by email (sabre@mhra.gsi.gov.uk) or by telephone from the SABRE Helpdesk on 020 3080 7336.

3.2 Registration

Before using SABRE you must first register with the MHRA SABRE helpdesk. From your internet browser go to http://www.mhra.gov.uk and select the red ‘SABRE – Report an adverse blood reaction/event’ link on the right hand side of the screen.

Registration is a simple process requiring 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 we can contact you. 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.

You are also asked to create and enter a password of your choice. This will be used each time you wish to log in to SABRE.

When you have completed the registration form, just click the ‘submit’ button to send your details to the SABRE helpdesk. A member of the SABRE team will then validate your request and send you an email containing your registration number. In certain circumstances staff on the helpdesk may wish to speak to you in person as part of the validation process.

The MHRA anticipates that many reporters will continue to operate as part of a haemovigilance team and may therefore choose to register using a shared email address. The MHRA recommends this approach. It will, however, still be possible for reporters to register individually. 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, but that it is accessible to more than one person so that reports can always be made as soon as possible even in the event of sickness or absence of the main reporter.

3.2.1 Updating registration details

You can change your password, email address, office address or telephone number. Simply log in to SABRE using your existing registration details and from your workspace click the ‘Update Registration’ button from the top navigation bar. Amend your details as necessary and submit.
If you change your email address, your original account will be temporarily suspended pending validation of the new one by the SABRE team. Until the account has been reactivated, you will not be able to log in using either your old details or your new ones.

3.3 Log in

Simply enter these three items and click ‘LogIn’
- an email address (the one submitted on your registration request)
- a registration number (sent to you by the MHRA SABRE helpdesk)
- your password (chosen by you when registering).

If you have forgotten your password then please call the SABRE helpdesk to have it reset.

3.4 Workspace

After successfully logging in, your workspace will be displayed.

The workspace serves two primary functions:

- as a searchable library of all your draft and submitted reports
- as the platform from which you can
  > create a new report
  > open, read, and/or edit an existing report
  > search the content of all draft and submitted reports and their attachments
  > create folders so that you can organise and manage your reports.

On your first visit your workspace will be empty. Each time you save a draft or submit a report (whether a notification or a confirmation, an event or a reaction, or a SHOT only report) identifying details of that report will appear in the workspace.

Your workspace is not visible to the MHRA or SHOT.

The columns of summary information in the workspace are clearly labelled. The icons that will appear on the left hand side describe the type of report and its status. The icons contain the letters N, C or S.

N identifies a notification, C a confirmation, and S a SHOT only report.

The yellow background colour indicates the report’s current status as draft, and the blue background indicates that you have submitted that report.

There are columns containing key identifying information from your notification and confirmation, and a separate column to indicate, where relevant, the date you requested a link to SHOT.

If you add a footnote to a submitted report, a letter F will also appear in that report’s workspace record (see section 3.8 on footnotes).

3.4.1 Folder management
SABRE allows you to organise and store your reports in folders. You can create folders and sub-folders using the folder manager option that is available from your workspace. All folders are displayed alphabetically. You can name and rename folders and also delete them – although you cannot delete the reports they contain.
You do not have to use the SABRE folders facility but, as the number of reports in your workspace increases, you may find that it will help you organise your workspace and make it more manageable.

There is an online help text for this section that will guide you through the creation and management of folders. Further assistance can be obtained from the SABRE helpdesk.

3.4.2 Searching
SABRE incorporates an internal search facility that is accessible from the workspace. This allows you to search the content of all saved reports and questionnaires – whether they have been submitted or are still in draft form.

3.4.3 Printing
Each section within SABRE includes a button at the top of the screen that enables you to access a ‘Printer Friendly Version’ of your form should you need a hard copy for your local records.

If you encounter difficulties printing reports then this may be due to the version of Internet Explorer in use. We suggest you try using the File > Print option from your main tool bar or alternatively cut and paste the information into a separate Word document and then print that.

3.5 Report source

Much of this section of the report form will be pre-populated by SABRE with information submitted on your registration form.

The MHRA anticipates that many reporters will operate as part of a haemovigilance team and that you may therefore choose to register using a shared email address. The MHRA recognises that in those circumstances the person completing a report form may not be the registered SABRE user. For this reason the reporter name and email fields in this section remain editable, i.e. if you are not the person in whose name the registration was made, you can enter your own name and contact details. This will ensure that any communications from the MHRA or SHOT are directed to the correct person.

3.5.1 Local incident reporting
Your local incident reference number is also required in this section. This (coupled with the MHRA reference number assigned upon submission of your completed report form) is vital in avoiding potential confusion between incident reports. The local incident reference number can be any reference used to identify a report locally but must not be the patient ID number, NHS number, donor number or any other reference that can be linked directly to personal details.

The MHRA is very keen to ensure that reporting to SABRE does not interfere with, or replace, existing local reporting systems (e.g. local risk management reporting systems). To ensure that you are able to advise your colleagues promptly and clearly when you submit a report form, SABRE allows you to enter email addresses for report copies. Any email address correctly entered will receive an electronic copy of your report when you click submit. You may find this useful for ensuring that colleagues, including local risk managers, clinical governance leads etc, are kept aware of your reports of such events and reactions. If more than one email address is entered, each must be separated by a comma.

3.5.2 SHOT accessibility
You are also required to indicate whether you wish SHOT to have access to your report. MHRA recommends that you tick ‘Yes’. You will then be sent an email link to the SHOT Dendrite database. However, please note that any additional details you submit in this report cannot be viewed by MHRA.

In circumstances where the incident observed is not reportable to MHRA (e.g. clinical errors where a patient was not harmed), you should report to SHOT Only. If you tick this box you will be sent a link to the SHOT Dendrite database only and your report cannot be viewed by MHRA.

3.5.3 Blood establishment notification
As well as indicating whether you have made a local report, you must also indicate whether you have submitted a report to the relevant blood establishment. This is of particular importance in TTI (transfusion transmitted infections) and TRALI (transfusion related acute lung injury) cases, or in any other circumstances where it is possible that the blood establishment will have to take prompt action to ensure the safety of blood or blood components that have been distributed elsewhere.

3.5.4 Reporting adverse incidents involving medical devices
Reporters are also reminded that adverse incidents involving failures or problems with medical devices (e.g. blood bags, syringes and needles, blood testing kits, refrigerated blood storage, blood salvage devices, irradiators, etc.) should also be reported to the MHRA Adverse Incident Centre – preferably using the appropriate online system.

Further information on this aspect of incident reporting may be obtained from the Adverse Incident Centre (telephone: 020 3080 7080) or from guidance documents on adverse incident reporting available on the MHRA website: www.mhra.gov.uk

3.5.5 Reporting adverse incidents relating to a licensed medicinal product
The Yellow Card Scheme is run by the MHRA and the Commission on Human Medicines (CHM), and is used to collect information from health professionals and the general public on suspected side effects or adverse drug reactions (ADRs) to a medicine. Its continued success depends on the willingness of people to report suspected ADRs.

We collect Yellow Card reports from anyone in the UK on both licensed and unlicensed medicines including:
- prescription medicines
- blood products such as anti-D, IVIg and Octaplas
- vaccines
- over-the-counter (OTC) medicines
- herbal remedies
- swine flu antiviral medicines (Tamiflu or Relenza)
- swine flu vaccines (Pandemrix, made by GSK or Celvapan, made by Baxter).

The easiest and quickest way to report adverse drug reactions (ADRs) is to complete the electronic Yellow Card form on www.yellowcard.gov.uk. Full instructions for registering and completing the form are given on the website. You can keep track of all the Yellow Cards that you send and easily submit updated information if necessary. Alternatively Yellow Cards are also available:
- by downloading a pdf copy from our website to print out
- by writing to: MHRA, CHM Freepost SW2991, London SW8 5BR
- by emailing: pharmacovigilance@mhra.gsi.gov.uk
- from the British National Formulary (BNF)
- from the ABPI Medicines Compendium
- from the MIMS Companion.
3.6 Serious adverse reactions

3.6.1 Notification report

The first decision you have to make as a reporter is whether the incident you are reporting was serious i.e. was it associated with the collection or transfusion of blood or blood components and was it fatal, life-threatening, disabling or incapacitating, or did it result in or prolong hospitalisation or morbidity.

Then you need to decide if you are reporting a serious adverse event (SAR) or a serious adverse reaction (SAE) – and to tick the appropriate box. If you tick event, then only the event section will be accessible for completion.

Similarly, if you tick reaction, only that section will be available. This and the local reference number comprise the minimum information that must be entered before you can save a draft report.

If you ticked serious adverse reaction (SAR) on the report source section, SABRE will automatically allow you access to this section and the serious adverse event (SAE) section will not be available. Your report will automatically be submitted as a notification only report. If you already have all the information required to complete your report it is possible to change the report type to notification and confirmation and submit both at the same time.

Notifications of SARs should be submitted to the MHRA as soon as possible.

Confirmations should be submitted as soon as possible after you have collated all the required information and your local investigation is complete. Where your report has been made available to SHOT, both the MHRA and SHOT recommend that you take appropriate account of the SHOT analysis of the incident when concluding your local investigation. The MHRA will send email reminders to reporters where a confirmation report has not been received within a reasonable time period. The time allowed will vary according to the nature of the reaction reported, but is generally one month.

Remember – SABRE allows you to save reports in draft whilst you collect the information required to complete all sections of the report form.

The SAR section has been designed by the MHRA primarily to collect only that data required by the EU haemovigilance system. In order to collect this data in a consistent manner suitable for summary analysis across Europe, standard picklists are provided for a number of areas. You will be required to choose from these lists when reporting:

- which blood component the serious adverse reaction is related to
- type of serious adverse reaction
- imputability level
- clinical outcome

Donors For serious adverse reactions of a donor, the blood establishment must notify the Competent Authority only where the quality and safety of the blood may be compromised.
3.6.2 Reaction types
These are:

- Immunological haemolysis due to ABO incompatibility
- Immunological haemolysis due to other allo-antibody
- Non-immunological haemolysis
- Transfusion-transmitted bacterial infection
- Anaphylaxis / hypersensitivity
- Transfusion related acute lung injury (TRALI)
- Transfusion-transmitted viral infection (HBV)
- Transfusion-transmitted viral infection (HCV)
- Transfusion-transmitted viral infection (HIV-1/2)
- Transfusion-transmitted viral infection, other (specify)
- Transfusion-transmitted parasitical infection (Malaria)
- Transfusion-transmitted parasitical infection, other (specify)
- Post-transfusion purpura
- Graft-versus host disease
- Other serious reaction(s) – specify (e.g. transfusion associated circulatory overload (TACO), transfusion associated dyspnoea (TAD), febrile non-haemolytic reactions (FNHTR) and uncategorised unintended responses)

NOTE: Please only select a reaction type from this list – listing symptoms is not appropriate in this field, but should be supplied under ‘Further details’ along with the results of any follow-up tests undertaken as part of the transfusion reaction investigation.

For ISBT definitions with clinical and laboratory features of reaction types please see Annex A.

3.6.3 Patient/donor information

Although some patient or donor information is required, this is only age and gender. Your local records will, of course, require further detail for fulfilling traceability requirements.

3.6.4 Confirmation report

When completing the confirmation section you must first indicate whether you are the person that submitted the Notification. If not, you will be asked to enter your own name and contact details.

Next you must indicate whether your original assessment was correct: i.e. which component type was implicated, whether there was a serious adverse reaction and whether that reaction was correctly described in the notification (and, if not, what the reaction actually was). You must also report the clinical outcome.

Please note that this relates only to the clinical outcome of the reaction. Deaths associated with a patient’s underlying condition or any other cause should not be included. Therefore, if the eventual outcome for the patient is death but the cause of death is not due to the transfusion reaction, then the clinical outcome of the reaction is most likely to be either complete recovery, minor sequelae or serious sequelae – please select an option from the pick list.

Death should only be selected as a reporting option where the patient failed to recover from the transfusion reaction before dying. In these instances the imputability level will
assign the likelihood that the reaction can be attributed to the transfused blood or blood component.

If any associated components, products or reagents were required to be recalled and/or investigated as a result of the serious adverse reaction, the report should also include explicit reference to their fate and to any subsequent actions taken to ensure the future safety of the supply chain.

Lastly, a further assessment of the imputability level is required, as your assessment may have altered following review of the results of your local investigation. Where the final imputability level is 2 or 3, a report of your local investigation is required. Where the imputability level is considered to be <= 1, it is useful to explain to what else the reaction could be attributed.

### 3.6.5 Imputability levels

Imputability means the likelihood that a serious adverse reaction in a recipient can be attributed to the blood or blood component transfused or that a serious adverse reaction in a donor can be attributed to the donation process. The table below defines the imputability levels:

<table>
<thead>
<tr>
<th>N/A</th>
<th>Not assessable</th>
<th>When there is insufficient data for imputability assessment.</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Excluded</td>
<td>When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to causes other than the blood or blood components.</td>
</tr>
<tr>
<td></td>
<td>Unlikely</td>
<td>When the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood or blood components.</td>
</tr>
<tr>
<td>1</td>
<td>Possible</td>
<td>When the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood or blood components.</td>
</tr>
<tr>
<td>2</td>
<td>Likely</td>
<td>When the evidence is clearly in favour of attributing the adverse reaction to the blood or blood component.</td>
</tr>
<tr>
<td>3</td>
<td>Certain</td>
<td>When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood or blood component.</td>
</tr>
</tbody>
</table>

When you have completed the notification and/or confirmation sections and you are satisfied that all the information provided is both correct and complete, you should click Submit to send the Report to the MHRA.

### 3.7 Serious adverse events

#### 3.7.1 Notification report

If you ticked serious adverse event (SAE) on the report source section, SABRE will automatically allow you access to this section and the serious adverse reaction (SAR) section will not be available. The system takes you directly to the notification only section but if you already have all the information required for both notification and confirmation you can change the report type in order to submit both at the same time.

Notifications of SAEs should be submitted to the MHRA as soon as possible. Consistently late submission of reports is an indicator of problems within the quality
management system and may prompt referral to the MHRA’s Inspection, Enforcement and Standards Division.

Remember – SABRE allows you to save reports in draft whilst you collect the information required to complete all sections of the report form.

The SAE section has been designed by the MHRA primarily to collect only the data that are required by the EU haemovigilance system. In order to collect the data in a consistent manner suitable for summary analysis across Europe, standard pick-lists are provided for a number of areas. You will be required to choose from these lists when reporting:

- where within the system the serious adverse event occurred
- specification of the serious adverse event.

Clear definitions and explanations of all the terms used in this section of the form and in the pick lists are available in the SABRE online help text.

Annex B gives examples of serious adverse events and how they should be classified according to the proposed format in annex III, part C (annual notification format for serious adverse events) of Directive 2005/61/EC [5].

**3.7.2 Event categorisation**

Under the terms of Directive 2005/61/EC [5] the activities of hospital blood banks are limited to storage, distribution (to external satellite sites only) and other (serious failures of the quality management system). Sites which process blood and blood components (e.g. irradiation process) will need to be registered as blood establishments and may also report processing errors.

The clinical act of transfusion is outside the scope of the Directive 2005/61/EC [5] which applies only up to the issue of the blood component for transfusion. Therefore a serious adverse event occurring at the bedside before, during or after a transfusion (e.g. phlebotomy, administration of a blood component or use of an infected needle) is **not** reportable under the Directive 2005/61/EC [5].

Based on the above, an SAE concerning ABO or other blood group incompatibility should be reported only if it originates from: a mistake concerning blood or blood components exclusively for transfusion (i.e. **not** the intended recipient's blood sample collected by phlebotomy or finger sticks) **and** which occurred within the blood establishment or hospital blood bank.

SAEs that occur within the hospital blood bank scope of responsibility as monitored by their quality system (i.e. training of staff, security of equipment and premises, adherence to policies and procedures) should be reported when one or more of the following criteria apply:

- inappropriate blood/blood components have been issued/distributed for clinical use, even if not used
- the adverse event resulted in the loss of any irreplaceable autologous blood/blood component (e.g. rare blood group) or any highly matched (i.e. recipient specific) allogeneic blood/blood component
- the adverse event resulted in the loss of a significant quantity of unmatched blood or blood components
- the adverse event could have implications for other patients or donors because of shared practices, services, supplies or donors (i.e. repeated event inside or outside the BE/HBB)
• the adverse event could have a significant impact on the blood transfusion system e.g. by jeopardising the confidence of blood donors or recipients in the system.

Although there is a space for patient or donor information (age and gender) this is not mandatory as the blood or blood component involved may not have reached a patient. The MHRA does not need or want patient or donor identifying information (e.g. patient/hospital identification number or name) to be reported on SABRE.

3.7.3 Confirmation report
When completing the confirmation section you must first indicate whether you are the person that submitted the notification. If not, you will be asked to enter your own name and contact details.

Next you must indicate whether your original assessment was correct i.e. whether there was a serious adverse event and whether that event was correctly described in the notification (and, if not, what the event actually was).

3.7.4 Root causes
You must also provide what is described in the legislation as a ‘root cause analysis’. What the MHRA requires here is simply details of the outcome of your local investigation into the SAE with evidence that as far as possible all root causes and contributory factors have been considered. This should help ensure that corrective and preventative measures are targeted effectively.

Serious adverse events are most frequently caused by human error. It is important that you do not report this as the root cause but investigate further into why the error was made e.g. distraction, recent process change, lack of knowledge/training, complexity of task etc.

3.7.5 Corrective measures
Finally, you are required to provide details of any corrective measures and preventative actions taken as a result of your investigation. Again you should provide information to explain what immediate action has been taken to deal with the serious adverse event and then explain what processes have subsequently been implemented to ensure that the situation does not recur; e.g. an expired unit of blood has been discovered, recalled and discarded and in future units due to expire at midnight will be held in the laboratory stock fridge and will only be issued up to 8 pm for immediate use.

3.7.6 Referral to the MHRA inspectors and the haemovigilance expert panel
Some reports may be referred to the MHRA Inspection, Enforcement and Standards division (IE&S) for further action where we are concerned that there may be a risk to patient safety e.g.

- death due to ABO incompatible transfusion
- multiple pre-transfusion testing errors
- recurrent failures of the quality management system/ineffective corrective and preventative actions
- late reports
- unusual recalls due to processing errors
- persistent issuing of wrong components.

Complex or unusual reports may be referred to the MHRA haemovigilance expert panel for their consideration and advice.
3.8 Footnotes

Once you have submitted a completed report form, the submitted sections are assigned read only status – you can review them but you cannot alter the content. If, however, you wish to submit some additional comments or information that cannot wait until the confirmation report is submitted, or if the confirmation report has already been submitted, then you may use the SABRE footnote facility. More than one footnote may be attached to a report. Attachments may also be made to footnotes.

3.8.1 Attaching files
Several parts of the report form are mandatory fields – you are required to enter information (by typing or ‘pasting’) or to choose from a pick list. However, the MHRA recognises that where you are asked for ‘further details’, for details of your local investigation, for information on any corrective action taken, or for an imputability report - it may be easier for you to attach a copy of an existing, locally produced, document.

At each stage of the reporting process, whether you are preparing a notification or a confirmation, SABRE allows you to attach a file to the form. This is done in the same way as you would attach a file to an email: you can browse through the files on your local system, and then click to attach the one you wish to submit. You may also add a descriptive comment to clarify the nature of the file.

3.9 Saving/submitting reports

When you have completed the notification and/or confirmation sections and you are satisfied that all the information provided is both correct and complete, you should click submit to send the report to the MHRA.

3.9.1 Acknowledgements and reference numbers

As soon as you submit your completed report form, SABRE will provide you with an electronic acknowledgement and an automatically generated, unique MHRA reference number. This number should be quoted in any correspondence or dialogue about your report, whether with the MHRA or with SHOT. The MHRA recommends that you cross-reference the MHRA reference number with your local records.

The reference number will appear in this format: 2010/011/008/HV1/001

It shows, from left to right, the year, month and day that the report is submitted. This is followed by an indicator that the report was submitted online via SABRE, and a sequential number for all reports submitted on that day.

The reference number is automatically entered onto the saved report form and onto the workspace listing, and is retained when a confirmation report is submitted. The same numbering system is used for SHOT only reports.

3.10 Logging out

It is important that you remember to log out after every session. Failing to log out may cause difficulties on the next occasion that you (or your colleagues) log in.
4 Additional information

4.1 Troubleshooting

Reports of serious adverse events and serious adverse reactions should only be submitted to the MHRA via SABRE. Other means of submission should only be considered if SABRE is temporarily unavailable and the report is urgent. In such cases the MHRA Adverse Incident Centre should be contacted for guidance on how to report.

Enquiries, advice and feedback

MHRA
Tel: 020 3080 7336
email sabre@mhra.gsi.gov.uk

SHOT
Tel: 0161 423 4208  Fax: 0161 251 4395
email shot@nhsbt.nhs.uk
## Annex A ISBT table of reportable serious adverse reactions (SARs)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Immunological Haemolysis due to ABO incompatibility</strong></td>
<td>Fever, chills/rigors, facial flushing, chest pain, abdominal pain, back/flank pain, nausea/vomiting, diarrhoea, hypotension, pallor, jaundice, oligoanuria, diffuse bleeding, dark urine, decreased haemoglobin levels. Reactions may occur within 24 hours (acute) or may not manifest for up to 28 days (delayed)</td>
<td>Haemoglobinaemia, haemoglobinuria, decreased serum haptoglobin, unconjugated hyperbilirubinaemia, increased LDH and AST levels. Blood group serology shows ABO incompatible mismatch between recipient and donor.</td>
</tr>
<tr>
<td><strong>Immunological Haemolysis due to other allo-antibody</strong></td>
<td>As above.</td>
<td>As above but blood group serology shows either allo-antibodies to donor red cells or auto-antibodies in the recipient.</td>
</tr>
<tr>
<td><strong>Non-immunological haemolysis</strong></td>
<td>As above</td>
<td>As above but due to non-immunological, possibly mechanical factors such as malfunction of a pump or blood warmer, or the use of hypotonic solutions etc.</td>
</tr>
<tr>
<td><strong>Transfusion-transmitted bacterial infection.</strong></td>
<td>Fever, rigors and joint pain with no evidence of symptoms pre-transfusion or alternative source of infection.</td>
<td>Positive blood cultures from recipient and donor pack (matching organisms) or at least one component received by the infected recipient shown to contain the agent of infection.</td>
</tr>
<tr>
<td><strong>Anaphylaxis/hypersensitivity</strong></td>
<td>Mucocutaneous signs and symptoms including urticaria, rash, pruritus, localised angioedema, oedema of lips, tongue, uvula and conjunctiva with airway compromise or severe hypotension requiring vasopressor treatment (or associated symptoms like hypotonia, syncope). Respiratory symptoms may be laryngeal (throat tightness, dysphagia, dysphonia, hoarseness, stridor) or pulmonary (dyspnoea, cough, wheezing/bronchospasm, hypoxemia) Usually occurs during or very shortly after transfusion.</td>
<td>Rising mast cell tryptase levels or IgA deficiency and/or anti-IgA in the recipient.</td>
</tr>
<tr>
<td><strong>Transfusion related acute lung injury</strong></td>
<td>Hypoxaemia (PaO₂/FIO₂ &lt; 300 mm Hg or O₂ sats &lt;90% on room air), bilateral infiltrates on frontal chest X-ray, no evidence of TACO, no temporal relationship to an alternative risk factor for ALI during or within 6 hours of completion of transfusion. Usually acute onset.</td>
<td>Evidence of anti-HLA or anti-HNA antibodies in recipient with incompatibility between donor and recipient.</td>
</tr>
<tr>
<td><strong>Transfusion-transmitted viral</strong></td>
<td>Include if the recipient shows</td>
<td></td>
</tr>
<tr>
<td>Infection Type</td>
<td>Definition</td>
<td></td>
</tr>
<tr>
<td>-----------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Transfusion-transmitted viral infection (HBV)</td>
<td>Evidence of infection post-transfusion and there was no evidence of infection prior to transfusion or any alternative source of the infection, <strong>PLUS either</strong> at least one component received by the infected recipient was shown to contain the agent of infection or <strong>at least one component received</strong> was donated by a donor who has evidence of the same transmissible infection.</td>
<td></td>
</tr>
<tr>
<td>Transfusion-transmitted viral infection (HCV)</td>
<td>As above</td>
<td></td>
</tr>
<tr>
<td>Transfusion-transmitted viral infection (HIV 1/2)</td>
<td>As above</td>
<td></td>
</tr>
<tr>
<td>Transfusion-transmitted viral infection - other</td>
<td>As above</td>
<td></td>
</tr>
<tr>
<td>Transfusion-transmitted parasitical infection (Malaria)</td>
<td>As above</td>
<td></td>
</tr>
<tr>
<td>Transfusion-transmitted parasitical infection – Other, specify</td>
<td>NOTE: All suspected TTIs must be reported to the Blood Services as a matter of urgency.</td>
<td></td>
</tr>
<tr>
<td>Post transfusion purpura</td>
<td>Bruising, severe haemorrhage, oozing wounds. Usually occurs 5-12 days post transfusion. Thrombocytopenia (5-12 days post transfusion) and anti-HPA antibodies present.</td>
<td></td>
</tr>
<tr>
<td>Graft versus host disease</td>
<td>Fever, rash, liver dysfunction, diarrhoea. Usually occurs 1-6 weeks after transfusion. Pancytopenia, characteristic histological appearances on bone marrow biopsy, bone marrow hypoplasia, chimerism.</td>
<td></td>
</tr>
<tr>
<td>Other serious reaction(s) - specify</td>
<td>E.g. Febrile non haemolytic transfusion reactions (FNHTR) where fever &gt;= 39 °C oral or equivalent and a change of &gt;= 2 °C from pretransfusion value, chills, rigors, headache, nausea. Usually occurs within 4 hours of transfusion and without any evidence of haemolysis, bacterial contamination or underlying condition. E.g. Transfusion associated circulatory overload (TACO) – acute respiratory distress, tachycardia, increased blood pressure, acute or worsening pulmonary oedema on frontal chest x-ray, evidence of positive fluid balance. Usually occurs within 6 hours of completion of transfusion. E.g. Transfusion associated dyspnea (TAD) – respiratory distress occurring within 24 hours of transfusion but without the symptoms of TRALI, TACO or allergic reactions and not explained by any underlying condition.</td>
<td></td>
</tr>
</tbody>
</table>
## Annex B Table of reportable serious adverse events (SAE)

<table>
<thead>
<tr>
<th>Specification</th>
<th>Equipment failure</th>
<th>Human error</th>
<th>Other (specify)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Serious adverse event, affecting quality and safety of blood component due to a deviation in:</strong></td>
<td>Serious adverse event which is mainly linked to a failure of the equipment. <strong>Equipment:</strong> any material used at any stage from the collection to the distribution of blood and blood components, such as whole blood collection machines, blood bags, aphaeresis kits and machines, production sets, reagents, test kits, bags for platelets or plasma storage, filters for leukocyte reduction, labelling machines, IT systems, etc. <strong>Note:</strong> Failures of the equipment – whether or not causing a Serious Adverse Event - should also be reported under the devices reporting procedure (e.g. pack check reveals a faulty seal and bag is discarded during processing: not a SAE but should be reported under the device reporting procedure).</td>
<td>Serious adverse event which is mainly linked to a human error. <strong>Human error:</strong> An inappropriate or undesirable human decision or behaviour that reduces, or has the potential for reducing, effectiveness, quality, safety, or system performance. It can be e.g. an omission: (forgetting to do something, or just leaving it out), a commission (performing an act incorrectly), a problem in sequence (right action, wrong order) or timing (too fast or too slow).</td>
<td>Any serious adverse event which cannot be classified in the already listed specifications.</td>
</tr>
<tr>
<td><strong>Definitions</strong></td>
<td>Serious adverse event which is mainly linked to a defect of the blood or blood components. <strong>Product defect:</strong> blood or blood component which does not meet the quality and safety requirements set in annex V of the Directive 2004/33/EC [4], or which contain (remaining) contaminating agents despite screening, testing and processing having been undertaken properly (e.g.: product discarded after positive infection test result following a window period). <strong>Example:</strong> Clotting factor rates not compliant with specifications for fresh frozen plasma.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

MHRA SABRE user guide December 2010
Annex C To report or not to report – worked examples

* please note in the following examples, if a transfusion resulted in a serious transfusion reaction, these would be reported as SARs, regardless of whether it would have been an SAE or not.

<table>
<thead>
<tr>
<th>Event</th>
<th>Decision</th>
<th>Reasoning</th>
</tr>
</thead>
<tbody>
<tr>
<td>a</td>
<td>Not an SAE</td>
<td>Although the error relates to the storage of the components, the error occurred in the clinical area. These errors are not covered by the Blood Safety and Quality Regulations. However, since the process of sending blood to the clinical areas is controlled by the blood bank the local investigation should consider how this can be improved.</td>
</tr>
<tr>
<td>b</td>
<td>Report as an SAE</td>
<td>The act of transfusing the blood inappropriately is still a clinical error and not reportable. However, the process of providing the blood to the clinical area is controlled by the blood bank. The process is not robust enough to prevent inappropriate components being transfused. Therefore the lack of a robust system is the adverse event. The adverse event is: associated with storage; was not highlighted by the QS at the time of the event; was discovered after the units had been issued; and might have led to harm.</td>
</tr>
<tr>
<td>c</td>
<td>Not an SAE</td>
<td>The blood bank has carried out their procedure to the letter. The only error that has occurred is clinical.</td>
</tr>
<tr>
<td>d</td>
<td>Report as an SAE</td>
<td>Again, the act of transfusing the inappropriate blood is not the reportable adverse event. The failure of the blood bank to carry out their procedure ‘allowed’ the inappropriate blood to be transfused, and this is the reportable adverse event. The adverse event is: associated with the storage; was not highlighted by the quality system; occurred after the blood was issued; and might have harmed the patient.</td>
</tr>
<tr>
<td></td>
<td>A sample was received in the blood bank with the patient’s name misspelled (sample and request form mismatch), but this was discovered immediately and the sample was rejected.</td>
<td>The blood bank quality system has highlighted a clinical error. The clinical error is not reportable.</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>f</td>
<td>A sample was received in the blood bank with the patient’s name misspelled (sample and request form mismatch), but this was discovered when the components were being labelled.</td>
<td>Not an SAE</td>
</tr>
<tr>
<td>g</td>
<td>A sample was received in the blood bank with the patient’s name misspelled (sample and request form mismatch), but this was discovered when the components were being labelled. This is the second occurrence within a month.</td>
<td>Not an SAE unless workload is small</td>
</tr>
<tr>
<td>h</td>
<td>A sample was received in the blood bank with the patient’s name misspelled on both form and sample. It was a new patient and the blood bank had no historical records. The error was not spotted at the bedside until after the first unit had been transfused.</td>
<td>Not an SAE</td>
</tr>
<tr>
<td>i</td>
<td>A sample was received in the blood bank with the patient’s name misspelled (sample and request form mismatch). The error should have been spotted in the blood bank in accordance with the local sample acceptance protocol, but was not discovered until incorrectly labelled blood was at the bedside.</td>
<td>Report as an SAE</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td><strong>j</strong></td>
<td>Midwife administers anti-D in error to a patient who is Rh positive</td>
<td>Not an SAE (report to SHOT)</td>
</tr>
<tr>
<td><strong>k</strong></td>
<td>A laboratory transcription error has resulted in a pregnant woman’s Rh group being recorded as Rh negative instead of Rh positive. As a result anti-D is issued in error and highlighted by the midwife.</td>
<td>Report as an SAE</td>
</tr>
<tr>
<td><strong>l</strong></td>
<td>A patient was admitted to A&amp;E and was incorrectly linked to the patient record of a different person. A sample was taken and labelled with the incorrect details and sent to the blood bank. There were no historical records for this patient and blood was issued and transfused.</td>
<td>Not an SAE</td>
</tr>
<tr>
<td><strong>m</strong></td>
<td>A patient was admitted to A&amp;E and was incorrectly linked to the patient record of a different person. A sample was taken and labelled with the incorrect details and sent to the blood bank. There were historical blood group records for this patient, but the blood bank failed to spot the blood group mismatch, ignored the warnings on the LIMS system and blood was issued and transfused. No transfusion reaction was occurred.</td>
<td>Report as an SAE</td>
</tr>
<tr>
<td><strong>n</strong></td>
<td>A 2 unit crossmatch request was received in the laboratory for a patient with anaemia. The request form indicated no other clinical details or special requirements. This was a new patient and there were no historical records. Non-irradiated group specific units were electronically issued and transfused.</td>
<td>Not an SAE</td>
</tr>
</tbody>
</table>
The laboratory was subsequently advised that this patient had lymphoma and required irradiated blood components.

A 2 unit crossmatch request was received in the laboratory. The request form indicated that the patient had NHL and was being treated with Fludaribine, however no special requirements were indicated. The laboratory SOP states that all patients with these clinical details should have a serological crossmatch and be given irradiated blood components. Non-irradiated group specific units were electronically issued and transfused.

Although there has been a clinical/admin error in not completing the request form correctly, there has still been a failure of the QMS as the local SOP has not been followed. This led to an inappropriate component being issued and transfused. The adverse event: resulted in the provision of inappropriate components to the clinical area; was not highlighted at the time the error was made; was highlighted by chance (i.e. not by blood bank quality system); and might have harmed the patient.
References


12 NHS Litigation Authority. Clinical Negligence Scheme for Trusts http://www.nhsla.com

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