

## 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. This will allow you to print the complete form if you require a hard copy for your local records.

## Saving

At any stage when you are drafting your Report on SABRE you are able to click Save. This will ensure that the work you have done is retained for completion at a later time. In order to Save a Report Form you must, as a minimum, have completed the Report Type and Local Reference Number fields on the Report Source section.

## Log 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.

## Back-up systems

Reports of Serious Adverse Events and Serious Adverse Reactions should only be submitted 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.

## Future developments

A Folder system, allowing draft and submitted reports to be organised in folders (in the same way as you would organise your emails or your files on your PC) will be introduced in Phase 2 of the implementation of SABRE. This will allow you to create and name folders, and to move saved Reports between folders.

Other enhancements are under consideration. MHRA welcomes your feedback on the existing SABRE system and your suggestions for future developments.

## Enquiries and Advice

### MHRA

tel 020 7084 3336  
fax 020 7084 3109  
email [sabre@mhra.gsi.gov.uk](mailto:sabre@mhra.gsi.gov.uk)

### SHOT

tel 0161 251 4208  
fax 0161 251 4395  
email [shot@nbs.nhs.uk](mailto:shot@nbs.nhs.uk)

**SHOT**

**MHRA**

# SABRE - a User Guide

## UK Blood Safety and Quality Regulations 2005 - Implementation of the EU Blood Safety Directive



### MHRA – the UK Competent Authority for Blood Safety

Medicines and Healthcare products Regulatory Agency  
Market Towers 1 Nine Elms Lane London SW8 5NQ

email: [sabre@mhra.gsi.gov.uk](mailto:sabre@mhra.gsi.gov.uk) tel: 020 7084 3336

### SHOT

Manchester Blood Service Plymouth Grove Manchester M13 9LL

email: [shot@nbs.nhs.uk](mailto:shot@nbs.nhs.uk) tel: 0161 251 4208

# SABRE – a User Guide

This document is to be read in conjunction with the document:

*MHRA Background and Guidance on reporting*

*Serious Adverse Events and Serious Adverse Reactions*

What is SABRE?	4
Help	4
Confidentiality	4
Reporting to SHOT	6
Existing reporting systems	6
Registration	7
Log In	7
Workspace	8
Report Source	9
Serious Adverse Reactions	10
Serious Adverse Events	12
SHOT	14
Attaching files	15
Acknowledgements and Reference Numbers	15
Footnotes	15
Searching	15
Printing	16
Saving	16
Log Out	16
Back up systems	16
Future developments	16
Enquiries and Advice	16

# What is SABRE?

The **Blood Safety and Quality Regulations** require that, from 8th November 2005, all serious adverse events or serious adverse reactions must be reported to the MHRA by Blood Establishments and hospital Blood Banks/Hospital Transfusion Teams.

The MHRA, the **UK Competent Authority for Blood Safety**, working with UK blood services and healthcare providers as well as SHOT (Serious Hazards of Transfusion), and other safety organisations, is aiming to further develop a reporting and investigation culture that will aid both consistency and improvement in blood safety and quality.

To facilitate this reporting requirement the MHRA, in consultation with the Adverse Events sub-group of the Operational Impact Group, has developed **SABRE (Serious Adverse Blood Reactions and Events)** – 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 single system allowing Blood Establishments and Blood Banks/Hospital Transfusion Teams to meet not only their regulatory obligations but also to report to SHOT electronically instead of via a paper system.

SABRE can be accessed via the MHRA website: [www.mhra.gov.uk](http://www.mhra.gov.uk) and the SHOT website: [www.shotuk.org](http://www.shotuk.org). The system is secure and provides access only to registered users. Registration is simple and merely requires the provision of some basic identifying information to accompany your reports.

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 are editable online and may have electronic files (e.g. images, documents) attached for submission.

Upon submission of a report, the reporter receives an automatic acknowledgement and a unique MHRA reference number.

## Help

**Online Help** is available at every stage and every level when using SABRE. Not only does every page (Registration, Log In etc) and every section of the Report Form have general **Helptext** (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).

The MHRA document **Background and Guidance on reporting Serious Adverse Events and Serious Adverse Reactions** coupled with the further advice provided on the SHOT website will also be of assistance when deciding what to submit using SABRE. Practical advice on the use of SABRE is available by email or by telephone from the MHRA Adverse Incident Centre.

## Confidentiality

The EU Traceability Directive and consequent UK legislation will 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. This information is not required to be submitted to MHRA as part of a notification or confirmation of a Serious Adverse Event or Serious Adverse Reaction. The link between any submitted report and the traceability records held by the reporting organisation will be made through a local incident reference number that you associate with your report and that you record on the Report Source section of the SABRE form. The local incident reference number can be any reference used to identify a report locally but must not be the Patient ID number, NHS number, donation number, donor number or any other reference that can be linked directly to personal details.

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

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

From 1 January 2005 the **Freedom of Information Act** obliges the MHRA to respond to requests for information which it holds and is recorded in any form, and creates a right of access to that information. The Agency will carefully consider its obligations to SABRE reporters under the Act prior to any release or non-release of information.

If you are concerned that, as a result of your disclosing 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") 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.

# Reporting to SHOT

The **Serious Hazards of Transfusion (SHOT)** scheme will continue to collect, analyse and report on serious sequelae of transfusion of blood components. Through the participating bodies, the information obtained contributes to: improving the safety of the transfusion process; informing policy within the Department of Health and the Blood Services; improving standards of hospital transfusion practice; and aiding production of clinical guidelines for the use of blood components.

The spectrum of events and reactions reportable to SHOT has not changed with the introduction of the SABRE system and SHOT data will continue to be used as a benchmark for the Joint Blood Safety Project between NPSA, SHOT and the National Blood Transfusion Committee. Further information on the work of SHOT may be found on their website: [www.shotuk.org](http://www.shotuk.org)

In addition to satisfying the requirements of the EU Directive for reporting to MHRA, SABRE has been developed to facilitate SHOT reporting by incorporating electronic versions of the SHOT Questionnaires. Reporters are first required to confirm that they wish their report to be shared with SHOT (this is recommended by the MHRA and SHOT) then, if SHOT wish a reporter to complete a questionnaire, an email will be sent to the reporter directing them, via their Workspace, to the SHOT section of their submitted report form. Here there will be a link that opens an electronic version of the relevant SHOT questionnaire. This can then be completed and submitted to SHOT via the SABRE system.

SABRE not only allows combined reporting to both MHRA and SHOT, but also, where the legislation does not require reporting of the incident to the MHRA, reporting to SHOT alone.

Reporting to SHOT remains voluntary, but is required for compliance with HSC/2004/009 “Better Blood Transfusion” and is a standard for the Clinical Negligence Scheme for Trusts in England. Active participation in SHOT by all hospitals was recommended by the CMO for England in his 2003 Annual Report. A number of blood safety initiatives depend on continuity of SHOT data for monitoring and evaluation and it is therefore vital that hospitals use the SABRE system to continue to report to SHOT.

# Existing reporting systems

SABRE does not replace existing procedures for reporting to local risk management systems, nor does it affect any arrangements for reporting to other organisations e.g. the National Patient Safety Agency, Health and Safety Executive, etc.

It must also be emphasised that the robust systems currently in place for rapid notification to the national blood services of suspected Transfusion Transmitted Infection (TTI) and Transfusion Related Acute Lung Injury (TRALI) and any other reaction or event involving the national blood services are unchanged.

Reporters can choose to use the facility incorporated within SABRE that allows them to enter the email addresses of colleagues and organisations to whom they wish electronic copies of their completed report form to be sent when the form is submitted to the MHRA.

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

Further information on this aspect of incident reporting may be obtained from the Adverse Incident Centre (telephone: 020 7084 3080) or from guidance documents on adverse incident reporting available on the MHRA website: [www.mhra.gov.uk](http://www.mhra.gov.uk)

# Registration

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

You are also asked to create and enter a Password of your choice. This will be used each time you wish to **Log In** to SABRE.

When you have completed the Registration form, just click the Log In button to send your details to the Adverse Incident Centre (AIC) AIC staff will then validate your request and send you an email containing your **Registration Number**. In certain circumstances AIC may wish to speak to you in person as part of the validation process.

MHRA anticipate that many reporters will operate as part of a haemovigilance team and may therefore choose to register using a shared email address. MHRA recommend this approach. It will, however, still be possible for reporters to register individually. For obvious reasons of security and confidentiality, we recommend that you take care to ensure that your chosen password is carefully guarded within your team.

# Log In

Three pieces of information are required for successful Log In to SABRE:

- an **email address** (the one submitted on your Registration request)
- a **Registration Number** (notified to you by the MHRA Adverse Incident Centre)
- your **Password** (chosen by you when Registering)

Online Helptext for this section provides advice on what to do if you have **Forgotten your Password**.

To Log In to SABRE, just enter these three items and click LogIn.

# WorkSpace

After successfully Logging In your WorkSpace will be displayed.

The WorkSpace serves two prime 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, or **Search** the content of all draft and submitted reports and their attachments.

You will also be able to **Update Registration** details. This may be when you wish to change your password or, for example, if you have to record a change of office address or telephone number.

On your first visit your WorkSpace will, of course, be empty. Each time you save a draft or submit a Report (whether a Notification or a Confirmation, an Event or a Reaction, or a SHOT Only Report) identifying details of that report will appear in the WorkSpace. Your WorkSpace is NOT visible to the MHRA or SHOT.

The screenshot shows the SABRE WorkSpace interface. At the top, there is a navigation menu with options: SABRE Workspace, Create New Report, Update Registration, Help, and Back to MHRA. Below the menu, a user is logged in as 'A Reporter of Hospital Transfusion Team'. The main area displays a table of reports with the following columns: Report Type, Reaction / Event related to, Incident Date, Local Ref No, MHRA Ref No, Last reported to MHRA, SHOT Questionnaire (No, Submitted), and Footnotes.

Report Type	Reaction / Event related to	Incident Date	Local Ref No	MHRA Ref No	Last reported to MHRA	SHOT Questionnaire		Footnotes
						No	Submitted	
S SHOT	Red blood cells	01/11/05	999000999	2005/011/001#V1/002				
N Reaction	Whole blood	01/11/05	12345	2005/011/001#V1/001				
C Reaction	Other	08/11/05	001	2005/011/001#V1/005				
N Event	Testing of donations	08/11/05	1234					

The columns of summary information in the WorkSpace are clearly labelled. The **icons** that will appear on the left hand side describe the type of Report and its status. The icons contain the letters N, C or S. N identifies a Notification, C a Confirmation, and S a SHOT Only report. The Yellow background colour indicates that Report's current status as **Draft**, and the Blue background indicates that you have **Submitted** that Report.

There are columns containing key identifying information from your Notification and Confirmation, and a separate column to indicate, where relevant, the date you submitted a completed Questionnaire for SHOT.

If you add a Footnote to a submitted Report, a letter F will also appear in that Report's WorkSpace record.

# Report Source

Much of this section of the Report Form will be pre-populated by SABRE with information submitted on your Registration Form.

As stated earlier, MHRA anticipate that many reporters will operate as part of a haemovigilance team and that you may therefore choose to register using a shared email address. MHRA recognises that in those circumstances the person completing a Report Form may not be the Registered SABRE user. For this reason the Reporter Name and Email fields in this section remain editable, i.e. if you are not the person in whose name the Registration was made, you can enter your own name and contact details. This will ensure that any communications from MHRA or SHOT are directed to the correct person.

The screenshot shows the 'Report Source' form. It includes fields for: Reporting Organisation, Reporting Organisation Address, Reporter's Name, Reporter's Email, Telephone Number, Fax Number, Position/Occupation, MIRA Ref No, Local Reference Number(s), Hospital Consultant, Incident Location, Serious Adverse Reaction (checkbox), Serious Adverse Event (checkbox), Do you wish shot to have access to this report (Yes/No), Report to SHOT only (checkbox), In addition, email this report to (text field), Reported locally (Yes/No), Has this been reported to a Blood Establishment (Yes/No), and If so, which Blood Establishment (text field). There is also a field for Blood Establishment Consultant.

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, donation number, donor number or any other reference that can be linked directly to personal details.

The first decision you have to make as a reporter is whether you are reporting a **Serious Adverse Event** or a **Serious Adverse Reaction** – and to tick the appropriate box. If you tick Event, then only the Event section will be accessible for completion. Similarly, if you tick Reaction, only that section will be available. This and the Local Reference Number comprise the minimum information that must be entered before you can save a draft Report.

You are also required to indicate whether you wish **SHOT** to have access to your report. MHRA recommends that you tick 'Yes'. The fields in the SHOT section will then be pre-populated with specified information from your completed Report Form. In those circumstances where the incident observed is not reportable to MHRA (e.g. clinical errors where a patient was not harmed), you should report to **SHOT Only**. If you tick this box, only the SHOT section is accessible and your report cannot be viewed by MHRA.

MHRA is very keen to ensure that the introduction of these new reporting arrangements 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.

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 and TRALI 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.

# Serious Adverse Reactions

If you ticked Serious Adverse Reaction (SAR) on the Report Source section, SABRE will automatically allow you access to this section and the Serious Adverse Event (SAE) section will not be available. Your first action must be to indicate (by ticking the box(es) at the top of the screen) whether you wish to submit a **Notification and/or a Confirmation Report**. Once again, only the section you tick will become accessible for completion. If you already have all the information required for both Notification and Confirmation it is possible to tick both boxes and to submit both at the same time.

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

Remember – SABRE allows you to save Reports in draft whilst you collect the information required to complete all sections of the Report Form.

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

- which blood component the Serious Adverse Reaction is related to
- type of Serious Adverse Reaction
- Imputability Level
- clinical outcome

The **Imputability Level** is 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. Clear **definitions and explanations** of Imputability Levels and all the terms used in this section of the form and in the picklists are available in the SABRE online **HelpText**.

Although some **Patient or Donor information** is required, this is only **Age** and **Gender**. Your local records will, of course, require further detail for fulfilling Traceability requirements.

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

Next you must indicate whether your original assessment was correct: i.e. which component type was implicated, whether there was a Serious Adverse Reaction, whether that Reaction was *correctly described* in the Notification (and, if not, what the Reaction *actually* was), and also what the **Clinical Outcome** was.

Lastly, a further assessment of the Imputability Level is required, as your assessment may have altered following review of the results of your local investigation. Where the final **Imputability Level is 2 or 3**, a report of your local investigation is required. The SHOT website contains advice on investigation techniques.

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

Provided you have ticked “YES” to allow SHOT to see your report, your completed report form will become available to SHOT at the same time.

If necessary, additional information may be added as a **Footnote**. Footnotes may be added after both the Notification and/or after the Confirmation has been submitted.

# Serious Adverse Events

If you ticked Serious Adverse Event (SAE) on the Report Source section, SABRE will automatically allow you access to this section and the Serious Adverse Reaction (SAR) section will not be available. Your first action must be to indicate (by ticking the box(es) at the top of the screen) whether you wish to submit a **Notification and/or a Confirmation Report**. Once again, only the section you tick will become accessible for completion. If you already have all the information required for both Notification and Confirmation it is possible to tick both boxes and to submit both at the same time.

Notifications of SAEs should be submitted to MHRA **as soon as possible**. Confirmations should be submitted as soon as possible after your local investigation is complete and you have all the required information. MHRA will send **reminders** to reporters where a Confirmation Report has not been received within a reasonable time period.

Remember – SABRE allows you to save Reports in draft whilst you collect the information required to complete all sections of the Report Form.

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

- where within the system the Serious Adverse Event occurred
- specification of the Serious Adverse Event

Clear **definitions and explanations** of all the terms used in this section of the form and in the picklists are available in the SABRE online **HelpText**.

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

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

Next you must indicate whether your original assessment was correct: i.e. whether there was a Serious Adverse Event and whether that Event was *correctly described* in the Notification (and, if not, what the Event *actually* was).

You must also provide what is described in the legislation as a “**root cause analysis**”. However, what the MHRA requires here is simply details of the outcome of your **local investigation** into the Event. Finally, you are required to provide details of any **Corrective Measures** taken as a result of your investigation.

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

The screenshot shows the SABRE 'Serious Adverse Event' report form. At the top, there are navigation tabs: 'SABRE Workspace', 'Create New Report', 'Update Registration', 'Help', and 'Back to MHRA'. Below these, there's a login status 'You are logged in as [ ] of [ ]' and buttons for 'Save', 'Save & Close', 'Submit', and 'Disca'. The main form is divided into sections: 'Report Source', 'Serious Adverse Reaction', 'Serious Adverse Event', 'Patient Details', and 'Confirmation'. The 'Serious Adverse Event' section has a 'Report Type' with checkboxes for 'Notification' and 'Confirmation'. Below this is the 'Notification' section with fields for 'Date of event', 'Event involving' (a dropdown menu), 'Specification' (a dropdown menu), and 'Implicated Component'. Two callout boxes are present: one pointing to the 'Event involving' dropdown with a list of options including 'Whole blood collection', 'Apheresis collection', 'Testing of donations', 'Processing', 'Storage', 'Distribution', 'Materials', and 'Other (specify)'; another pointing to the 'Specification' dropdown with a list including 'Product defect', 'Equipment failure', 'Human error', and 'Other (specify)'. Below the 'Notification' section is the 'Patient Details' section with fields for 'Date of Birth (dd/mm/yyyy)' and 'Gender' (radio buttons for 'Male' and 'Female'). The 'Confirmation' section includes 'Confirmation report submitted by' (radio buttons for 'Original Reporter' and 'Other'), 'Date of Confirmation', 'Confirmation of Serious Adverse Event' (radio buttons for 'Yes' and 'No'), 'Root cause Analysis (details)', and 'Corrective Measures taken (details)'. Each of the last three sections has a table with columns 'File Name & Comment', 'Date', and 'Actions', and an 'Attach a file' button.

# SHOT

To enable SHOT to see the content of your report to the MHRA, you must first tick the box on the Report Source section of the form. MHRA and SHOT recommend that you tick this box.

The SHOT section within SABRE requests the basic information that SHOT require to determine which, if any, SHOT Questionnaire you may be invited to complete.

If the incident you have observed is not reportable under the legislation and you are submitting a “SHOT Only” report (e.g. clinical errors where a patient was not harmed), you will need to complete all the fields on the SHOT section. However, if you are reporting to MHRA and have already completed the sections for a Serious Adverse Event or a Serious Adverse Reaction, the information you have entered will automatically appear in the relevant places in this section, and will be available to SHOT when you click Submit.

Upon receipt, SHOT will review the information submitted and will decide whether completion of a questionnaire is appropriate. If they wish a questionnaire to be completed, they will send the reporter an email directing them to Log In and then, via their Workspace, go to the SHOT section of their submitted report form. Here there will be a link that opens an electronic version of the relevant SHOT questionnaire. The questionnaire can then be completed and submitted to SHOT via the SABRE system. The submitted questionnaires will be reviewed by the SHOT panel, and their interpretation of a case may be helpful when completing Confirmation reports for MHRA.

Any questions about the completion of the SHOT Questionnaires should be directed to the SHOT office: [shot@nbs.nhs.uk](mailto:shot@nbs.nhs.uk) or telephone 0161 251 4208.

The screenshot shows the SABRE: Serious Adverse Blood Reactions & Events interface. At the top, there are navigation links for 'SABRE Workspace', 'Create New Report', 'Update Registration', 'Help', and 'Back to MHRA'. Below this is a user login area with 'You are logged in as' and 'Log out' buttons. A menu bar contains 'Report Source', 'Serious Adverse Reaction', 'Serious Adverse Event', 'SHOT', and 'Foot Notes'. The 'SHOT' section is active and displays a form with the following fields: \*Gender, \*DOB, \*Age, \*Local Reference Number, \*Date of Transfusion, \*Time of Transfusion, \*Implicated components, and \*Further Details. A table with columns 'File Name & Comment', 'Date', and 'Actions' is visible at the bottom right, with an 'Attach a file' button below it.

# Attaching files

Several parts of the Report Form are mandatory fields – you are required to enter information (by typing or 'cutting and pasting') or to choose from a Pick List. However, MHRA recognises that where you are asked for 'further details' - for details of your local investigation, for information on any corrective action taken, or for an Imputability report - it may be easier for you to attach a copy of an existing, locally produced, document.

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

**NOTE:** A file can only be attached to a Report that 'exists' within the SABRE system. You must, therefore, have already saved your draft Report within SABRE before you can successfully attach a file.

# Acknowledgements and Reference Numbers

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

The Reference Number will appear in this format: **2005/011/008/HV1/001**

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

The Reference Number is automatically entered onto the saved Report Form and onto the WorkSpace listing, and is retained when a Confirmation report is submitted. The same numbering system is used for SHOT Only reports.

# Footnotes

Once you have submitted a completed Report Form, the submitted sections are assigned Read Only status – you can review them but you cannot alter the content. If, however, you wish to submit some additional comments or information that cannot wait until the Confirmation Report is submitted, or if the Confirmation Report has already been submitted, then you may use the SABRE Footnote facility. More than one Footnote may be attached to a Report. Attachments may also be made to Footnotes.

# Searching

SABRE incorporates an internal search facility that is available 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.