UK Haemovigilance

User guide for mandatory and professionally mandated haemovigilance reporting in the UK

Contents

Overview and aims

The MHRA and SHOT (Serious Hazards of Transfusion) have collaborated to improve haemovigilance reporting by producing an integrated single SHOT and MHRA incident reporting process by linking the SABRE and SHOT online reporting systems.

The main aims of this system are:

a. A reporting system that avoids duplication of reporting, by the reporter, whilst maintaining the reporter's regulatory and professionally mandated obligations to report, as defined under the Blood Safety and Quality Regulations 2005 (as amended) (BSQR), to the competent authority and to SHOT.

b. Maintain MHRA as the UK's competent authority (CA) for Serious adverse reaction (SAR) and Serious adverse event (SAE) reporting.

c. Provide a system that maximises the clinical scrutiny of reports, by SHOT, to ensure that they are correctly classified and imputability ratings identified as directed by BSQR.

d. Ensure that the data collected accurately reflect the number, type and imputability score of all UK SAR and SAE reports annually.

e. That both MHRA and SHOT have the appropriate access to the reporter for clarification of SAR and SAE data.

f. Maintain the legal requirement that ALL SARs and SAEs must be reported to the CA as soon as known.

This guide provides the legal framework for reporting all haemovigilance incidents in the UK and guides the reporter through the keys steps for reporting on SABRE and the SHOT online reporting systems.

1 WHY – the legal framework in the UK

1.1 UK legislation and the blood safety and quality regulations

Quality and safety of human blood and blood components from 1 January 2021

From 1 January 2021, you should continue to work to the same quality and safety standards as you do now. You will not need to change your current practice.

This is because the UK will maintain the existing quality and safety standards for the collection, testing, processing, storage and distribution of human blood and blood components.

Before importing or exporting blood and blood components from the EU, Norway, Iceland or Liechtenstein you should consult with the MHRA.
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.

The Blood Safety and Quality Regulations apply to **blood establishments** and to **hospital blood banks**. The 2006 Amendment Regulations [3] 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.) Further additional amendments to the BSQR have been made to incorporate minor changes and amendments to fees. Collectively they are referred to as the Blood Safety and Quality Regulations 2005 (as amended).

1.2 Reporting to the MHRA and SHOT

The reporting requirements for MHRA and SHOT are similar but not the same. These requirements are detailed below. The joint reporting system is designed to allow reporters to report all incidents which need to be reported to either MHRA or SHOT. Reports which are not required by either organisation can be excluded or withdrawn as appropriate.

This document will assist reporters in knowing how and when to report adverse events and reactions. It also includes guidance to help identify what constitutes a serious adverse reaction and a serious adverse event and, therefore, what is or is not reportable to the CA. However, this document 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 and/or SHOT for advice. In cases of doubt, a report should be submitted.

To ensure that all SAR reports are captured and classified correctly SHOT and the MHRA have combined their efforts to produce a single reporting arrangement which is detailed below.

1.3 Annual summary reports

The CA is required to submit an annual report to the UK Competent Authority by 30 June of each year to include all reports for the 12 month period January to December of the preceding year. The MHRA haemovigilance team will generate and email a summary report, or a nil-report, to each reporter to review in January each year. In addition to the summary data, each reporter is required to complete a table notifying the CA of the number of units of each component issued, the number of recipients and the number of units transfused. Once completed, this must be returned before March 31.

1.4 Annual haemovigilance fees

The Regulation 22 of the BSQR requires fees to be payed to the CA for maintenance of the haemovigilance reporting system. These fees are required to be paid by the person who is responsible for the management of a hospital blood bank or a blood establishment. As the fees are payable by the person responsible for the management of the hospital blood bank, this means they are the responsibility of the Chief Executive of the hospital trust, or the responsible officer of a private organisation. Where transfusion activities are undertaken by a 3rd party provider, it is the trust's responsibility to make local arrangements for payment to the MHRA. The MHRA will not directly invoice the 3rd party provider.

Invoices are raised by the Finance Division of the MHRA on behalf of the Secretary of State for Health and payment is required within 30 days. They will be raised during the first or second quarter of the financial year and cover the period of 1st April to 31st March.

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

Personal information about patients, donors or staff involved in an investigation 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 report 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.

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** [3]. This could be for statistical analysis, management, planning or in the provision of services by the Agency. The MHRA and SHOT 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** [4] 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 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)** [5] 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.

The General Data Protection Regulation (GDPR) came into effect as of May 2018 and states;

> ‘where parties must obtain permission from the data provider, if the information provided such as email addresses, to provide those people with details about what the parties are using their data for, where this relates to direct marketing sent electronically (email, SMS or social media direct message), the parties must seek the data providers consent in advance and respect their wishes should they want to stop receiving this information.’

The MHRA collect data solely for the use of regulatory compliance and therefore do not use any mailing list information for any purpose outside the regulatory framework of the BSQR.

2 WHAT – legal definitions and guidance

2.1 Serious adverse reactions (SAR)

MHRA

Definitions
All italicised quotes are from the BSQR.

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'*

The reporting requirements are:

'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'

Notifications of SARs should be submitted on SABRE **as soon as known**.

All SAR reported under BSQR are also reportable to SHOT, as the reporting requirements for SAR are very similar. However, in addition, SHOT also accepts reports of reactions to solvent-detergent fresh frozen plasma (FFP) (Octaplas) which are not reportable under BSQR.

Please report these to SHOT via the SAR page, however they will be excluded by the MHRA.

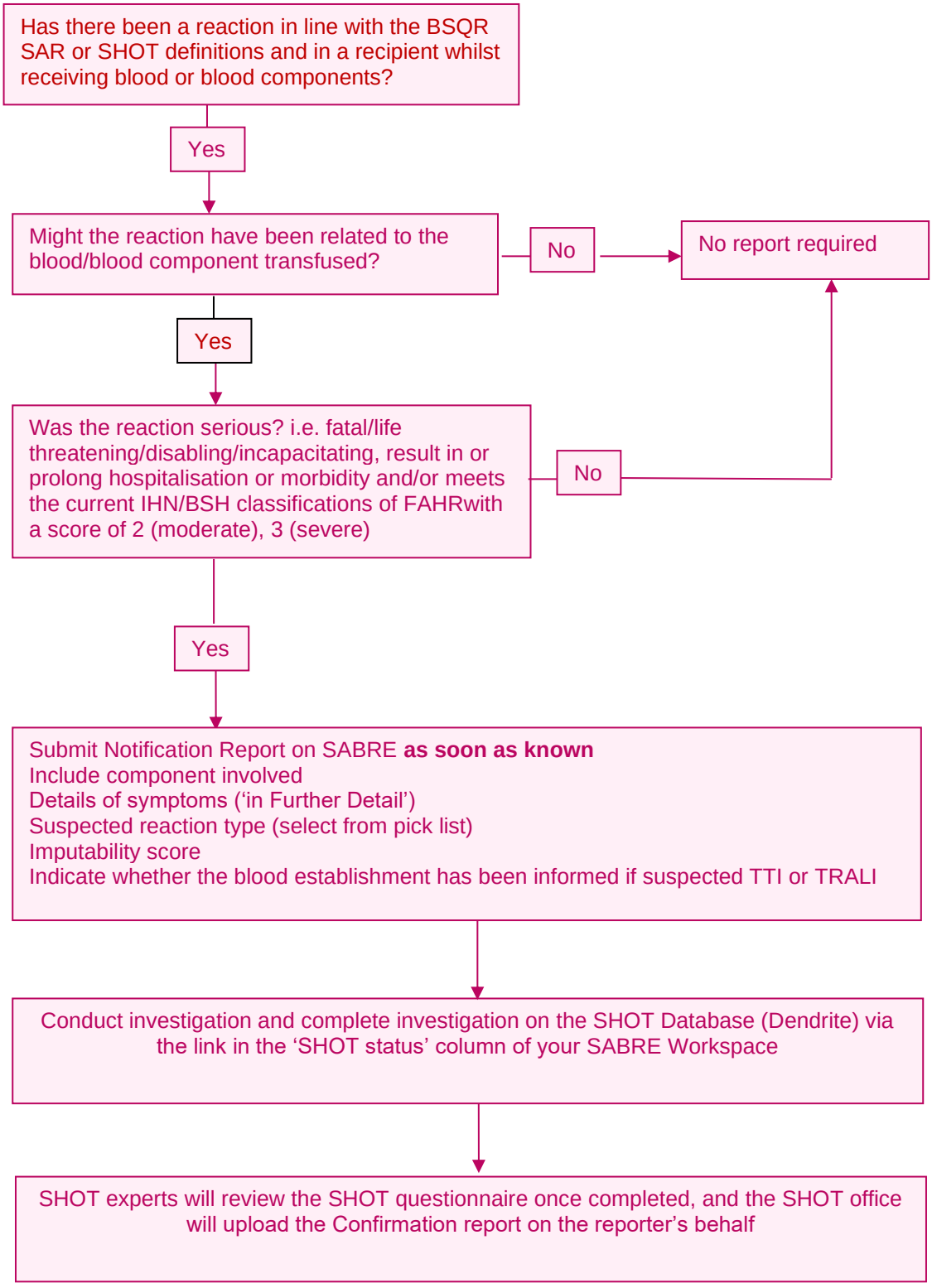
For further information about reporting definitions, please see the SHOT Definitions Document which is available on the SHOT website (www.shotuk.org).

International Society of Blood Transfusion (ISBT) definitions, clinical and laboratory features of reaction types.

The table in Annex A reproduces the ISBT internationally agreed definitions of the serious adverse reactions terms listed in Part 7, Section A of the BSQR.

An easy to follow flow diagram is located at Figure 1 below

Figure 1 SAR reporting flow chart



2.2 Serious adverse events (SAE)

MHRA

Definitions
All italicised quotes are from the BSQR

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.'

The reporting requirements are:

'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,'

Notifications of SAEs should be submitted on SABRE **as soon as known**.

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'

Issue
'the provision of blood or blood components by a blood establishment or a hospital blood bank for transfusion to a recipient'

The following terms, though used, are not defined in the BSQR. 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 both blood establishments and 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).

An additional category, **Donor Selection,** has been added to collect data on collections from Donors who should have been deferred.

The reporter is NOT now expected to decide at Notification if an event qualifies as an SAE, this will be left to the MHRA and SHOT. All previously defined SAEs, other laboratory errors, clinical errors and near misses should be reported via the SAE Notification form. It will be MHRA's responsibility to decide whether your report qualifies as an SAE under the BSQR and SHOT's responsibility if it qualifies as reportable under their definitions.

In the case where a reported event falls outside of the BSQRs the MHRA will contact the reporter via E Mail to exclude the report from the annual summary

Reporters are reminded that the MHRA only has responsibility for acting upon reports that are SAEs, as defined by the BSQR, and they will not take action regarding any clinical error, near miss or laboratory error that is outside of the scope of the BSQR and therefore scrutiny of these reports will solely lie with SHOT.

A decision-making flow diagram which MHRA use to assess SAEs is located at Figure 2 below.

2.2.1 Definitions of reportable SAE

The table in Annex B provides examples of serious adverse events and how they should be classified according to the format in Part 8, Section A of the BSQR.

2.2.2 Reporting error-related reports to SHOT

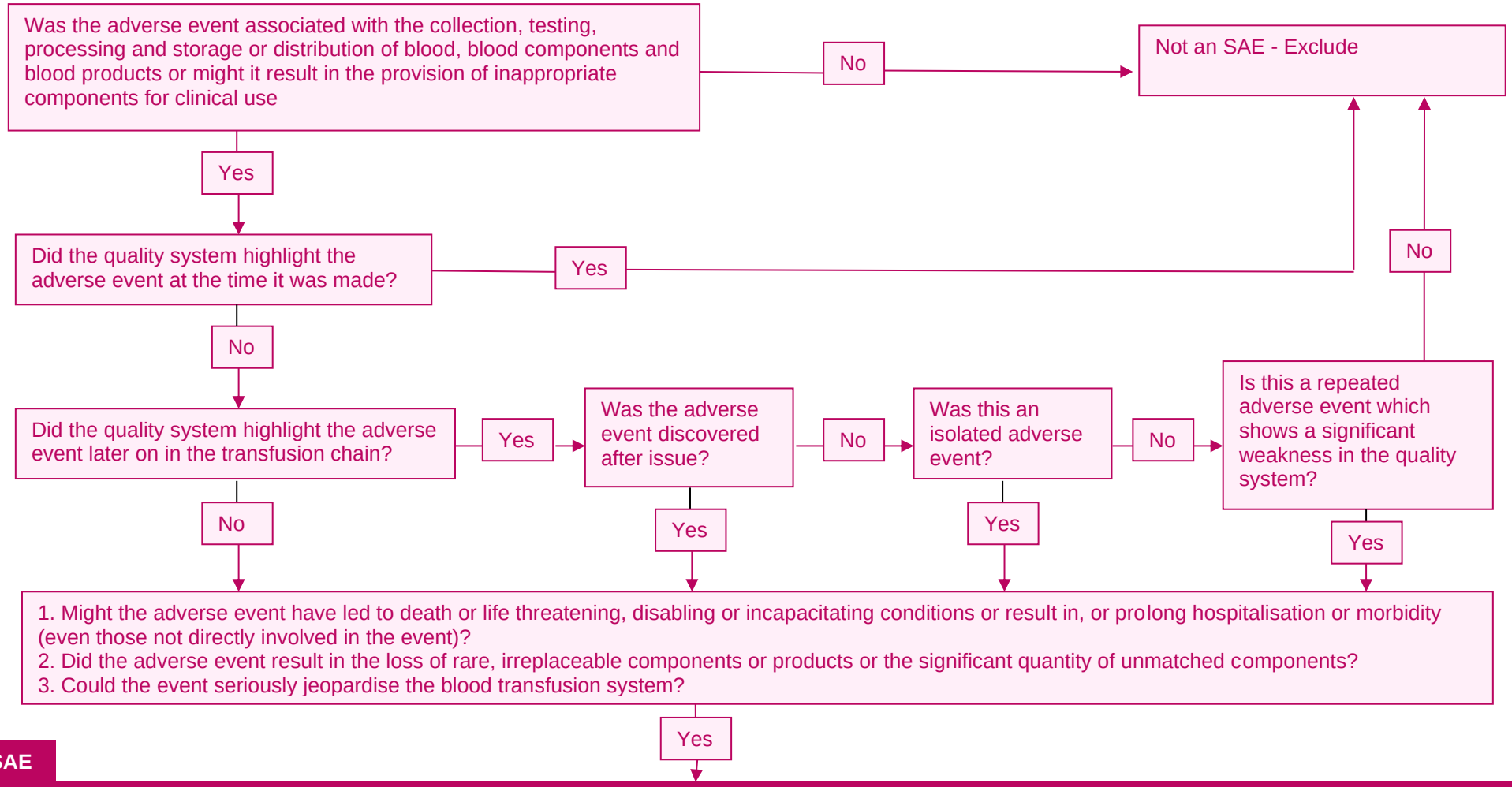
Any report that does not involve a reaction in the patient should be reported via the SAE route of the SABRE workspace.

This includes any non-BSQR reports, for example wrong blood in tube, avoidable transfusions, delays in transfusion, and any incorrect blood component reports where the error originated in the clinical area.

Reports relating to errors in anti-D immunoglobulin (Ig) or PCC administration, and new anti-D immunisations should also be reported here.

For further information about SHOT reporting definitions, please see the SHOT Definitions Document which is available on the SHOT website (**www.shotuk.org**).

Figure 2 MHRA SAE decision making flow chart



2.3 Reporting adverse incidents involving medical devices or licensed medicinal products

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:

i. prescription medicines
ii. blood products such as anti-D Ig, IVIg and Octaplas
iii. vaccines
iv. over-the-counter (OTC) medicines
v. herbal remedies
vi. swine flu antiviral medicines (Tamiflu or Relenza)
vii. swine flu vaccines (Pandemrix, made by GSK or Celvapan, made by Baxter).

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 Yellow Card online reporting system https://yellowcard.mhra.gov.uk/ .

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: https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

3 HOW – using the UK Haemovigilance online reporting system

SABRE can be accessed via the following link:

https://aic.mhra.gov.uk/mda/sabresystem.nsf/Login?Open

and the SHOT Database can be accessed via the link in the 'SHOT Status' column of the Workspace.

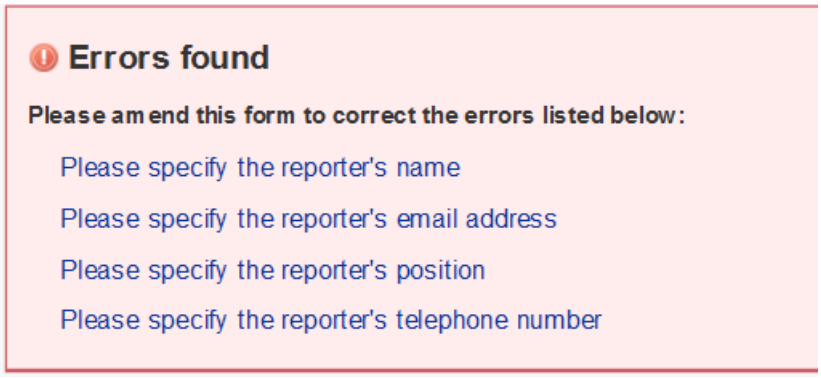
To register for an account please use the following link:

https://aic.mhra.gov.uk/mda/sabresystem.nsf/Registration?Open

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.

At all stages of the SABRE reporting process, you will need to have completed all required fields before progressing to the next stage. If there is missing information, error messages will be displayed. Clicking on these messages will take you directly to the field which needs to be provided.

Figure 3 Errors found



3.1 Help

Online help is available at every stage and every level when using the SABRE system. 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 the UK Haemovigilance system is available from the following sources:

SHOT team – shot@nhsbt.nhs.uk or 0161 423 4208

MHRA SABRE helpdesk – sabre@mhra.gsi.gov.uk or 020 3080 7336

3.2 Registration

Before using the UK Haemovigilance reporting system reporters must first register on SABRE with the MHRA helpdesk.

To register for an account for the UK Haemovigilance reporting system please use the following link:

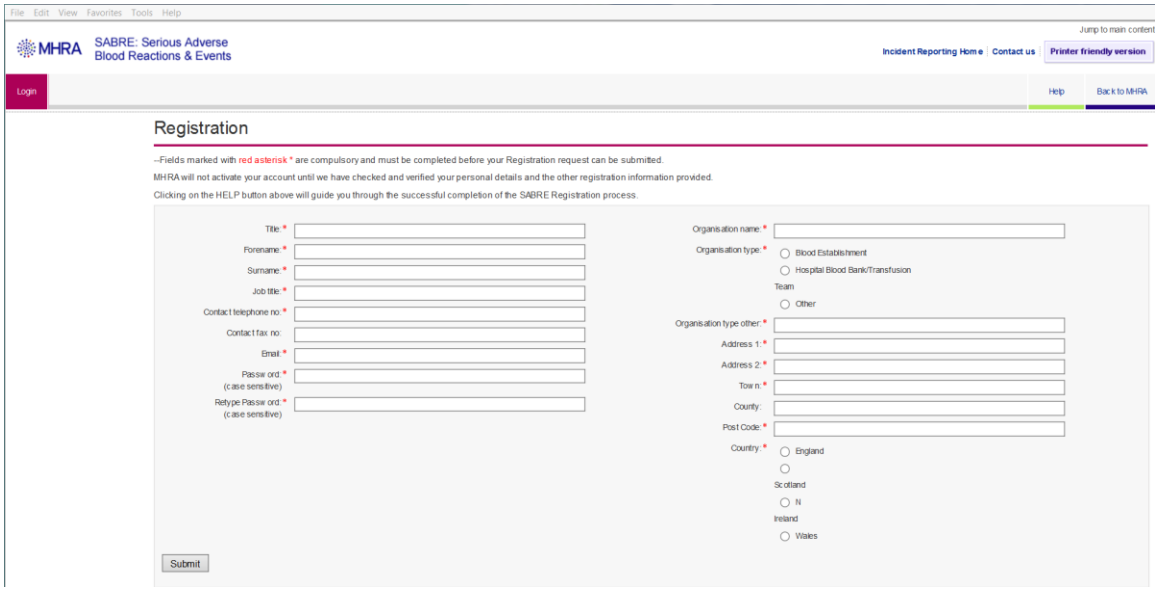
https://aic.mhra.gov.uk/mda/sabresystem.nsf/Registration?Open

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. Separate registration for SHOT is not required as a link will be provided to the SHOT system in the SHOT Status column of the SABRE workspace.

When you have completed the registration form, just click the 'submit' button to send your details to the MHRA helpdesk. A member of the MHRA 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.

Figure 4 Registration form



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. Once an account has been created, individual reporters can be added to the main account (see 3.2.2).

It will, however, still be possible for reporters to register individually. However, should individual SABRE accounts be registered, individual account holders will not be able to view reports made from other accounts.

For 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 (see 3.3) 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 or organisation name, your original account will be temporarily suspended pending validation of the new one by the MHRA team. Until the account has been reactivated, you will not be able to log in using either your old details or your new ones.

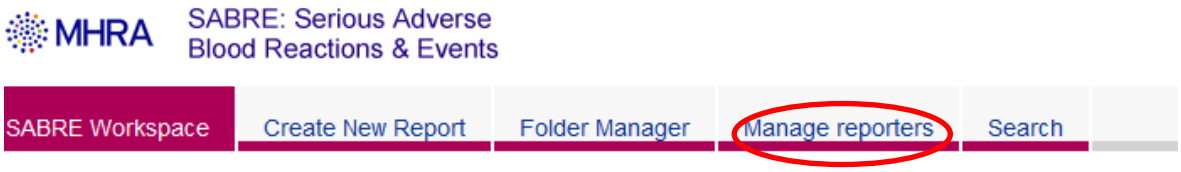
If you have forgotten your log-in details, then telephone the SABRE helpdesk on 020 3080 7336.

3.2.2 Registering reporters on an individual account

Once logged into SABRE, the main account details will automatically be filled into any subsequent SAE or SAR report made. A SABRE account can contain a list of other reporters' details, which can be selected when that reporter makes a report.

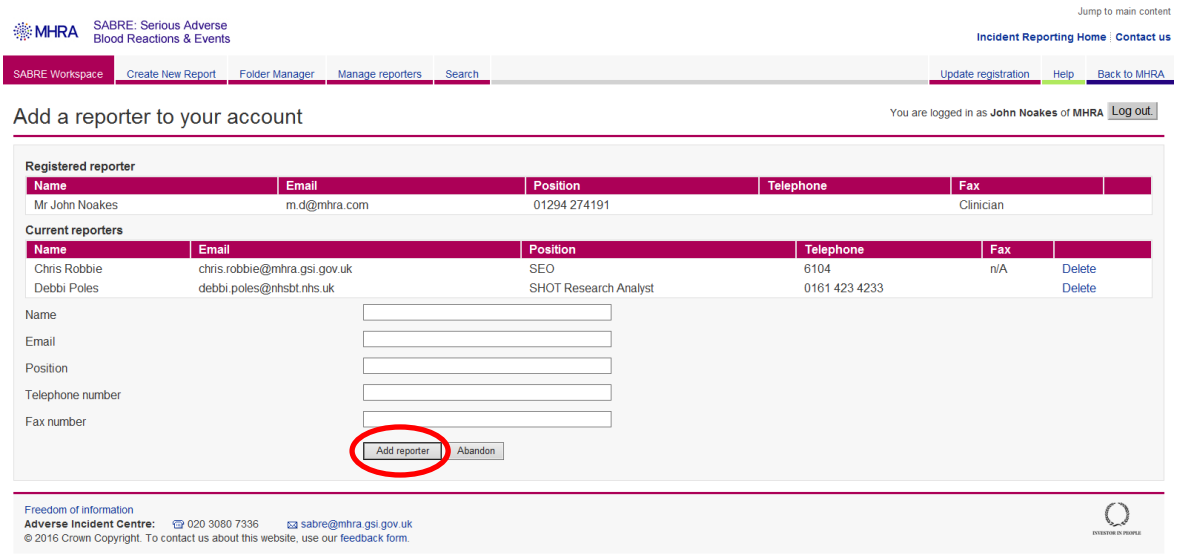
- From the Workspace click the 'Manage reporters' button

Figure 5 Manage reporters



- Enter the details
- To add reporters, click the 'Add Reporters' button

Figure 6 Add a reporter

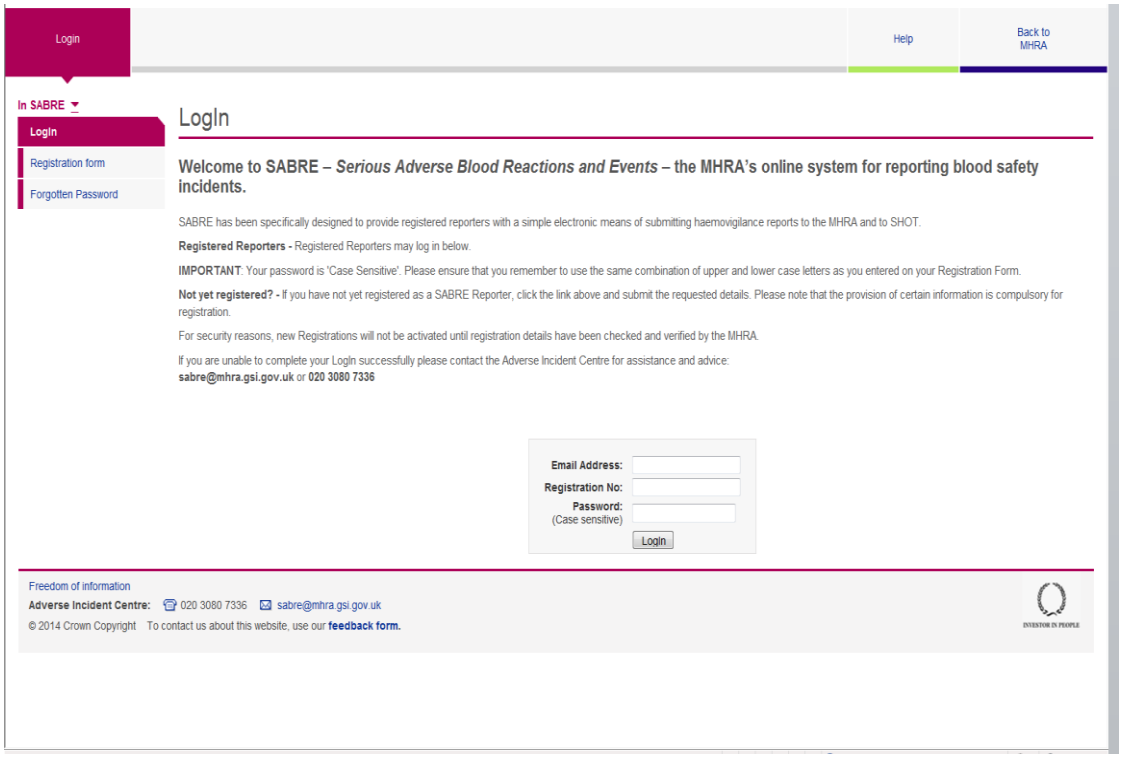


- Changes to individual reporter details will need to be deleted and re-added individually

3.3 Log in

Access UK Haemovigilance via the appropriate link on SABRE and the reporter will be presented with the following log in page see below:

Figure 7 Log in page



Simply enter these three items and click ‘Login’

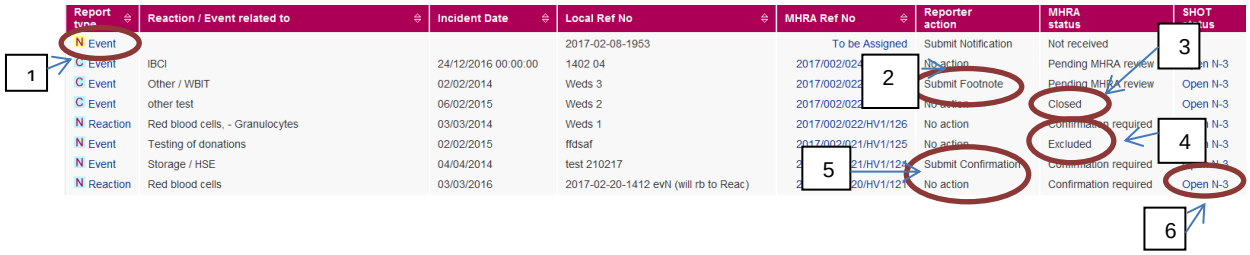
- an email address (the one submitted on your registration request)
- a registration number (sent to you by the MHRA SABRE helpdesk)
- your password (chosen by you when registering)

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 as shown below.

Figure 8 Workspace



1. Indicates a draft SAE Notification report which requires submission as MHRA and SHOT have not received the report
2. Indicates that a Footnote has been requested
3. Indicates that MHRA has closed the report
4. Indicates MHRA has excluded the report
5. Indicates an SAE where Confirmation is required on SABRE and action required by the reporter and an SAR where Confirmation is required by SHOT, but no action is required by the reporter on SABRE
6. Indicates the status of the SHOT report and the web link or N3 link to access the SHOT database directly (see section on ‘SHOT status’ 3.4.1).

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 report) identifying details of that report will appear in the workspace.

Your workspace is **not** visible to the MHRA or SHOT. However, report details are visible to both organisations once the report has been submitted.

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 or C.
N identifies a Notification, C a Confirmation.

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.

Table 1

Column header	Explanation	Expected values
Report type	Indicates if it is a reaction or event, a Confirmation or a Notification and a draft or submitted report	Event or reaction, N or C, yellow or blue
Reaction/event related to	Describes the components related to the reaction reported or the Event category. This information may be changed by MHRA on review	Reaction related to field (SAR) or Event involving (SAE)
Incident date	The date the incident occurred	User defined
Local reference number	Local reference number	User defined
MHRA Reference no	The reference number assigned to the report once submitted. A draft report will state 'To be assigned'	In the format YYYY/MMM/DDD/HVX/NNN Where Y= year, M = month, D = Day, X = 1(online report) or = 2 (input by MHRA), N = sequential number in order of receipt
Reporter action	Describes the action expected to be taken next by the reporter, in relation to the MHRA report only.	• Submit Notification • Await MHRA review • Submit Confirmation • Submit Footnote • No action
MHRA Status	Describes the status of the report for MHRA	• Not received • Review pending (for Notifications) • Confirmation required • Pending MHRA review (For Confirmations) • Excluded • Closed
SHOT Status	Describes the status of the SHOT questionnaire	• Open • Closed • Withdrawn

3.4.1 SHOT status

This column shows the reporter the status of the corresponding report on the SHOT Database. Also, this column provides a link directly to the SHOT Database without the need for a separate log-in.

The link to the SHOT database will not be instantaneous, but should be generated within a few minutes of submitting the SABRE notification. You may need to refresh the screen (press 'F5') if the link does not appear automatically.

There are two choices, 'Open' (or any other status) for a link via the general internet or 'N-3' for those reporters who require an N3 connection (the internal NHS network). The different statuses are:

- Open: The SHOT report is open and requires completion by the reporter
- Closed: The SHOT report has been completed and closed by the reporter
- Withdrawn: The SHOT report has been reviewed and withdrawn by the SHOT Team

It is hoped that the addition of these columns will give each reporter more feedback from MHRA and SHOT with regard to the assessment of each report and the expected next steps without having to keep records of 'Excluded reports', 'Outstanding Confirmations' and records of 'additional Footnotes required'.

Please review your Workspace regularly so as to be pro-active in addressing outstanding action statuses.

3.4.2 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.

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.

3.4.3 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.

3.4.4 Printing

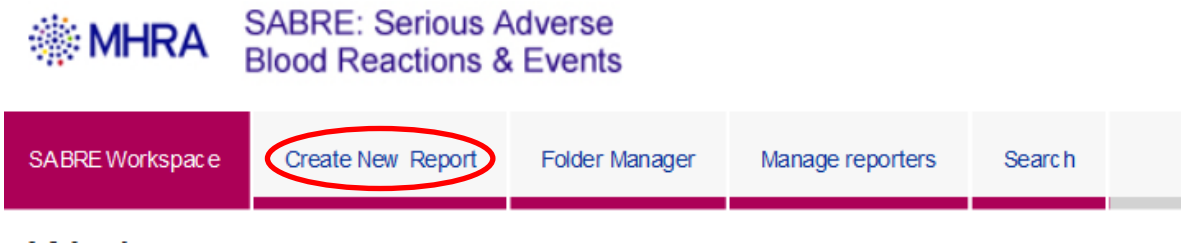
Each section within SABRE includes a button at the top of the screen that enables you to access a 'Printer Friendly Version' of your form should you need a hard copy for your local records.

On the SHOT database clicking the 'Data Summary' button from within any report will display a printable summary of all data entered within the SHOT questionnaire.

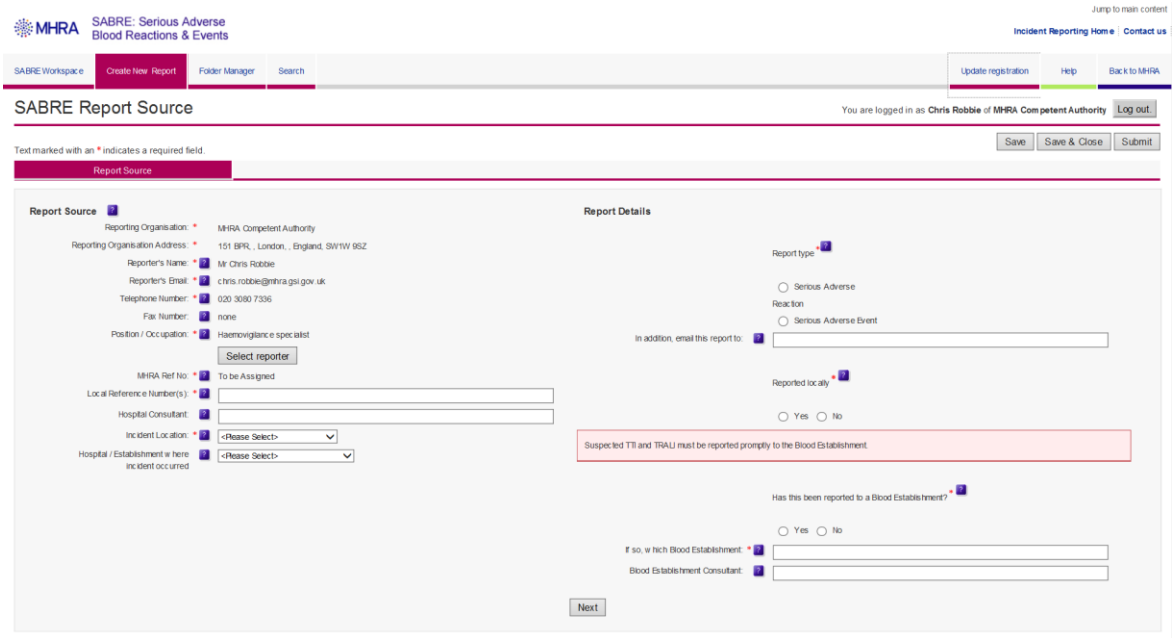
3.5 Creating a new report

To create either an SAR or an SAE report to be viewed by both MHRA and SHOT, click Create New Report on the Workspace to open the SABRE Report Source page.

Figure 9 Create new report



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



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 and SHOT are very keen to ensure that reporting to the UK haemovigilance system 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 Blood establishment notification

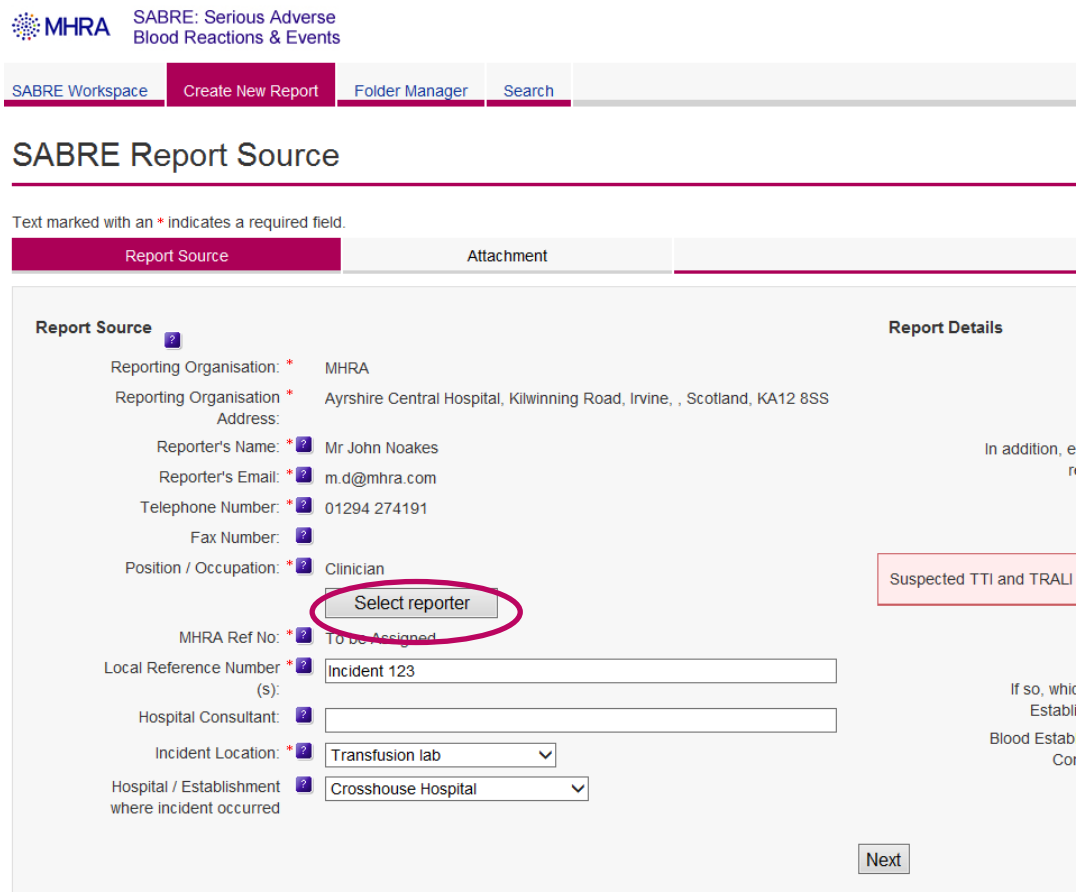
As well as indicating whether you have made a local report, you must also indicate whether you have submitted a report to the relevant blood establishment. This is of particular importance in TTI (transfusion-transmitted infections) and TRALI (transfusion-related acute lung injury) cases, or in any other 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.

3.5.3 Changing the reporter details

To use the details of the added reporters, certain mandatory questions must first be completed before a different reporter can be selected.

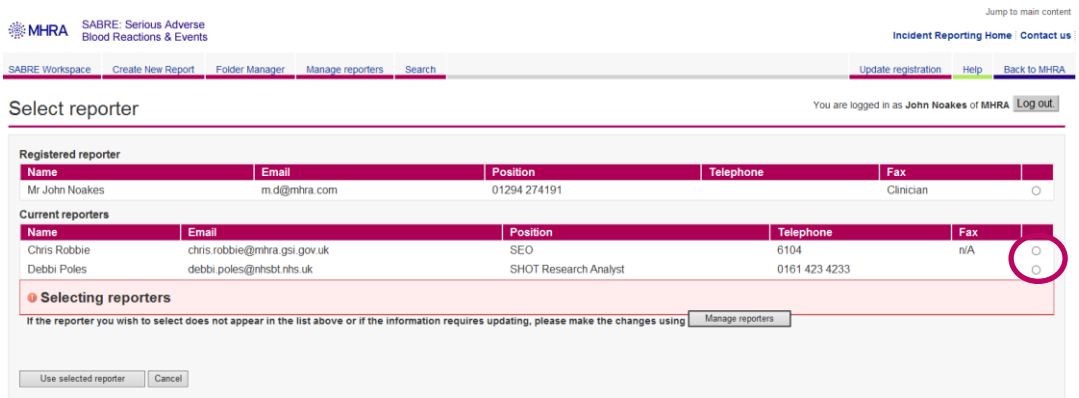
- Enter the local reference number
- Select report type serious adverse reaction or serious adverse event
- Click select reporter

Figure 10a Selecting a different reporter



- Select the reporter's details by selecting the radio button adjacent to the reporter's details

Figure 10b Selecting a different reporter



- Click Use selected reporter

3.5.4 Completing the report source page

Complete the rest of the mandatory fields and any of the additional fields as required

- Incident location is the area or department of the hospital where the error occurred
- Hospital/ Establishment where the incident occurred is a list of hospitals and facilities pre-determined by SHOT particular to your original reporting location. If any changes are required to the list of hospitals, please contact the SABRE helpdesk

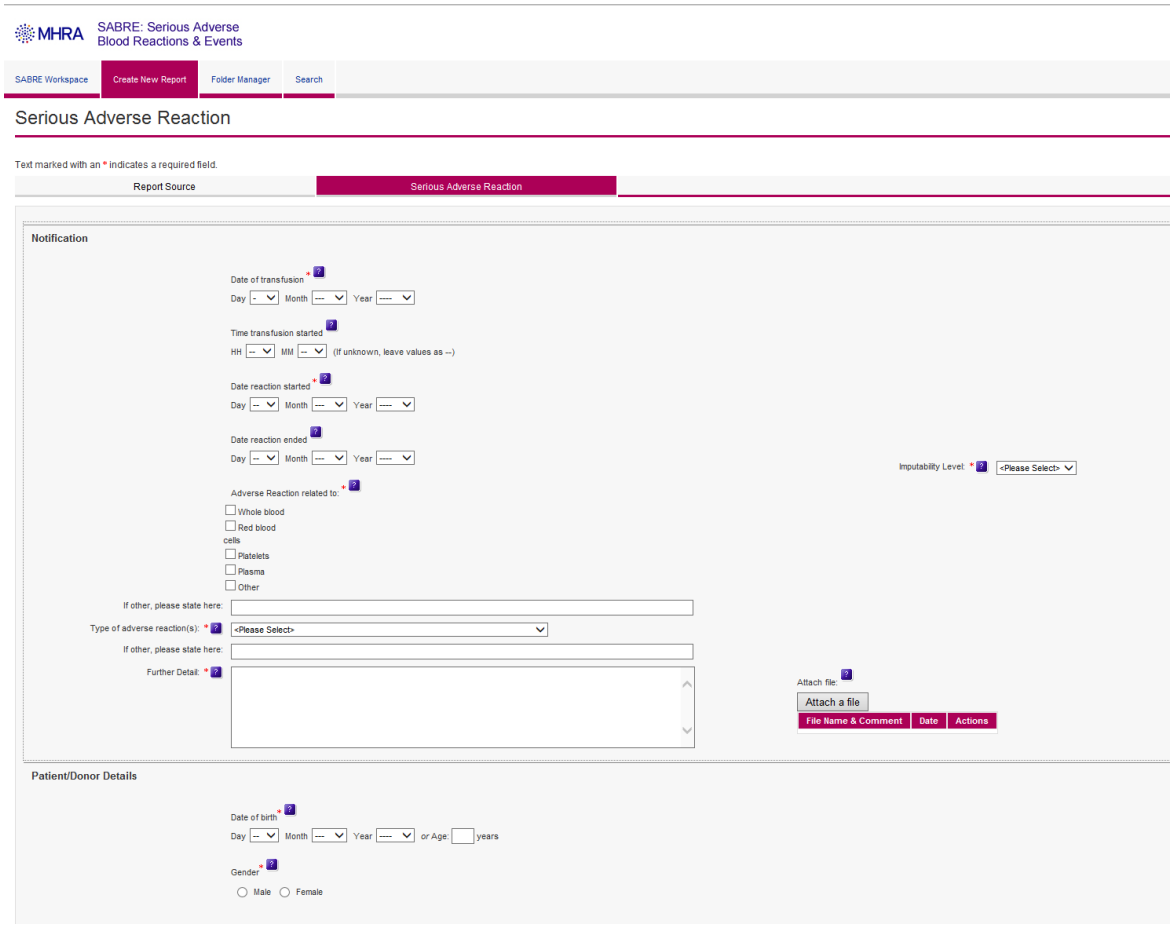
Click next to proceed to the SAR or SAE report form.

3.6 Serious adverse reactions – notification and confirmation

3.6.1 Notification report

Once the reporter has correctly completed the ‘Report Source details’ and selected the ‘SAR option’ and clicked on the ‘Next’ button they will be directed to the following SAR Notification screen:

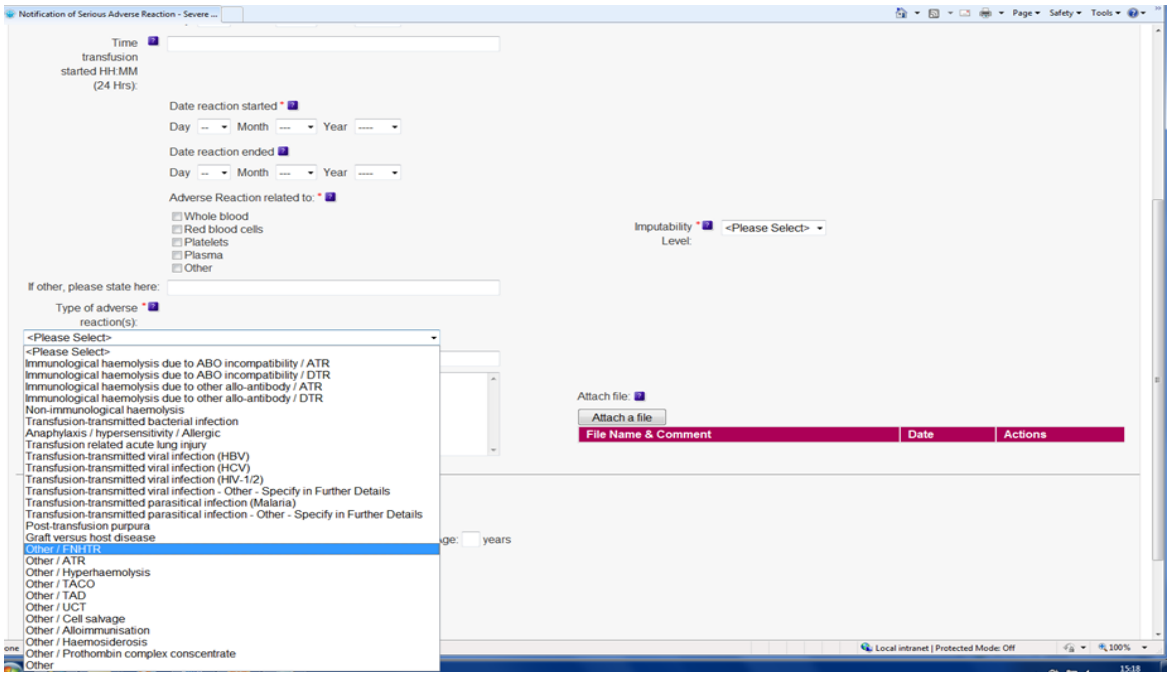
Figure 11 SAR notification report



Complete the data fields in the Notification section of the SAR where appropriate.

- Use the drop-down lists to record the date and time fields.
- Select the most likely imputability. The imputability is the level at which the blood was likely to have caused the reaction (see section 3.6.5). It is recognised that at this stage, without having completed the investigation, the imputability may have to be an estimate.
- Select all blood components involved in the suspected reaction. Multiple selections are allowed.
- The drop down list for 'Type of adverse reaction' has been designed so that the reporter can add a reaction type that is relevant to both MHRA and SHOT categories. See screen below:

Figure 12 Type of adverse reaction



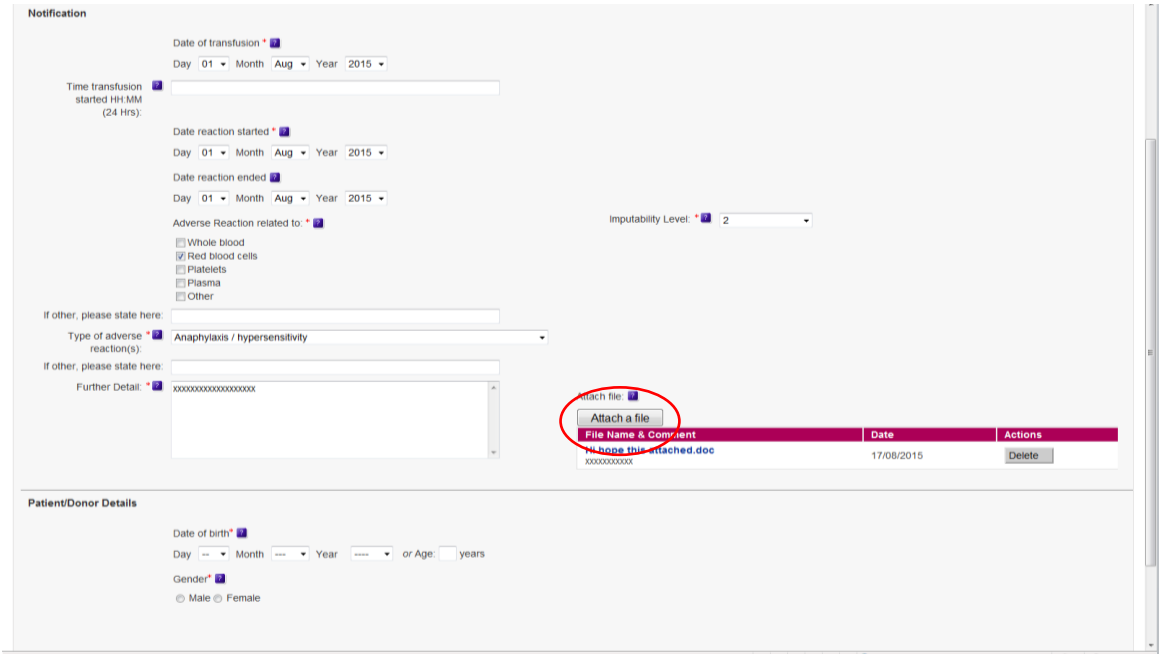
Reporters can select 'Other/ xxxx' as the reaction type from the drop down list without having to enter free text into the 'If Other, please state here' box. If the reaction type is not specified in the drop down list, reporters should select the lone 'Other' selection and then specify the reaction type as they do currently in the 'If Other, please state here' box.

The 'Type of adverse reaction(s)' field will determine the category of report that is pre-populated on the SHOT database. From the screenshot above, the category name after the last '/ ' denotes the equivalent SHOT category. Where there is no SHOT category specified, then the category is the same, or in the case of 'Non-immunological haemolysis' there is no specific SHOT equivalent.

- Add a full description of the reaction to allow a third party without access to your local records to fully understand the nature of the reaction being reported.

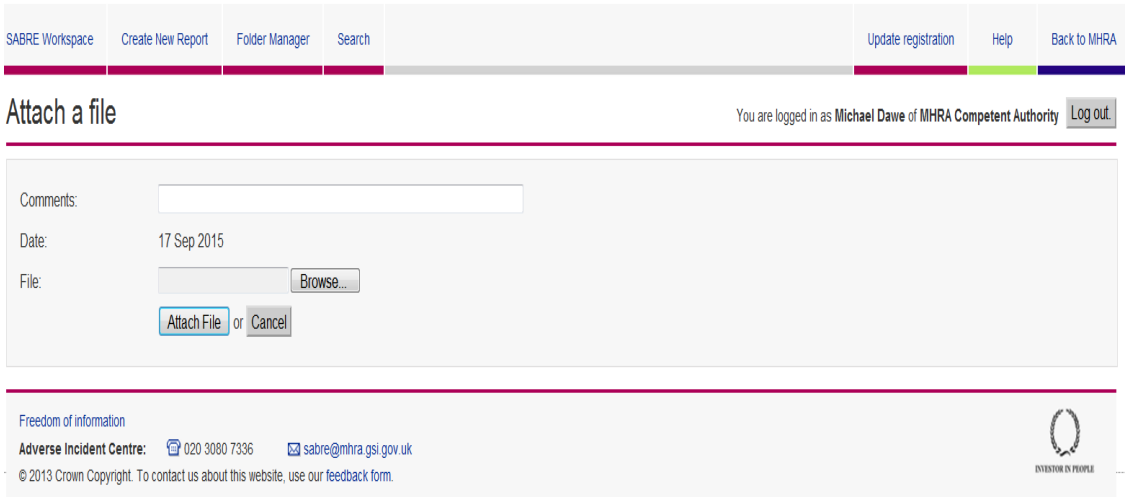
- Locally written documents are allowed to be attached containing details of the reaction and supporting evidence instead of detailing in the Further Detail section. Please remember, any attachments should NOT contain any patient identifiable information, and must be fully anonymised. To attach a file, click on the 'Attach a file' button as highlighted below:

Figure 13a Attach a file



Reporters will then be directed to the following screen:

Figure 13b Attach a file



Reporters can add a comment, browse from their documents and attach an appropriate file from their document library. Once the appropriate file has been located and is highlighted in

the ‘Browse’ field click on the ‘Attach File’ button. (Attachments added here will transfer across to the SHOT Database when the report is submitted).

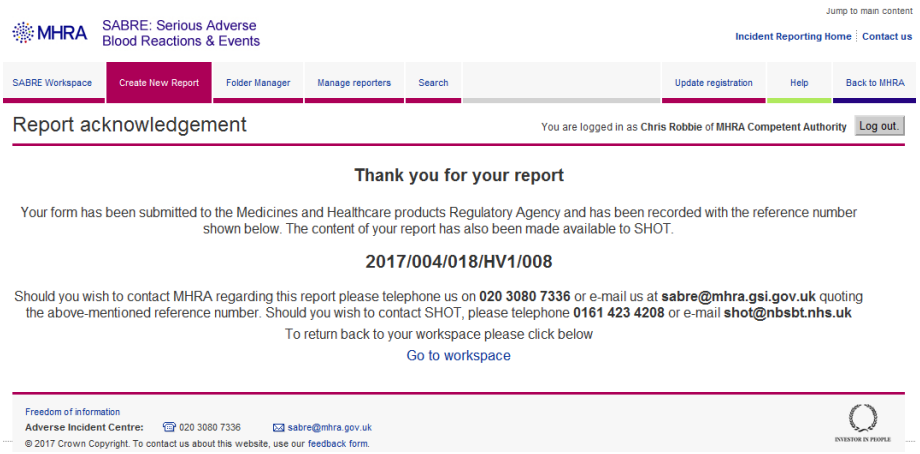
- Add the patient details

Reporters can ‘save’, ‘save and close’, ‘discard’ the report at any stage by clicking on the appropriate button as highlighted below:

Figure 14 Submitting the report

- The ‘save’ function will allow the reporter to save the Notification report at any stage as you complete it i.e. like a word document.
- The ‘save and close’ option will allow you to save and close the report so you can return to it later for completion.
- A draft report i.e. (‘to be assigned’) can now be deleted in its entirety if it is no longer required. A submitted report (i.e. with an MHRA reference number) cannot be deleted.
- Once reporters have completed the SAR Notification report click on the Submit button. Clicking the Submit button is the only way MHRA and SHOT will have access to your report.

Figure 15 Acknowledgement screen



Once the investigation is complete, the reporter must complete the questionnaire on the SHOT online reporting system. Access this by clicking the link in the ‘SHOT status’ column of the workspace. Please see section 5 for more details about completing the SHOT questionnaire.

Figure 16 SHOT questionnaire

SAR confirmations will be undertaken by SHOT (following completion of the SHOT questionnaire by the reporter) and will be submitted as soon as possible after SHOT subject matter experts have collated all the required information and their expert assessment is complete.

3.6.2 Donors

For serious adverse reactions in a donor, the blood establishment must notify the Competent Authority only where the quality and safety of the blood may be compromised.

3.6.3 Reportable reaction types

Under the new SAR reporting arrangements, at the notification stage, reporters are requested to enter a reaction type which includes:

- Immunological haemolysis due to ABO incompatibility / IBCT
- Immunological haemolysis due to other alloantibody / HTR
- Non-immunological haemolysis
- Transfusion-transmitted bacterial infection
- Anaphylaxis / hypersensitivity / Allergic / ATR
- Transfusion-related acute lung injury
- Transfusion-transmitted viral infection (HBV)
- Transfusion-transmitted viral infection (HCV)
- Transfusion-transmitted viral infection (HIV-1/2)
- Transfusion-transmitted viral infection - Other - Specify in Further Details
- Transfusion-transmitted parasitical infection (Malaria)
- Transfusion-transmitted parasitical infection - Other - Specify in Further Details
- Post-transfusion purpura
- Graft versus host disease
- Other / Febrile ATR
- Other / Mixed febrile / allergic ATR
- Other / Hypotensive ATR
- Other / ATR
- Other / Hyperhaemolysis
- Other / TACO
- Other / TAD
- Other / UCT
- Other / Cell salvage
- Other / Haemosiderosis
- Other / HSE
- Other

NOTE: Please see the SHOT Definitions Document which is available on the SHOT website (www.shotuk.org) or contact SHOT directly for help with a reaction type – 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.

3.6.4 Patient/donor information

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

Confirmation reports will not be carried out by the reporter but by SHOT. MHRA and SHOT will undertake regular consolidation exercises to ensure that the number of reports submitted are accurate by number, classification and imputability score.

The confirmation process will be undertaken by SHOT who will have access to the confirmation area of the SAR in SABRE so it can be populated after the appropriate clinical expert input.

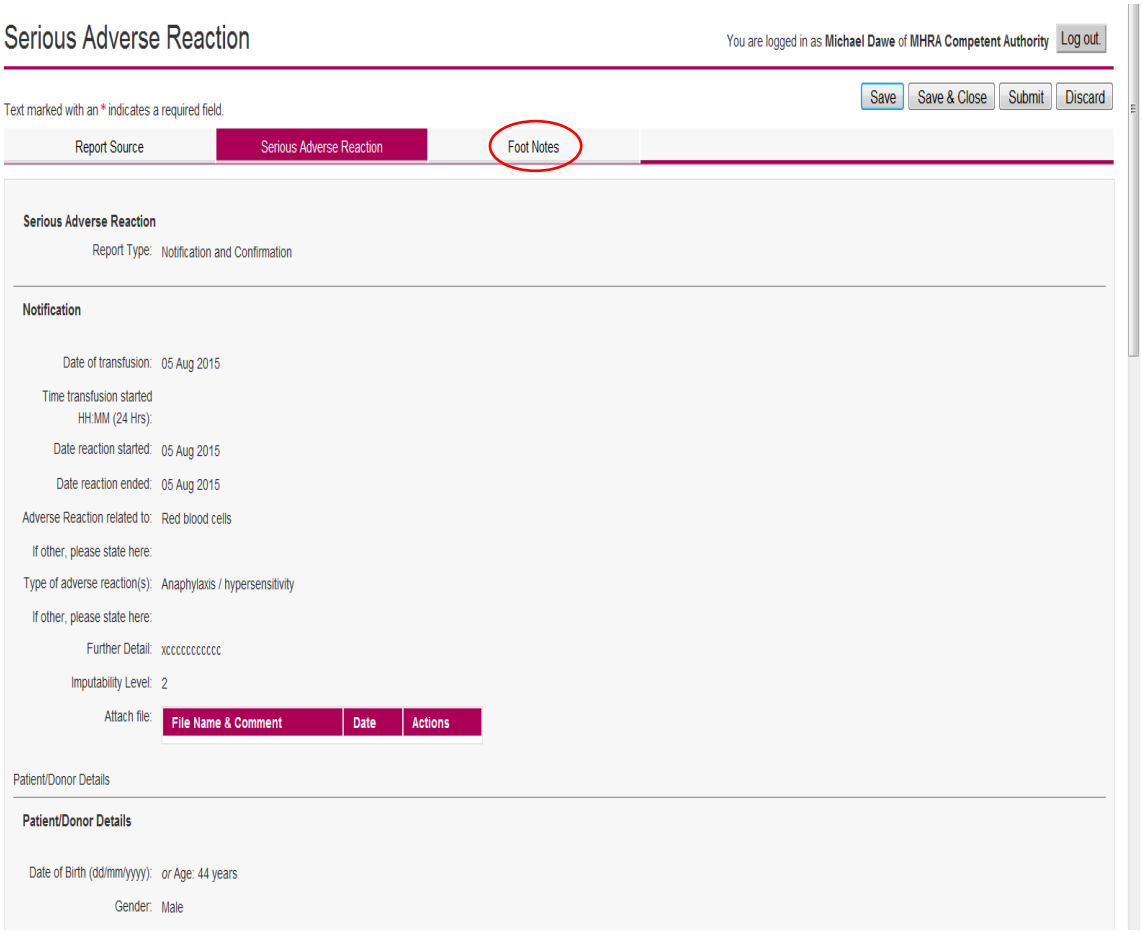
Once SHOT has submitted the final SAR confirmation report the Confirmation report will appear on the Workspace.

Once the reporter has logged into their SABRE account they will be able to view the completed SAR confirmation report, including attached files and Footnotes.

Reporters may be asked to complete a Footnote after they have submitted the SAR Notification report. This can be done as follows:

Access the appropriate SAR report via the SABRE 'workspace' and you will be directed to the following screen:

Figure 17a Adding a footnote

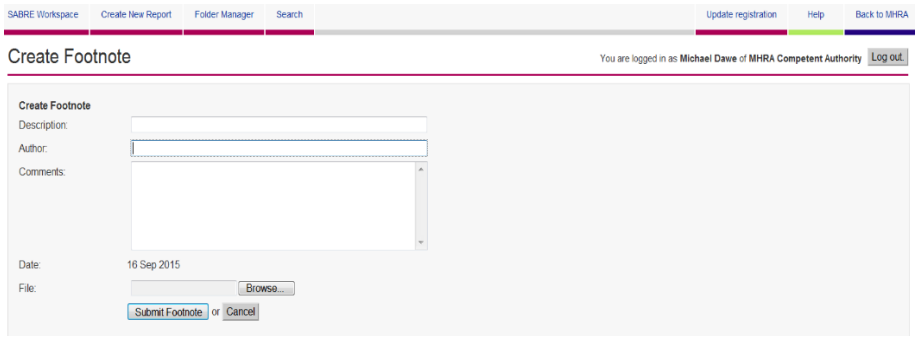


Click on the footnotes tab and you will see the following screen:

Figure 17b Adding a footnote

Click on the Create Footnote function, and the reporter will be directed to the following screen:

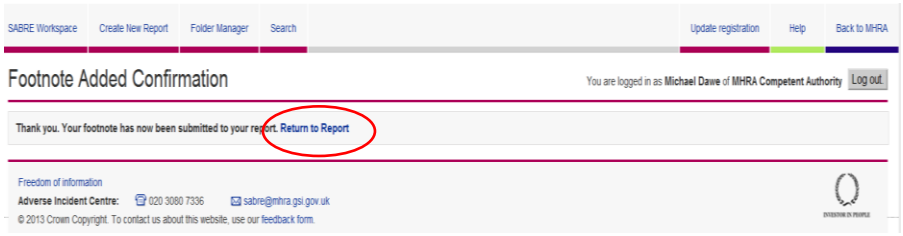
Figure 17c Adding a footnote



Complete the 'Description', 'Comments' and or 'browse' to attach a file and then click on 'Submit Footnote' button. Reporters can cancel the footnote at any time before clicking on the 'Submit Footnote' button by clicking on the 'Cancel' button.

Once you have clicked on the 'Submit Footnote' button reporters will see the following screen:

Figure 17d Adding a footnote



Click on the Return to Report option and you will now see an overview of the footnote you have just submitted. SHOT will also receive a copy of the footnote and attachment.

SHOT will be the primary contact for reporters for SARs. Reporters can contact SHOT for confirmation of their decision and/or for any further information.

The MHRA adverse incident haemovigilance team will liaise with SHOT to ensure that the SARs meet the BSQR reporting requirements and are appropriately classified.

Adverse reactions that do not fall within the BSQR definition of an SAR will be excluded from the MHRA database but not necessarily from SHOT. Reporters will be informed by e mail that the report has been excluded and the reasons why.

3.6.5 Imputability levels

This is an essential part of the data sets that are reported, therefore the confirmation report that is submitted by SHOT will have an imputability score assigned. This will be transferred to the SABRE database when the confirmation report has been completed.

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 2 Imputability levels

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

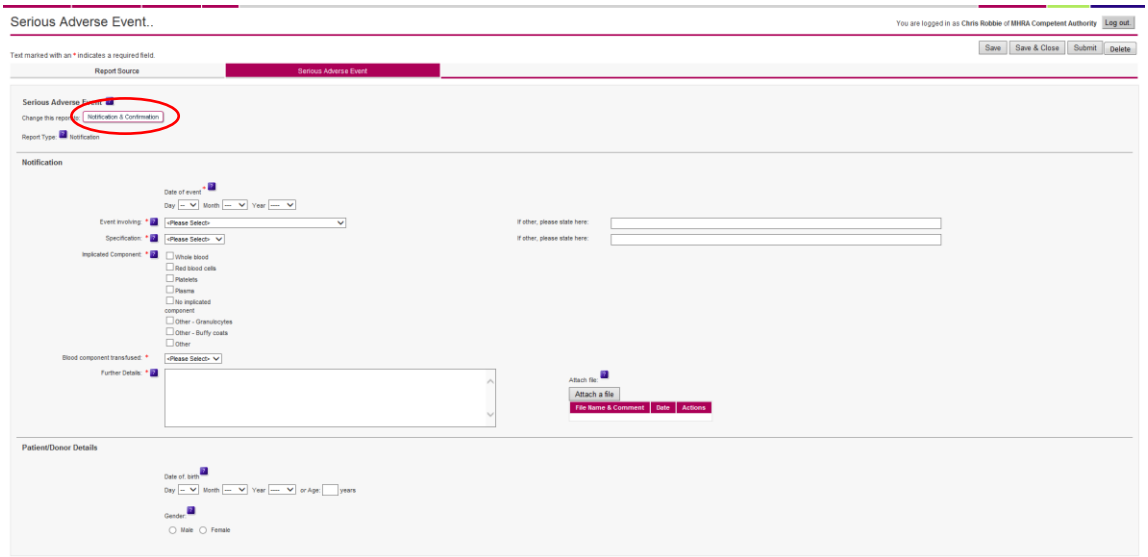
Although imputability levels are defined by the reporter at the notification stage of the report this may be changed at the confirmation stage following review by the SHOT expert. If further information is required relating to the confirmation report decision, please contact the SHOT office.

3.7 Serious adverse event notification and confirmation

3.7.1 Notification report

Once the reporter has correctly completed the ‘Report Source details’ and selected the ‘SAE option’ and clicked on the ‘Next’ button they will be directed to the following SAE Notification screen:

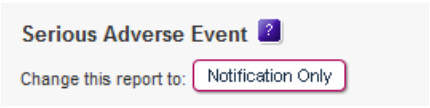
Figure 18a SAE notification report



The SAE reporting process is a two-step processing requiring a Notification report and then a Confirmation report. The SAE reporting requirements request you report a notification of an SAE as soon as known. Usually this will be before the investigation has been completed. However, in some circumstances, it is acceptable to report the Notification and Confirmation reports simultaneously. 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 (IE&S).

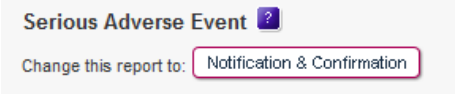
To report a Notification and Confirmation simultaneously, click the button labelled 'Change this report to: Notification & Confirmation'. This will then change the report to a Notification and Confirmation report and the button will display as

Figure 18b SAE notification report



To convert the report back to a Notification report only, then click on the button 'Change this report to: Notification only'. The Confirmation section will then disappear, and the button will be displayed as

Figure 18c SAE notification report



Complete the data fields in the Notification section of the SAE where appropriate.

- Use the drop-down lists to record the date fields.
- Select the most appropriate '*Event involving*' category to determine the correct SHOT questionnaire. If the event is not in the drop down list, the reporter should select the lone 'Other' selection and then specify in the 'If other, please state here' box.
- Select the most appropriate Specification category. This is a broad description of the main root cause of the SAE. If the Specification is not in the drop down list, the reporter should select the lone 'Other' selection and then specify in the 'Other, please state here' box.
- MHRA may change these two categories on review to reflect the most appropriate BSQR categories.
- Select all blood components involved in the suspected reaction. Multiple selections are allowed.
- State whether a blood component was transfused using the drop-down list. This will help SHOT determine the correct questionnaire is assigned to your report.
- If a patient or donor was involved, enter the data in the Patient/Donor Details section.

SAE reports that fall outside the MHRA remit such as Wrong Blood in Tube (WBIT), Anti D etc. must be reported via the UK Haemovigilance system as normal. The MHRA Adverse Incident Team will exclude these reports from the MHRA database and inform the reporter by email.

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

Figure 19 Submitting the report

- The 'save' function will allow the reporter to save the Notification report at any stage as you complete it i.e. like a word document.
- The 'save and close' option will allow you to save and close the report so you can return to it later for completion.
- A draft report i.e. ('to be assigned') can now be deleted in its entirety if it is no longer required. A submitted report (i.e. with an MHRA reference number) cannot be deleted.
- Once reporters have completed the SAE Notification report click on the Submit button. Clicking the Submit button is the only way MHRA and SHOT will have access to your report.

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.

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.

The SAE section has been designed to primarily collect the data that is required by the BSQR and SHOT. In order to collect the data in a consistent manner that is suitable both for SHOT and for MHRA summary analysis, standard pick-lists are provided for a number of areas. The available '*Event involving'* categories are:

Table 3 Event involving categories

'Event involving' category	Correct use
Whole blood collection	Blood establishment only relating to collection of blood from a donor
Apheresis collection	Blood establishment only relating to collection of apheresis components from a donor
Testing of donations	Blood establishment only relating to testing of donor blood
Processing	Blood establishment only relating to processing or secondary processing of donor blood
Storage / HSE	Storage including 30minute rule, Miscellaneous, Component expiry, Failure to action alarm, Incorrect storage of component, Return to stock error, Sample expiry, Security, Storage temperature deviation
Distribution / HSE	The act of transporting blood from one legal entity to another. Not for internal stock transfers.
Materials	Errors relating to the materials used in the transfusion service
Other / BSQR event	Any other SAE covered by BSQR that is not also SHOT reportable
Other / IBCT - WCT	Wrong component transfused
Other / IBCT - SRNM	Specific requirements not met
Other / ADU	Avoidable, delayed or undertransfusion
Other / RBRP	Right blood, right patient
Other / WBIT	Wrong blood in tube
Other / Near Miss	Near miss
Other / Anti-D administration	Anti-D administration
Other / Anti-D immunisation	Anti-D immunisation
Other / Cell salvage	Cell salvage
Other / Prothrombin Complex Concentrate (PCC) administration	Prothrombin complex concentrate administration (PUCT)
Other / HSE	Handling and storage errors not covered by Storage / HSE or Distribution / HSE
Other	Any SAE or SHOT-reportable incident not covered by the above
Other / Acknowledging Continuing Excellence (ACE)	To report examples of good practice only to SHOT – this option should not be selected for reporting a serious adverse event

Annex B gives examples of serious adverse events and how they should be classified according to the proposed format in part 8, section C (annual notification format for serious adverse events) of the BSQR.

The '*Event involving'* field in combination with the 'Blood component transfused' field will determine the category of report that is pre-populated on the SHOT database.

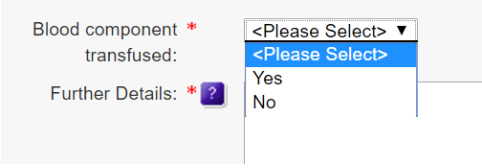
From the table below, the category name after the last '/ ' denotes the equivalent SHOT category. Those with no SHOT category listed are generally not SHOT reportable, and would only be reportable to the MHRA under the BSQR. These reports will still transfer across to the SHOT database, but will have no SHOT category pre-selected.

If the report does not fulfil the SHOT reporting criteria, then please e-mail the SHOT team at shot@nhsbt.nhs.uk and request that the report be withdrawn.

The second field that determines the SHOT category is *'Blood component transfused'*. This is a mandatory field unless the *'Implicated component'* question is answered as 'No implicated component'.

If answered 'Yes', a full incident report will be generated on the SHOT database. If answered 'No' a Near Miss report will be generated regardless of the SHOT category selected in the *'Event involving'* field. This question only has an impact on 'Labile component' categories.

Figure 20 Blood component transfused



So, for example the combinations of data entry below would result in the following SHOT categories (this table is not an exhaustive list):

Table 4 Examples of how SABRE categories map to SHOT questionnaires

Event involving	Blood component transfused	SHOT Category
Other / IBCT-WCT	Yes	IBCT-WCT
Other / IBCT-WCT	No	Near Miss
Storage / HSE	Yes	HSE
Storage / HSE	No	Near Miss
Other / Anti-D administration	Yes	Anti-D
Other / Anti-D administration	No	Anti-D
Other / Anti-D administration	N/A (if 'no implicated component')	Anti-D

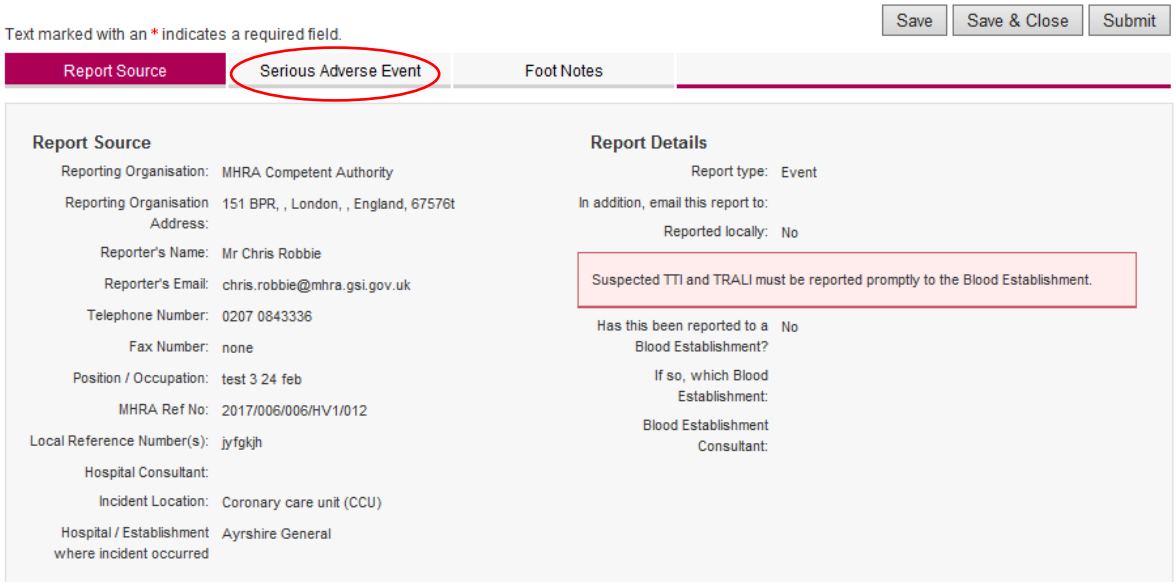
If the incorrect SHOT category is chosen, this can be amended in the SHOT database. See section 5.5 on Changing SHOT categories.

3.7.3 Confirmation reports and SHOT questionnaires

Log into SABRE as described in Para 3.3 above and the reporter will then be directed to their workspace, see Para 3.4 above.

Select the appropriate SAE report from your workspace and you will be directed to the completed SAE 'Report Source' page relevant to the SAE report accessed.

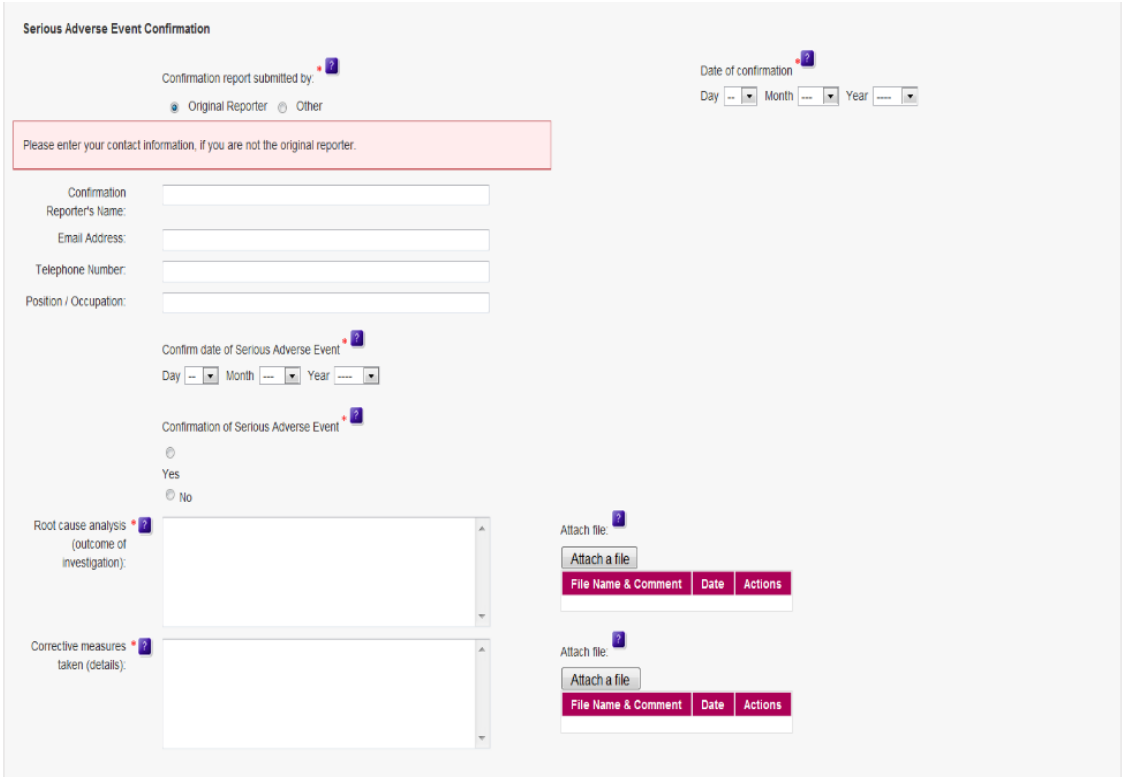
Figure 21a SAE confirmation report



Now click on the 'Serious Adverse Event' Tab above

You will now have access to the confirmation section of the selected SAE report as shown below:

Figure 21b SAE confirmation report



Complete all the mandatory fields.

- If you are the original reporter **do not** complete the four reporter details fields
- If you are **not** the original reporter select 'Other' in the 'Confirmation report submitted by' field and complete the four reporter fields below
- Enter the date of the completion of the investigation in the 'Date of confirmation' field
- Enter the date of the SAE
- Confirm if the reported event was an SAE or not
- Complete the Root cause analysis and Corrective measures boxes (see 3.7.4 and 3.7.5). These 2 fields will also transfer across to the associated SHOT questionnaire and be displayed on the 'Procedural review' page.
- Click the submit button to submit the report to MHRA for review. An incompletely submitted Confirmation report cannot be viewed by MHRA.

Note: Because SHOT and MHRA review SAE reports from a clinical and a BSQR point of view, SHOT may additionally require a separate questionnaire to be completed to address the clinical and/or laboratory errors involved in the report. For example, if a wrong unit is collected from a fridge, and a failure of the administration checks results in the wrong patient being transfused, MHRA will assess the report at the point of collection, and SHOT will assess the report at the point of administration.

3.7.4 Root causes

This is where you must enter details of the outcome of your local investigation into the event that has occurred. The term *root cause analysis* is taken directly from the BSQR. It is not intended that SABRE reporters must undertake specialist root cause analysis training in order to complete this section of the report form.

In this section, you must provide enough detail to describe not just **how** the event occurred, but **why** the incident occurred. It will benefit your corrective and preventive action to identify all the human factors involved. Write this section with enough detail so a third party without access to your local incident system can fully understand the root cause. You may attach files with an internal report or supporting evidence.

3.7.5 Corrective measures

Enter details of any actions taken to ensure that the circumstances that led to the occurrence of this SAE will not be repeated. Please ensure that all human factors and contributory factors identified are addressed.

Successful CAPA may involve re-designing critical processes, re-writing procedures, re-training staff or otherwise improving the overall Quality Management System such as managing distractions or addressing workload or staffing issues. Do not rely on CAPA which simply reminds staff of the correct procedure, or employs additional checking for errors instead of preventing the error from occurring. Write this section with enough detail so a third party without access to your local incident system can fully understand the corrective measures. You may attach files with an internal report or supporting evidence.

Both MHRA and SHOT are concerned of the effects of resourcing, staffing and workload on the root causes of SAEs. It is vital that if these factors result in the events reported, that these are detailed and addressed in the report to allow us to properly categorise and analyse the data collected.

3.7.6 Changes made by MHRA to SABRE reports

Once a reporter has submitted a SABRE report, the MHRA will sometimes amend categories and data within those reports on the MHRA SABRE HITS database.
Previously, these changes were not reflected on SABRE and MHRA notified reporters by email to changes made that would be reflected in the next Annual summary report.
Now, when changes are made following assessment by the MHRA haemovigilance team, or additional information from the reporter or SHOT, these changes will be reflected in your report. Reporters will still receive notification emails from MHRA and you will still have the opportunity to discuss any changes made.

3.7.7 Referral to the MHRA inspectors

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
- issuing of wrong components/ incorrect special requirements.

3.8 Logging out

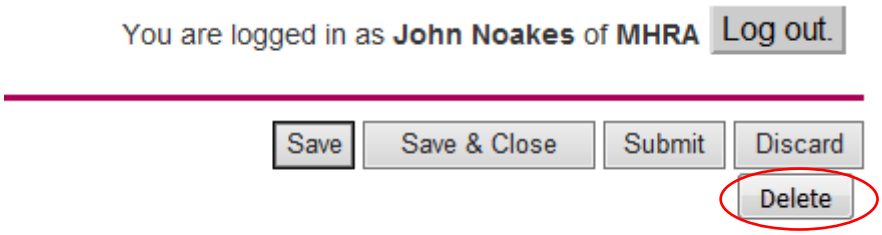
It is important that you remember to log out after every session. Failing to log out may cause difficulties on the next occasion that you (or your colleagues) log in.

4 Additional information

4.1 Deleting draft reports

Previous versions of SABRE have not allowed you to delete reports in case one reporter accidentally deleted the wrong report. However, this has often resulted in a number of blank reports which clutter up the Workspace. SABRE now allows you to delete draft reports only. To do this, simply open the report to be deleted and click the delete button.

Figure 22 Delete button



4.2 Amending report types (rollback)

If a reporter incorrectly reported an SAE instead of an SAR, or vice versa, previously the reporter was required to report the incident again in the correct format, while the original report was excluded. **New functionality will allow MHRA to change the Report type of Notification reports only**. Once this has been done, the reporter is required to then re-submit the amended form.

In the image below, 2017/003/001/HV1/164 has been submitted as an SAE.

Figure 23a Amending report types (rollback)

Report type	Reaction / Event related to	Incident Date	Local Ref No	MHRA Ref No	Reporter action	MHRA status	SHOT status
N Reaction			2017-02-27_1111 Rn	To be Assigned	Submit Notification	Not received	
N Event			test	To be Assigned	Submit Notification	Not received	
N Event	Processing	04/04/2013	2017-02-08-1953	2017/003/001/HV1/164	Submit Confirmation	Confirmation required	

If this is incorrect, contact MHRA or MHRA will contact you to arrange the change of report type. Once MHRA have made the change, your report will appear in the Workspace as below.

Figure 23b Amending report types (rollback)

Report type	Reaction / Event related to	Incident Date	Local Ref No	MHRA Ref No	Reporter action	MHRA status
N Reaction			2017-02-27_1111 Rn	To be Assigned	Submit Notification	Not received
N Event			test	To be Assigned	Submit Notification	Not received
N Reaction			2017-02-08-1953	2017/003/001/HV1/164	Submit Notification	Not received

The Report type has now changed from a submitted SAE Notification report to a draft SAR with the original MHRA reference number. You are required to complete the new form and submit as usual.

4.3 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.

5 Completing the SHOT questionnaire

5.1 Documentation & help

Further information about the SHOT reporting categories is available in the SHOT Definitions Document which can be accessed via the SHOT website under the Reporting page. https://www.shotuk.org/reporting/

Full details of the data required for each reporting category are available for download from the Documents section of the SHOT database (Dendrite). These datasets contain a flowchart of questionnaire pages, and a list of questions and answer options on each page.

To access them go into a SHOT questionnaire via SABRE. This questionnaire must be either completed, or at least have the mandatory questions on the registration page completed or you will be unable to move off the page until those fields are completed.

- Click the 'Documents' button in the top right-hand corner of the screen
- Click the download link next to the dataset you wish to view
- Click 'Main Menu' when finished
- Click 'Enter report' to return to your list of SHOT reports

Documents available:

- SHOT Dendrite Database User Manual
- Reporting FAQs (SHOT Bite No. 6)
- Dataset of questions and answer options for each SHOT reporting category

5.2 Completing the SHOT database record

Once a report has been submitted on the SABRE system, a link will be generated on the SABRE workspace which will lead directly to the associated SHOT report on the SHOT database.

Figure 24 SHOT link

On clicking this link, the SHOT Database will be opened and the ***Registration Details*** page for that specific report will be displayed. Most fields will be pre-populated from the information entered onto SABRE but the remaining fields will need to completed as far as possible.

Fields populated directly from SABRE where data is present:

- Date event reported
- Date and time of event
- Gender
- Reporter name
- Reporter telephone number
- Local reference number
- Patient date of birth
- Patient age (auto-calculated from date of birth and date and time of event fields)
- Reporting organisation
- Reporting hospital
- Description of the adverse event or reaction
- Is this event related to (and subsequent question if applicable)
    - Was a component transfused (Labile components only)

The database has been designed so that the response to certain questions will determine which questionnaire pages are generated.

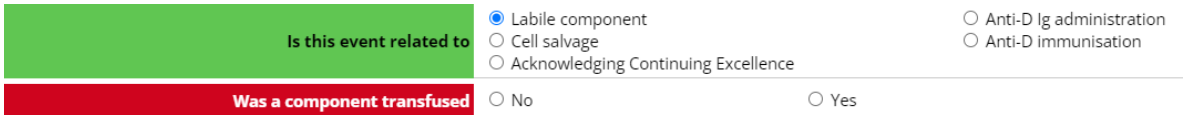
If the incident is related to Anti-D Ig administration, Anti-D immunisation, Cell Salvage or Acknowledging Continuing Excellence (ACE) the relevant pages for these reporting categories only will be available to complete.

If 'Anti-D Ig administration' is selected, there is an additional question before the main Anti-D questionnaire pages are generated. 'Was Anti-D Ig omitted, administered late or administered incorrectly'.
The purpose of this question is to determine whether the report is a full Anti-D Ig error incident, or whether it was an Anti-D Ig 'near miss':

- Answering *'Yes'* to this question will generate the Anti-D incident pages
- Answering *'No'* will generate the Near Miss incident pages (for example where an error was discovered before anti-D Ig was administered to the wrong woman)

If the report is for an incident related to blood and blood components (labile components), the next question is: Was a component transfused.

Figure 25 Labile components



If the answer is *'Yes'* the following pages will need to be completed:

Implicated Component
Indication for Transfusion
Transfusion
Transfusion Event

Some of these pages may contain data that has been pre-populated from SABRE. The ***Transfusion Event*** page determines the reporting category for all labile component reports where a component has been transfused. The choice of reporting category made here will determine which pathway the report is taken down. In most cases these selections will be pre-populated based on the initial data entered on SABRE.

If the answer is *'No'*, a new question will be generated 'Was there a delay which resulted in no component being transfused'.

- Answering *'Yes'* to this question will generate the usual labile component pages (listed on the previous page). This option should only be used to report a delay in transfusion (ADU) that meant no component was transfused which resulted in harm or potential harm to the patient.
- Answering *'No'* will generate the Near Miss incident pages i.e. no component was transfused because the error was identified prior to transfusion

5.3 Entering data and navigating the database

Please note any patient or staff-identifiable information must not be included in the record or in any documents that you upload.

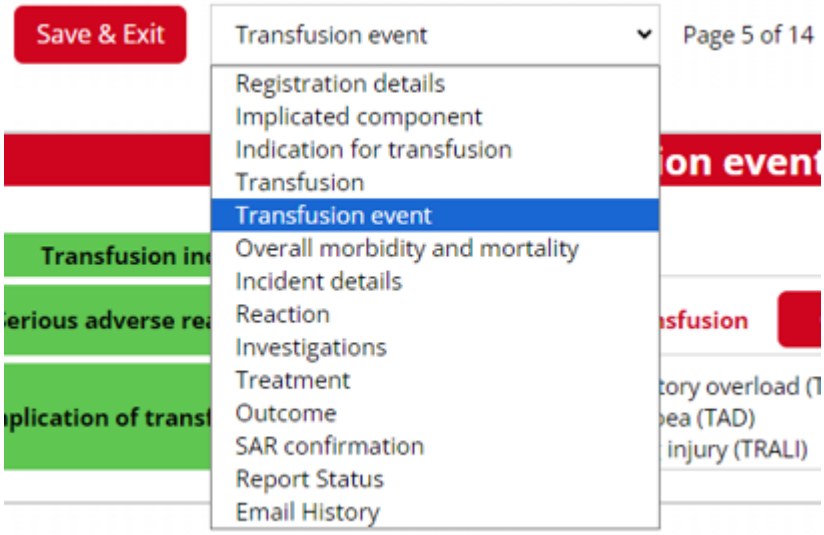
5.3.1 Navigating the database and saving records

To navigate through the database, use the Previous Page and Next Page which are situated at the top and bottom of every page. When clicking on these buttons the data on the screen will be saved and the next page or the previous page will be displayed. The data on the screen will also be saved if the Save and Exit button is clicked.

Figure 26a Navigation

There is also the facility to navigate directly to another page within the questionnaire by using the drop down list of pages next to the buttons at the top of the page.

Figure 26b Navigation

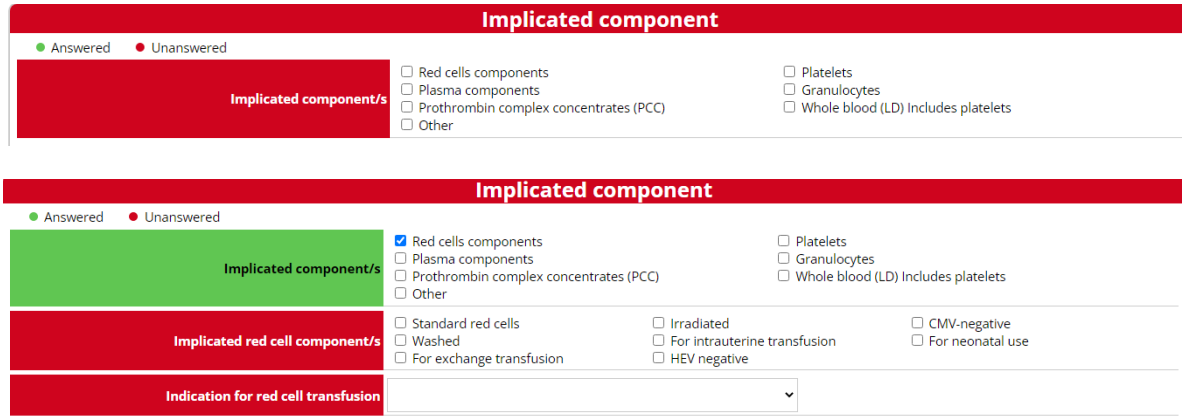


5.3.2 Interactive questions

Most questionnaire pages contain some interactivity, which means that certain questions are hidden until they become relevant. For example, on the ***Implicated component*** page. Further questions are displayed when different options are selected.

All questions will initially be in a red colour, until the question is answered, when it will turn green. This helps to indicate easily at a glance what questions need to be answered on that page.

Figure 27a Interactive questions

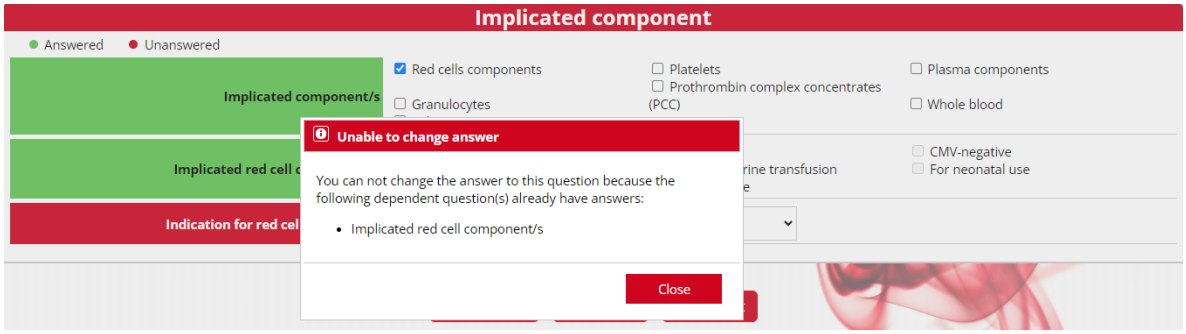


Once data are entered in one of the sub questions, the primary question cannot be changed.

For example, if *'Standard red cells'* is selected in the 'Implicated red cell component/s' question, the option *'Red cells components'* cannot be un-checked in the question above, 'Implicated component/s'.

Trying to do this will result in the error message below.

Figure 27b Interactive questions



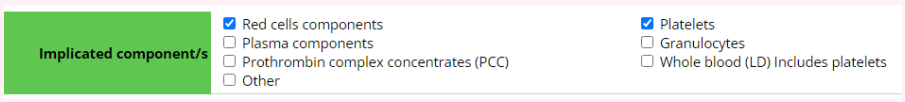
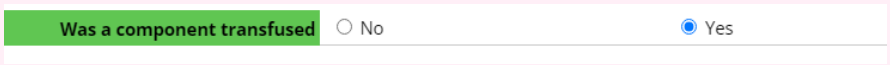
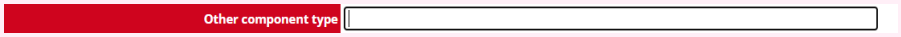
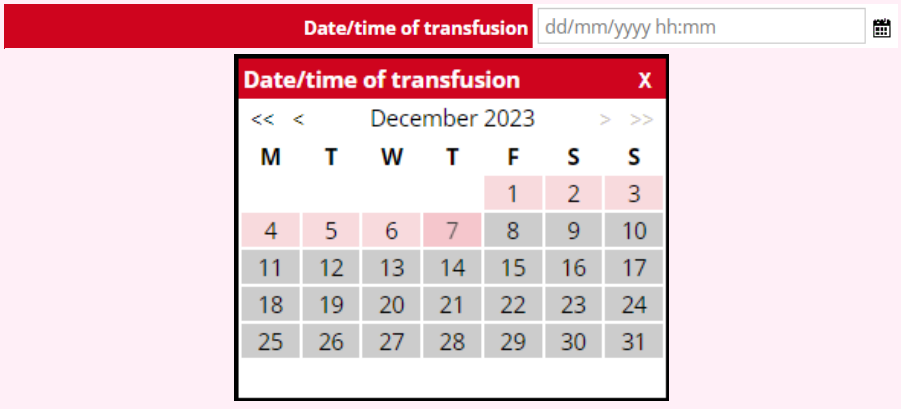
Therefore, the type of red cells will need to be de-selected before this can be removed as an implicated component.

The same principles apply to any primary and sub questions throughout the database.

5.3.3 Question types and entering data

The SHOT questionnaire pages are made up of different question types:

Table 5 Question types and data entry

Multiple choice More than one option can be selected. Tick all options that apply, and click once on a checkbox to remove its entry.	
Single choice Only one option can be selected. Clicking on a different option will change the selection, unless there is dependant data entered further down the page. To remove a selection completely, double click on it to 'de-select' the entry.	
Drop down list Click the arrow on the right hand side of the box to open the drop down list. Choose an item from the list, and click to select it.	
Free text fields Any text can be entered in these fields, but avoid using symbols or quotation marks " where possible.	
Date/time Click on the calendar symbol on the right hand side and select a date from the pop up calendar. Alternatively, the date and time can be typed directly into the box. This must be a valid date format to be accepted e.g. dd/mm/yyyy.	

5.3.4 Completing and closing a record

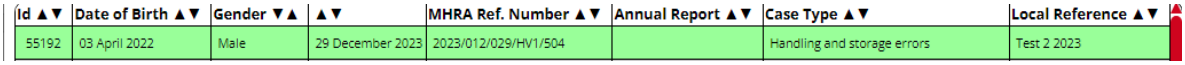
It is extremely important to include the outcome of the final local review before closing the report, as this is essential for SHOT to appropriately analyse and assess the case.

When all the data necessary have been entered and the record is complete, please ensure that the report is closed by answering 'Yes' to the question below. This is the last question on the ***Procedural Review*** page.

Figure 28a Completing and closing a record

When clicking 'Save and Exit', the record will turn green on the workspace, which indicates that it is complete. The record is now locked as 'read only' so the completed data can be reviewed by the SHOT Team. If any changes are required after completion, please contact the SHOT Office.

Figure 28b Completing and closing a record



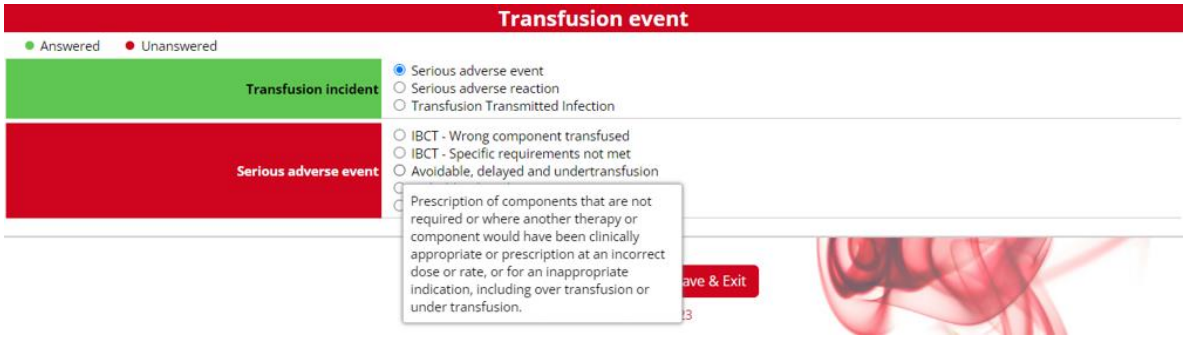
Id ▲▼	Date of Birth ▲▼	Gender ▼▲	▲▼	MHRA Ref. Number ▲▼	Annual Report ▲▼	Case Type ▲▼	Local Reference ▲▼
55192	03 April 2022	Male	29 December 2023	2023/012/029/HV1/504		Handling and storage errors	Test 2 2023

5.4 General SHOT database features

5.4.1 Hover prompts

Some fields will show what is known as a 'hover prompt' when the cursor is rested on them. They contain definitions or details of what information is required to complete the field. While the cursor rests on them they will persist and will only disappear when the cursor is moved on. See below.

Figure 29 Hover prompts



If the hover prompt does not disappear when the cursor is moved, then clicking on the hover prompt text will remove the message.

5.4.2 Uploading documents

There is a document upload facility on the ***Procedural Review*** page which enables relevant documents to be uploaded, such as Root Cause Analyses. SHOT would encourage this so that a thorough analysis can be undertaken for the SHOT Annual Report.

From 2021 there will be restrictions on the type of files that can be uploaded on the SHOT database. Permitted file types are: .pdf, .docx, .xlsx, .pptx, .txt.

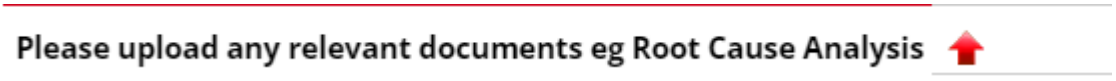
The preferred, and most secure format for any document upload is pdf.

Please ensure any documents uploaded are anonymised so that there is no identifiable patient or staff member data included

In addition, any documents uploaded to SABRE will transfer across to the SHOT database and will be held on a new page called ***Footnotes.*** This page will only exist in the record if an attachment has been transferred across from SABRE.

To upload a document on the ***Procedural Review*** page, click on the red arrow (shown below).

Figure 30a Uploading documents



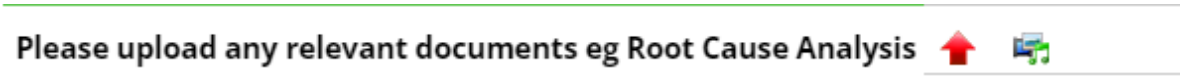
Add a description in the 'Media Description' field, for example 'Root cause analysis' or 'Investigation report' etc.

Then click the 'Choose file' button and select the file to upload. Once there is a file selected, click 'Upload'. The filename will be displayed in place of the text 'No file chosen'.

Figure 30b Uploading documents

Click the back button to return to the ***Procedural Review*** page. There will be an additional media icon displated to the right of the red arrow, which indicates that there is an attachment now available to view.

Figure 30c Uploading documents



5.4.3 Reminder e-mails

SHOT will send reminder e-mails for any report that is still incomplete (i.e. 'Open' on the SABRE workspace, or 'yellow' on the SHOT workspace) one month or more from the date the report notification was submitted.

Monthly reminder e-mails will continue to be sent until the report is either completed, or the report is more than 6 months old. After a report is 6 months old, SHOT will need to consider whether the report should be withdrawn from the analysis. However, SHOT will not withdraw any report without first attempting to contact the reporter to discuss by telephone.

If there is a particular reason why the report cannot be completed, for example, awaiting the results of an investigation or root cause analysis etc. then please contact the SHOT office to arrange for the report to be kept open longer. Alternatively, if the report is not SHOT reportable, then please e-mail the SHOT office and request that it is withdrawn.

Reminders for Anti-D Ig immunisation reports will be sent once the expected date of delivery (EDD) has passed so please ensure this date is added on page 2 of the new report on the SHOT database.

5.5 Changing SHOT categories

On occasion, it may become necessary to change the category of a report, usually following review by the SHOT Incident Specialists (in these cases the SHOT Incident Specialists will transfer the case type for you, and request that you complete the questionnaire pages for the new category).

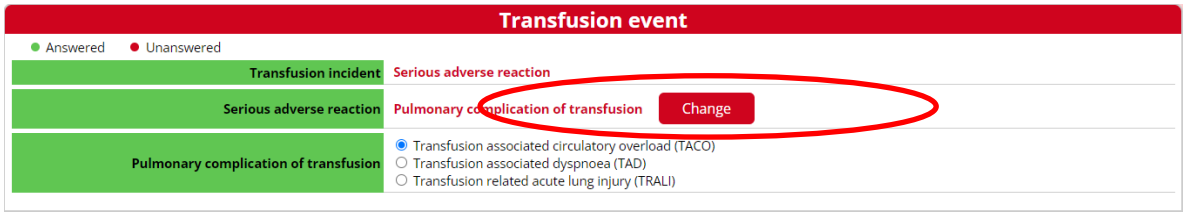
To do this, any data entered on the ***Transfusion event*** page must first be 'de-selected' by double clicking on the selected options, starting from the bottom of the page and working upwards.

Example steps have been provided below for 3 example category changes; however, the same principles will apply for all category amendments. The original category selection must be removed first before trying to select a new category. If in doubt, please contact the SHOT Office for advice and assistance.

Example 1: Changing from SAR (TACO) to SAE (ADU)

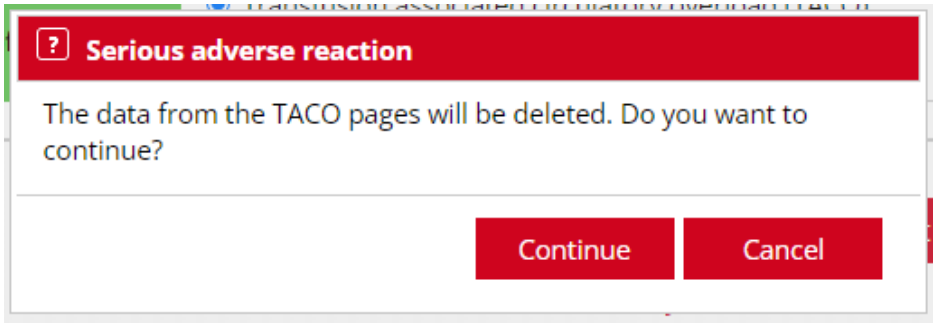
1. **Click** 'Change' in the 'Serious adverse reaction' section.

Figure 31a Changing SHOT categories



2. This will produce a warning message from the system to inform you that any data entered in the TACO pages will be deleted.

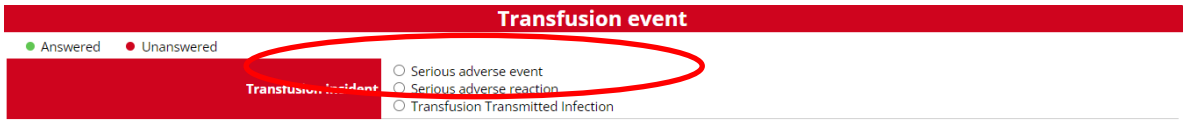
Figure 31b Changing SHOT categories



3. Click ‘Continue’ and the TACO entry will be de-selected.

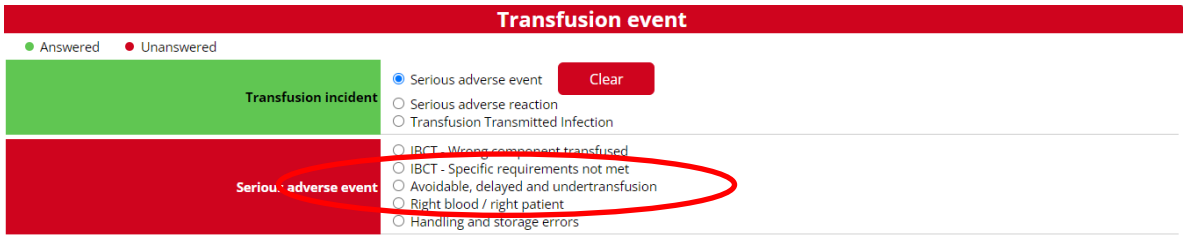
4. Click once on ‘Serious adverse event’

Figure 31c Changing SHOT categories



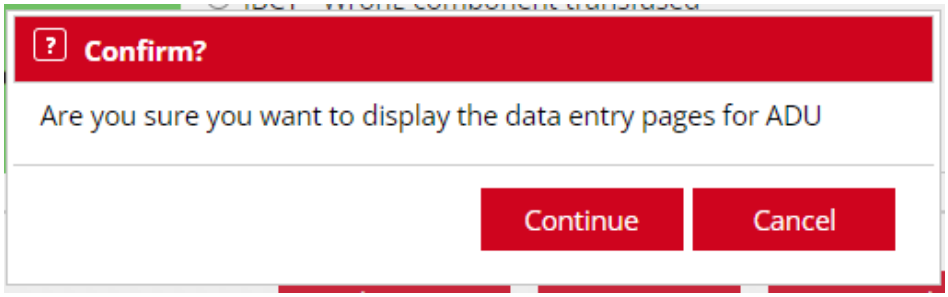
5. Click once on ‘Avoidable, delayed and undertransfusion’

Figure 31d Changing SHOT categories



6. This will produce a message from the system asking you to confirm that you want to display the data entry pages for ADU.

Figure 31e Changing SHOT categories

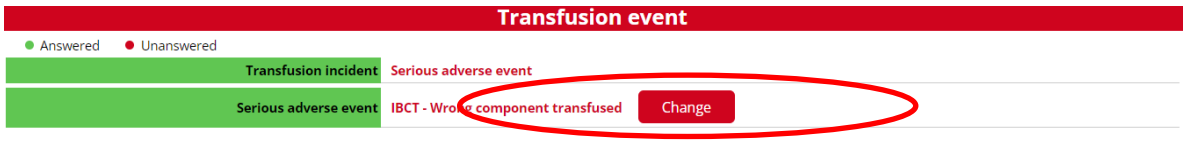


7. Click ‘Continue’ and click ‘Next page’ twice to continue to answer the ADU incident questions.

Example 2: Changing from SAE (IBCT-WCT) to Near Miss (if no component transfused)

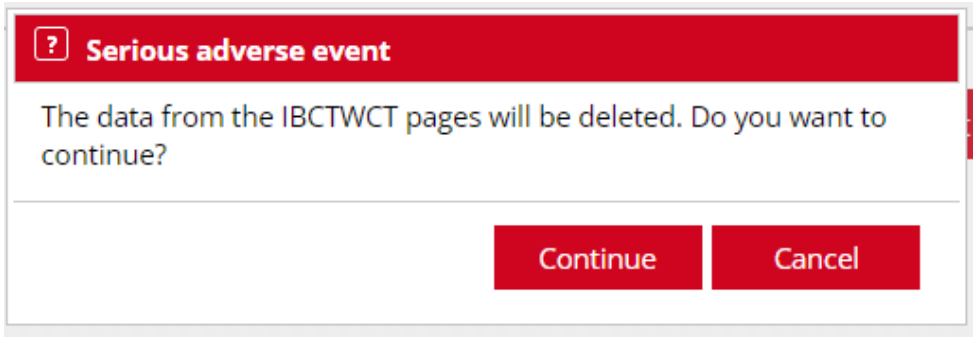
1. Starting from the ***Transfusion event*** page, **click** the ‘Change’ button next to ‘IBCT – Wrong component transfused’ to de-select it.

Figure 31f Changing SHOT categories



2. This will produce a warning message from the system to inform you that any data entered in the IBCTWCT pages will be deleted.

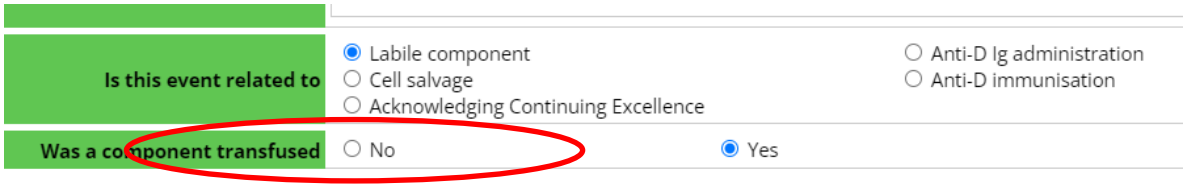
Figure 31g Changing SHOT categories



3. Click ‘Continue’ then navigate back to the ***Registration details*** page. (Either by clicking on the ‘Previous page’ button or by using the drop down list of pages at the top.)

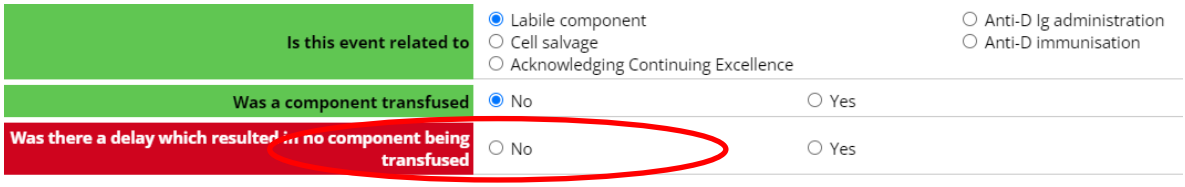
4. Click ‘No’ to change the answer to the question ‘Was a component transfused’

Figure 31h Changing SHOT categories



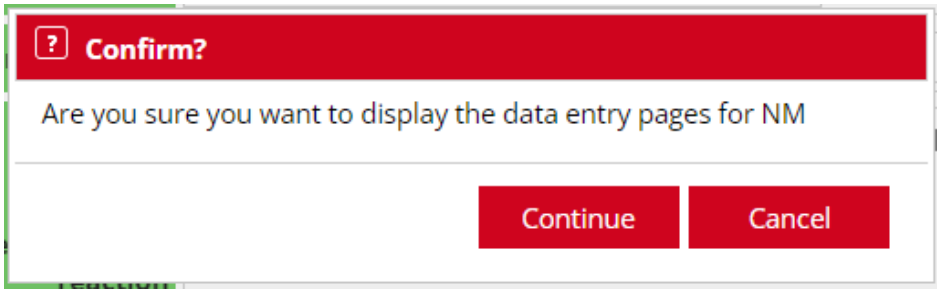
5. Click 'No' to new question 'Was there a delay which resulted in no component being transfused'

Figure 31i Changing SHOT categories



6. Click 'Continue' and click 'Next page' to continue to answer the near miss incident questions.

Figure 31j Changing SHOT categories



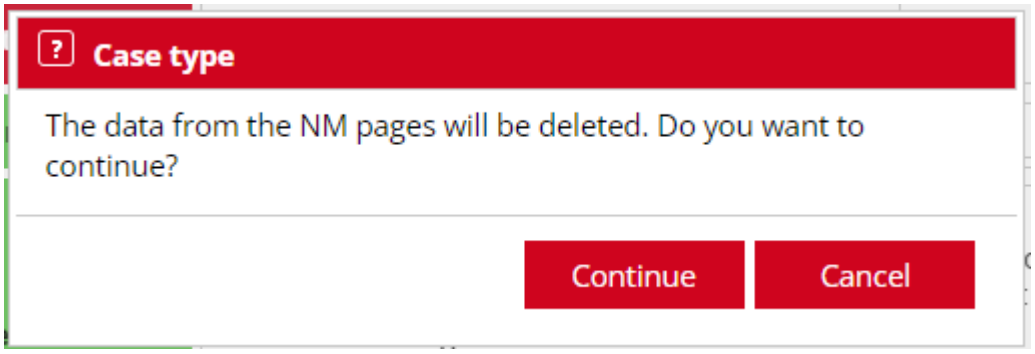
Example 3: Changing from Near Miss to a Labile component category (i.e. SAE or SAR where a component was transfused)

1. Starting from the ***Registration details*** page, click 'Change' next to the Case type.

Figure 31k Changing SHOT categories

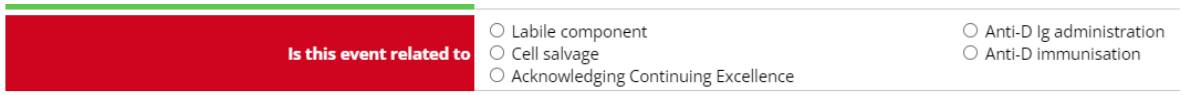
2. This will produce a warning message from the system to inform you that any data entered in the NM pages will be deleted.

Figure 31l Changing SHOT categories



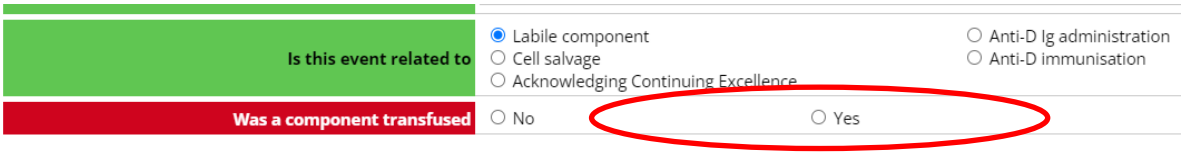
3. Click once on ‘Labile component’

Figure 31m Changing SHOT categories



4. Click once on ‘Yes’ to the question ‘Was a component transfused’. This changes the report to a transfused labile component report, and the following pages should be completed and a new category selected on the ***Transfusion event*** page.

Figure 31n Changing SHOT categories



Enquiries, advice and feedback

For any further advice or assistance with regards to haemovigilance reporting, or anything contained in the guide, please contact the relevant organisation below.

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 (SAR)

Directive 2005/61/EC [5] **categories**	**ISBT Definitions**	
	Clinical features	**Laboratory features**
Immunological Haemolysis due to ABO incompatibility	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)	Haemoglobinaemia, haemoglobinuria, decreased serum haptoglobin, unconjugated hyperbilirubinaemia, increased LDH and AST levels. Blood group serology shows ABO incompatible mismatch between recipient and donor.
Immunological Haemolysis due to other alloantibody NOTE – Delayed serologic transfusion reactions (alloimmunisation) without clinical or laboratory signs of haemolysis are **not** reportable to SABRE.	As above.	As above but blood group serology shows either alloantibodies to donor red cells or auto-antibodies in the recipient.
Non-immunological haemolysis	As above	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.
Transfusion-transmitted bacterial infection. **Note** – MUST be reported to the supplying Blood Establishment as soon as possible	Fever, rigors and joint pain with no evidence of symptoms pre-transfusion or alternative source of infection.	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.
Anaphylaxis/hypersensitivity NOTE – minor allergic reactions which respond quickly to symptomatic treatment like anti-histamine or steroid medications are NOT reportable to SABRE	Mucocutaneous signs and symptoms including urticaria, rash, pruritus, localised angioedema, oedema of lips, tongue, uvula and conjunctivae 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.	Rising mast cell tryptase levels or IgA deficiency and/or anti-IgA in the recipient.
Transfusion-related acute lung injury	Hypoxaemia (PaO_2/FiO_2 < 300 mm Hg or O_2 sats <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.	Evidence of anti-HLA or anti-HNA antibodies in recipient with incompatibility between donor and recipient.

Directive 2005/61/EC [5] categories	ISBT Definitions Clinical features	Laboratory features
Transfusion-transmitted viral infection (HBV)		Include if the recipient shows evidence of infection post-transfusion and there was no evidence of infection prior to transfusion or any alternative source of the infection, **PLUS either** at least one component received by the infected recipient was shown to contain the agent of infection **or** at least one component received was donated by a donor who has evidence of the same transmissible infection.
Transfusion-transmitted viral infection (HCV)		As above
Transfusion-transmitted viral infection (HIV 1/2)		As above
Transfusion-transmitted viral infection - other		As above
Transfusion-transmitted parasitical infection (Malaria)		As above
Transfusion-transmitted parasitical infection – Other, specify. NOTE: All suspected TTIs must be reported to the Blood Services.		As above
Post transfusion purpura	Bruising, severe haemorrhage, oozing wounds. Usually occurs 5-12 days post transfusion.	Thrombocytopenia (5-12 days post transfusion) and anti-HPA antibodies present.
Graft versus host disease	Fever, rash, liver dysfunction, diarrhoea. Usually occurs 1-6 weeks after transfusion.	Pancytopenia, characteristic histological appearances on bone marrow biopsy, bone marrow hypoplasia, chimerism.
Other serious reaction(s) - specify	E.g. Febrile non-haemolytic transfusion reactions (FNHTR) where fever >= 39 ºC oral or equivalent and a change of >= 2 ºC 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. Cases of TACO characterised by any four of the following which occur within six hours of transfusion • Acute respiratory distress. • Tachycardia. • Increased blood pressure. • Acute or worsening pulmonary oedema. • Evidence of positive fluid balance. 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.	

Annex B Table of reportable serious adverse events (SAE)

Serious adverse event, affecting quality and safety of blood component due to a deviation in:	Specification Product defect	Equipment failure	Human error	Other (specify)
Definitions	Serious adverse event which is mainly linked to a defect of the blood or blood components. **Product defect:** 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). **Example:** Clotting factor rates not compliant with specifications for fresh frozen plasma.	Serious adverse event which is mainly linked to a failure of the equipment. **Equipment**: 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. **Note:** 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).	Serious adverse event which is mainly linked to a human error. **Human error**: 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).	Any serious adverse event which cannot be classified in the already listed specifications.

Annex C Terms and conditions of use for the SABRE platform

Account management terms and conditions

Definitions

Medicines & Healthcare products Regulatory Agency

The Medicines and Healthcare Products Regulatory Agency (or simply 'the Agency') is an Executive Agency of the Department of Health protecting and promoting public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance, and effectiveness, and are used safely. The Agency is comprised of three regulatory centres: MHRA, CPRD and NIBSC.

MHRA

The MHRA is the UK's Competent Authority for Medical Devices and Medicines.

Registration for the collection of blood safety incident data

The MHRA's responsibility is 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. This is a joint haemovigilance reporting system for both the MHRA and the serious Hazards of transfusion (SHOT).

The UK Legal Framework

The legal framework is based on the following regulations however they only apply to data collected by the MHRA as the UK Competent Authority.

The Blood Safety and Quality Regulations 2005 No. 50 and the Blood Safety and Quality (Amendment) (No.2) Regulations 2005 No. 2898.

The Blood Safety and Quality Regulations apply to **blood establishments (BE)** and to **hospital blood banks (HBB)**. The 2006 Amendment Regulations 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.)

Registration

With regards to the SABRE registration service, "registration" refers to the requirements under the UK legal framework as described above.

User

A person, who is authorised by the MHRA to use SABRE provided by the Agency.
The MHRA reserves the right to refuse access to the Devices registrations service and to terminate an account, or service access at its absolute discretion.

Authorised representative

The natural or legal entity which is explicitly designated by the HBB, BE, care home, independent clinic, hospitals and other NHS facilities and services, manufacturers of medicines and medical devices and biomedical research, acts on behalf of the organisation and which may be addressed by the MHRA or other authorities and bodies instead of the organisation regarding the latter's obligations under the relevant UK legislation.

Service

The online systems made available to eligible entities and their Users by the Agency and/or the MHRA.

Account organization

An organisation who has setup an Agency account. Designated users are able to access the account for the organisation.

Confidentiality and protection of personal data

Directive 2005/61/EC [5] traceability requirements and consequent UK legislation, section 1(1) Data Protection Bill 2017 2019 and the Data Protection Act 2018 Part 1 section 2, 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 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.

The Agency is bound by its obligations under these regulations and It endeavours to ensure that its employees, representatives, and agents comply with the relevant legislation meeting all obligations under the act which arise under these Terms and Conditions of Use.

Agreement

The Agency agrees:

a) that eligible stakeholders of the Agency are granted an account to allow for the accessing and use of services offered by the Agency;

b) to provide Secure Socket Layer (“SSL”), Username and Password protection to meet the requirement in the Medical Device Directives to observe confidentiality;

By creating an account to use the Devices registration service the User agrees:

c) That submission of an account request to the Agency is not the fulfilment of any regulatory obligation applicable to you as a stakeholder of the agency;

d) That if notified that information that it has sent to the MHRA is incomplete, inaccurate, or corrupted, it must take prompt action to submit a corrected registration;

e) To be responsible and accountable for all use of its Username and Password. The User must take sensible measures to protect these if they wish to protect the data it places in the system. To submit data to the MHRA using the system the User may only use the access provided by these details;

f) Any unauthorised attempt to access or modify computer system information or to interfere with normal system operations, whether on MHRA computer systems or on networks accessible from the MHRA website, may result in the suspension or termination of the User's access. Access by any persons other than those authorised by the manufacturer and the MHRA is prohibited. Depending on the nature of any such activity the MHRA, or any other body with the power to do so, may initiate legal proceedings of whatever kind are appropriate;

Without prejudice to point 4(f) above, the User shall not:

g) resell or make commercial use of the system or its contents;

h) make a collection of and use any product listings, descriptions, or prices;

i) make any derivative use of the service or its contents;

j) download or copy any account information for the benefit of a third party [save where the User is an Authorised Representative and is downloading or copying such account information relating to a Manufacturer, under the terms or in fulfilment of the agreement under which it has been designated an Authorised Representative];

k) knowingly download any worm, cancelbot, Trojan horse, virus or any other malware onto the system;

l) The User may not reproduce, duplicate, copy, sell, resell, visit or otherwise exploit for any commercial purpose the system or any portion of the system without the MHRA's express prior written consent.

The User shall only use the system for lawful purposes. The User shall not use the system for:

m) fraudulent purposes, or in connection with a criminal offence or other unlawful activity;

n) to send, use or reuse any material that is illegal, offensive, abusive, indecent, defamatory, obscene or menacing;

o) or in breach of copyright, trademark, confidence, privacy or any other right;

p) or otherwise injurious to third parties;

q) or objectionable;

r) or which consists of or contains political campaigning, commercial solicitation, chain letters, mass mailings or ‘spam’ to cause annoyance, inconvenience, or needless anxiety;

Whilst authorized Users have the ability to nominate a person to become an additional User for their organisation account, the Agency reserves the right to deactivate any User access to its systems and services.

Limitation of liability

a) The MHRA reserves the right without notice to disable or discontinue the service as required. This may be for the purposes of routine maintenance or other reasons, or as part of an emergency termination of electronic computer connections designed to protect resources from illegal access or other damage.

b) The MHRA reserves the right to reject submissions to the service on the basis that the incidents reported, which are the subject of the submission, are not recognised by MHRA as either meeting the definition of a Serious Adverse Reaction (SAR) and or Serious Adverse Event (SAE) as defined within the relevant UK Blood Safety legislation.

c) In the case of an unanticipated service failure the MHRA and/or its agents will endeavour to restore the service to normal operating conditions as quickly as possible. Temporary disruption of the service will not constitute termination of the Agreement or relieve the User from their general obligations to the MHRA.

d) The MHRA accepts no responsibility for any loss, damage, or inconvenience of any kind, except for death or personal injury which is the result of the negligence of the MHRA that the User of this service may suffer as a result of its use. By using this service, the User specifically accepts all legal and general liability for any loss that may arise from such use.

e) In the event of a contact being deactivated the Agency accepts no responsibility for any loss, damage, or inconvenience of any kind.

Copyright

a) All content included on the MHRA SABRE platform, such as text, graphics, logos, button icons, images, audio clips, digital downloads, data compilations, and software, is the property of the MHRA and is protected by United Kingdom and international copyright, authors’ rights and database right laws. The compilation of all content on the MHRA website is the exclusive property of the MHRA and is protected by United Kingdom and international copyright and database right laws.

b) The User may not systematically extract and/or reutilise parts of the MHRA website without the MHRA’s express prior written consent. In particular, the User may not utilise any data mining, robots, or similar data gathering and extraction tools to extract (whether once or many times) for reutilisation any substantial parts of the MHRA website, without the MHRA’s express prior written consent. The User may not create and/or publish its own database that features substantial parts of the MHRA website without the MHRA’s express prior written consent.

Communications

When we refer, in these Terms, to "in writing", this will include email.

Any notice or other communication given by you to us, or by us to you, under or in connection with the Contract shall be in writing and shall be delivered personally, sent by prepaid first-class post or other next working day delivery service or email.

A notice or other communication shall be deemed to have been received: if delivered personally, when left at our registered office; if sent by prepaid first-class post or other next working day delivery service, at [9.00 am] on the [second] business day after posting or if sent by email, one business day after transmission.

In proving the service of any notice, it will be sufficient to prove, in the case of a letter, that such letter was properly addressed, stamped and placed in the post and, in the case of an email, that such email was sent to the specified email address of the addressee.

The provisions of this clause shall not apply to the service of any proceedings or other documents in any legal action.

Alternative dispute resolution

The Agency and the Service User agree that in the event of a dispute or disagreement as to the effect of any term or condition, or the consequences of the application of any such term or condition, they will jointly seek to resolve the dispute or disagreement by mediation using the services of a mediator appointed by the Centre for Dispute Resolution (CEDR) prior to the initiation of any proceedings in the Courts.

Use of collected Data within the Joint Haemovigilance reporting agreement with SHOT

MHRA and SHOT acknowledges and agrees that only authorised users are permitted to have access to and use of the data. Each party, and in particular their respective Lead Investigator, will be responsible for independently maintaining their own register of authorised users and for ensuring that the data is used solely for undertaking the Joint UK Reporting Arrangement and for MHRA within the regulatory framework of the Blood Safety and Quality Regulations (BSQRs) and shared with SHOT, for a legitimate purpose, to improve patient safety within the clinical and laboratory areas of haemovigilance and not for any other purpose.

The information shared through this agreement may not be shared with any other organisation not party to these terms and conditions without the prior written consent of the organisation deemed the original provider of that data and with a clear indication of what the information, if shared, will be used for.
Each party will undertake to make no attempt to link the data to other datasets held by different recipients not party to these terms and conditions or for different projects without the prior written consent from the relevant data provider, or to use the data to identify data subjects or further information about them of a confidential nature other than for purposes of carrying out the requirements of UK Joint Haemovigilance reporting and within the regulatory framework of the BSQR's.

Each party will hold and use the data in accordance with:

i. the IG requirements of the relevant data provider;
ii. all other applicable laws and relevant regulations; and
iii. If the data constitutes personal data within the legislation of section 1(1) Data
iv. Protection Bill 2017 2019 and the Data Protection Act 2018 Part 1 section 2.

Each party shall hold the data as Data Controllers, for each reporter and subject to the legal responsibilities as laid out in the relevant legislation and within the terms and conditions of this agreement.

As an Agency the MHRA collect and store data in accordance with BSQR's, Directive 2002/98 Article 14.3, but with reference to the General Data Protection Regulation (GDPR) MHRA will not use reporter's data for anything other than for a regulatory purpose and within the BSQR regulatory framework. A consequence of the Joint haemovigilance reporting platform allows SHOT to have access to the reporters mailing list.

MHRA have a legitimate reason to share the collected data with SHOT to help maximise the analysis of data to ensure its correct interpretation and therefore help with safe transfusion practice methods. SHOT use this data to send out SHOT-related communications, for example advertising the SHOT symposium, surveys related to SHOTs work and SHOT newsletters. To comply with the GDPR regulations SHOT are responsible for obtaining reporters consent, in advance, to use their data for direct marketing sent electronically (email, SMS or social media direct message) and respect their wishes should they want to stop receiving the information from SHOT.

Each party undertakes not to use data or derived data for any commercial purpose or any purpose that is subject to consulting or licensing obligations to third parties without prior written consent from the relevant data provider and will consult their respective Data Protection Officers before processing the data for any new purpose.

Governing Law and Jurisdiction

These Terms and Conditions of Use shall be governed by and construed in accordance with the Laws of England and Wales, the MHRA and the User expressly agree to submit to the exclusive jurisdiction of the Courts of England and Wales.

Price and payment methods

There is no direct payment levied for the use of SABRE as this is included in the fees collected as part of a organisation regulation fees as laid out in the BSQR.

Other important terms

The Agency reserves the right to change its Terms and Conditions at any time and whilst it will endeavour to advise Users beforehand this may not always be possible. Users should regularly check these Terms and Conditions regularly to ensure they are current.

In providing this service the Agency may direct Users to other websites outside of its control. In such cases Users should not assume that the Agency Terms and Conditions still apply.
You may only transfer your rights or your obligations under these Terms to another person if we agree in writing.

This Contract is between Users of the Haemovigilance service and the MHRA. No other person shall have any rights to enforce any of its terms, whether under the Contracts (Rights of Third Parties) Act 1999 or otherwise.

Each of the paragraphs of these Terms operates separately. If any court or relevant authority decides that any of them are unlawful or unenforceable, the remaining paragraphs will remain in full force and effect.

If we fail to insist that you perform any of your obligations under these Terms, or if we do not enforce our rights against you, or if we delay in doing so, that will not mean that we have waived our rights against you and will not mean that you do not have to comply with those obligations. If we do waive a default by you, we will only do so in writing, and that will not mean that we will automatically waive any later default by you.

This Contract and any dispute or claim arising out of or in connection with it or its subject matter or formation (including noncontractual disputes or claims) shall be governed by and construed in accordance with the law of England and Wales.

We both irrevocably agree that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim arising out of or in connection with a Contract or its subject matter or formation (including noncontractual disputes or claims). The Agency reserves the right to change its Terms and Conditions at any time and whilst it will endeavour to advise Users beforehand this may not always be possible. Users should regularly check these Terms and Conditions regularly to ensure they are current. In providing this service the Agency may direct Users to other websites outside of its control. In such cases Users should not assume that the Agency Terms and Conditions still apply.

Contact Details

SABRE Helpdesk Tel 020 3080 7336

SABRE E Mail: Sabre@mhra.gov.uk

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