SHOT Database User guide

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Contents

1. Introduction

This guide covers the use of the SHOT database (Dendrite) reporting system. The details in this guide can also be found in the Joint UK Haemovigilance Reporting User Guide which covers both the SABRE and SHOT systems.

Who to contact

If you are having problems with entering data into the SHOT questionnaires, please contact the SHOT Office by phone on 0161 423 4208 or by e-mail to shot@nhsbt.nhs.uk.

For any issues with your SABRE workspace, please contact the SABRE helpdesk on 020 3080 7336 or by e-mail sabre@mhra.gsi.gov.uk.

2. 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 that are required for each reporting category are available for download from the Documents section of the SHOT database (Dendrite). These datasets contain flowcharts of questionnaire pages, and lists 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

3. Reporting an Adverse Event or Reaction to SHOT (via SABRE)

To report an adverse event or reaction to SHOT, first login to your SABRE workspace and submit a new report notification.

SABRE will notify the SHOT database and create a new record to be completed which can be accessed directly from the SABRE workspace via a hyperlink in the 'SHOT status' column (far right-hand side of the workspace). The links are not instantaneous but should be available within a few minutes. Press 'F5' button on your keyboard to refresh the screen.

These hyperlinks reflect the status of the SHOT report and will default to 'Open N-3'. This means that the SHOT questionnaire is open and waiting to be completed.

If the SHOT questionnaire is subsequently completed and closed by the reporter or withdrawn by the SHOT staff, then this status will update to 'Closed N-3' or 'Withdrawn N-3' accordingly.

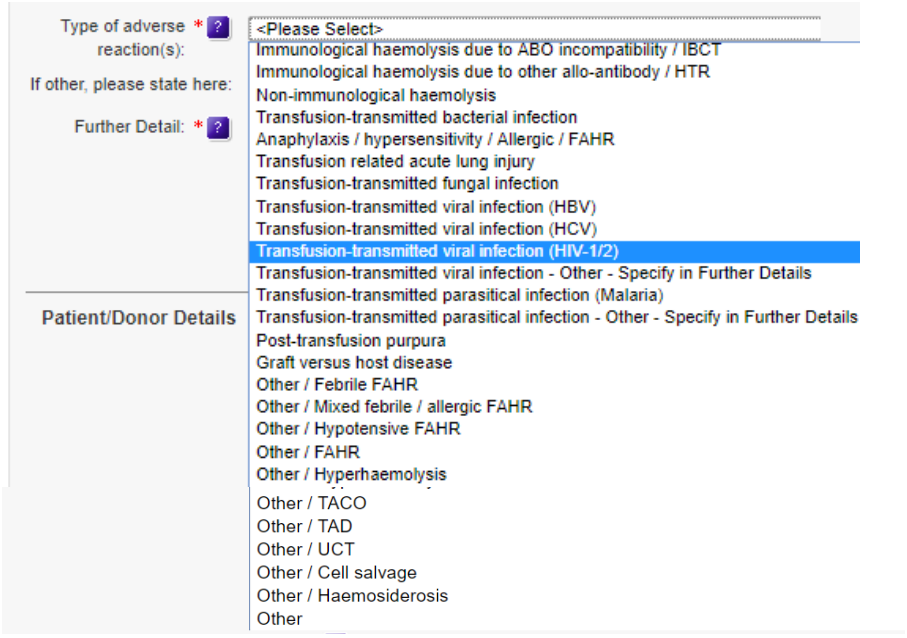
If a report is withdrawn, an e-mail containing the reason for withdrawal will be sent to all reporter e-mails registered to the reporting organisations SABRE account.

3.1 Reporting a Serious Adverse Reaction (SAR) to SHOT

The *'Type of adverse reaction(s)'* field on SABRE for SAR will determine the category of report that is pre-populated on the SHOT database.

From the screenshot below, 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.

If there has been a reaction due to ABO incompatibility this should always be reported to the MHRA as a SAR, however, the report would be categorised as an Incorrect Blood Component Transfused – Wrong Component Transfused on the SHOT database. The reason for this is that the reaction must be reported to the EU, whereas the reasons for the ABO incompatibility are investigated by SHOT so it is included within an error category.



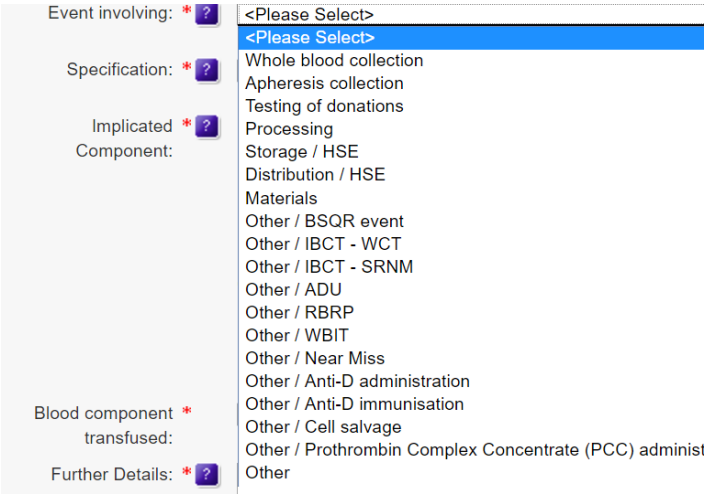
Once the notification report has been submitted on SABRE, the SHOT report will be created based on the selections above. If there is a corresponding SHOT category, the appropriate options will be pre-selected on the SHOT database. If the incorrect SHOT category is chosen, this can be amended in the SHOT database. See section 7. Changing SHOT Categories.

3.2 Reporting a Serious Adverse Event (SAE) to SHOT

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

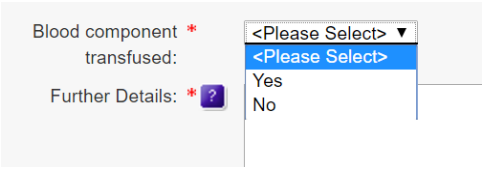
From the screenshot below, the category name after the last '/ ' denotes the equivalent SHOT category. Those with no SHOT category listed are generally not SHOT reportable and would only be reportable to the MHRA under the BSQR. These reports will still transfer across to the SHOT database but will have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



So, for example the combinations of data entry below would result in the following SHOT categories:

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 7. Changing SHOT Categories.

4. 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.

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)
- 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)

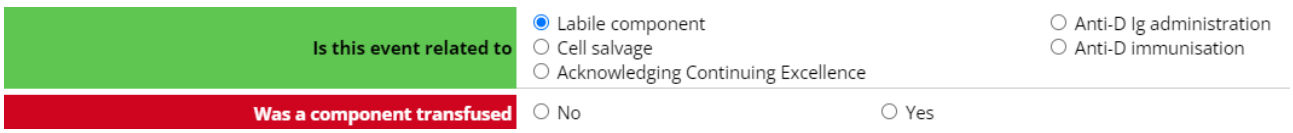
The database has been designed so that the response to certain questions will determine which questionnaire pages are generated.

If the incident is related to Anti-D Ig, Anti-D immunisation, Cell Salvage or Acknowledging Continuing Excellence (ACE) only the relevant pages for these reporting categories 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 Ig 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 will be: Was a component transfused.



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 have 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 displayed '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

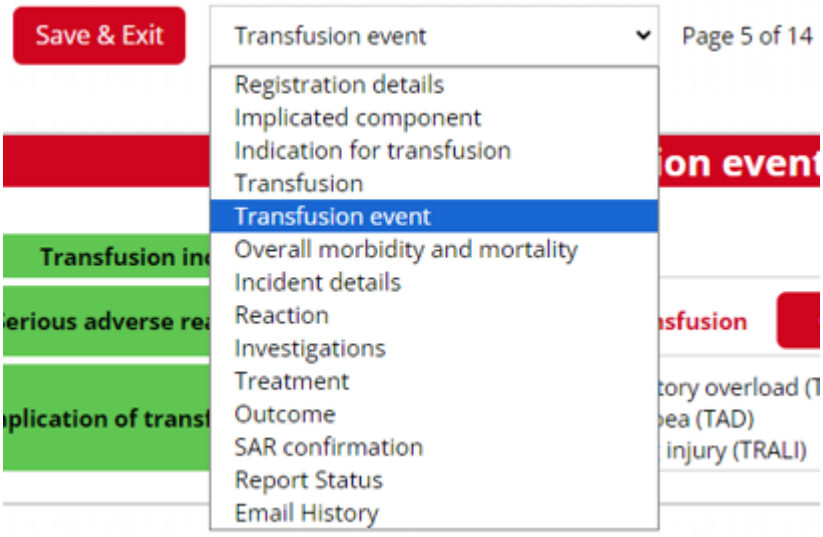
5. Entering Data and Navigating the Database

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

5.1 Navigating the database and saving records

To navigate through the database, use the Previous Page and Next Page buttons 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.

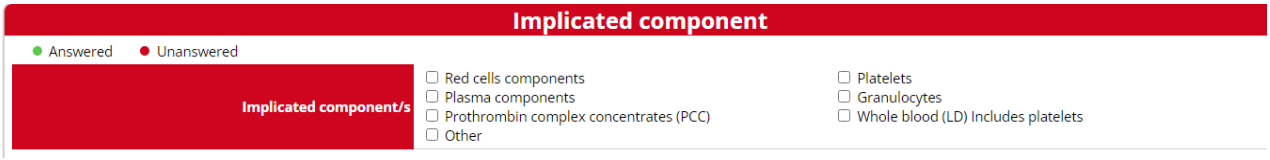
There is also the facility to navigate directly to another page within the questionnaire by using the drop down list of pages next to the buttons at the top of the page.

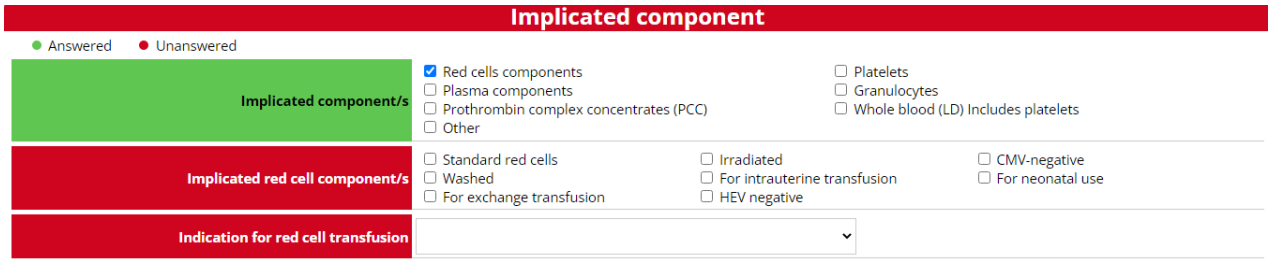


5.2 Interactive questions

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.

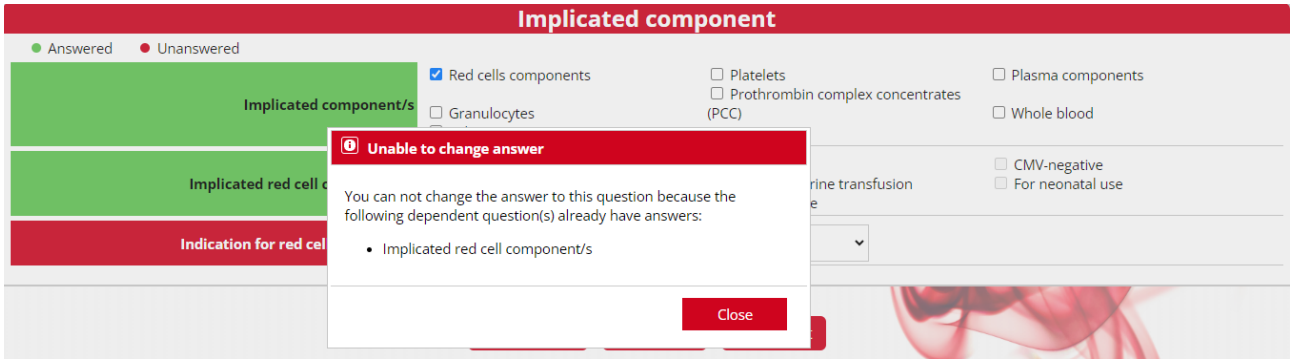




Once data are entered in one of the sub questions, the primary question cannot be changed.

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.

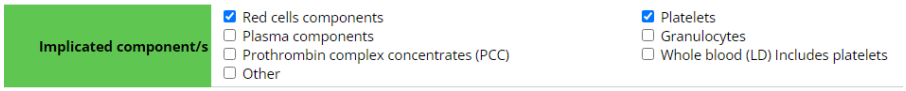
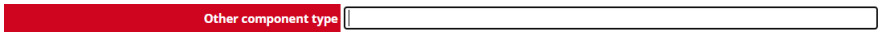
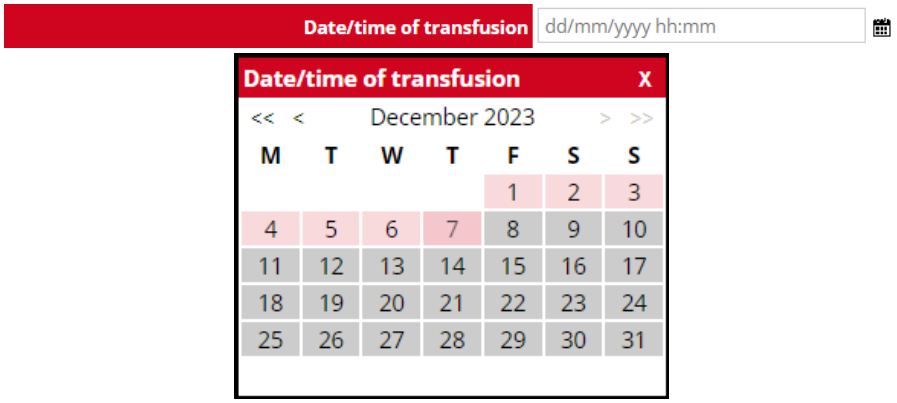


Therefore, the type of red cells will need to be de-selected before this can be removed as an implicated component.

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

5.3 Question types and entering data

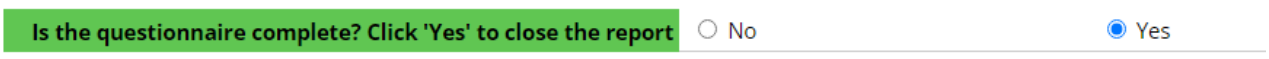
The SHOT questionnaire pages are made up of different question types:

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.	

5.4 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 necessary data 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.



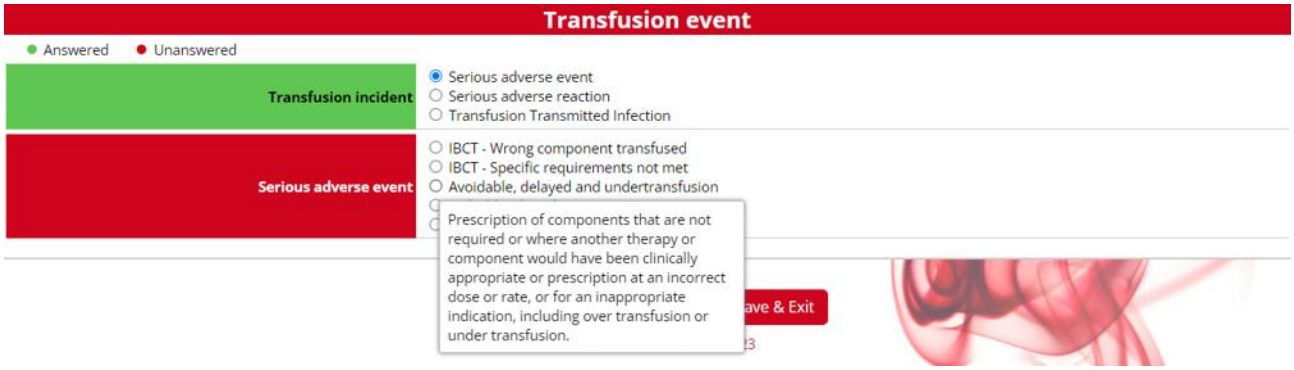
When clicking ‘Save and Exit’, the record will turn green on the workspace, which indicates that it is complete. The record is now locked as ‘read only’ so the completed data can be reviewed by the SHOT Team. If any changes are required after completion, please contact the SHOT Office.

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

6. General SHOT Database Features

6.1 Hover Prompts

Some fields will show what is known as a ‘hover prompt’ when the cursor is rested on them. They contain definitions or 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.



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

6.2 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.

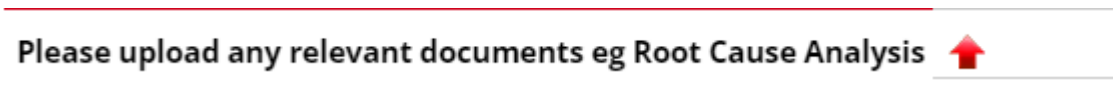
From 2021 there will be restrictions on the type of files that can be uploaded on the SHOT database. Permitted file types are: .pdf, .docx, .xlsx, .pptx, .txt.

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.

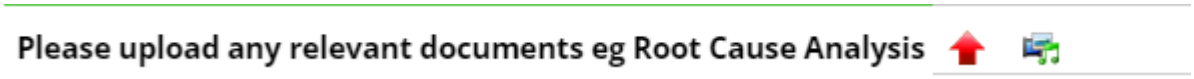
In addition, any documents uploaded to SABRE will transfer across to the SHOT database and will be held on a new page called ***Footnotes.*** This page will only exist in the record if an attachment has been transferred across from SABRE.

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



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

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



6.3 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, waiting 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 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.

7. Changing SHOT Categories

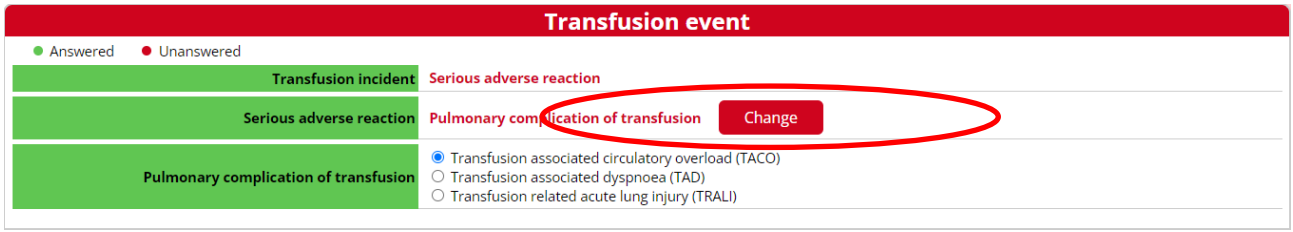
On occasion, it may become necessary to change the category of a report, usually following review by the SHOT Incident Specialists (in these cases the SHOT Incident Specialists will transfer the case type for you, and request that you complete the questionnaire pages for the new category).

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.

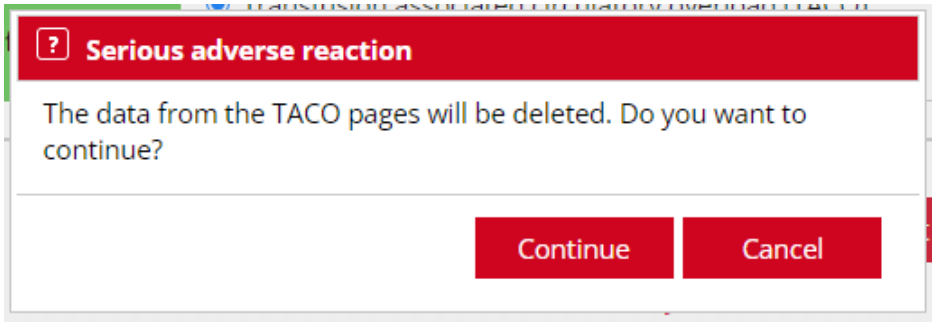
Example steps have been provided below for 3 example category changes; however, the same principles will apply for all category amendments. The original category selection must be removed first before trying to select a new category. If in doubt, please contact the SHOT Office for advice and assistance.

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

1. **Click** ‘Change’ in the ‘Serious adverse reaction’ section.

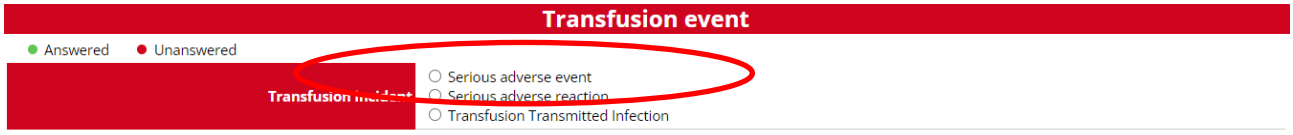


2. This will produce a warning message from the system to inform you that any data entered in the TACO pages will be deleted.

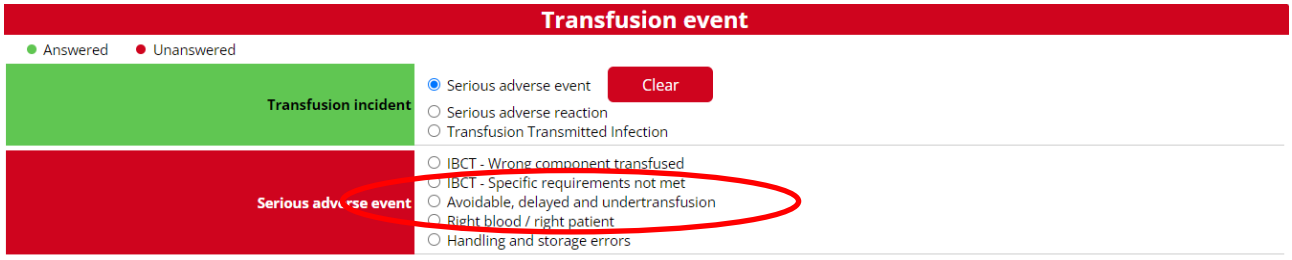


3. Click ‘Continue’ and the TACO entry will be de-selected.

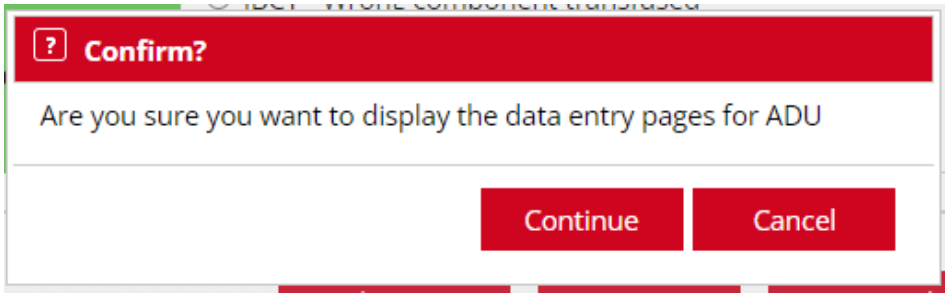
4. Click once on ‘Serious adverse event’



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



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

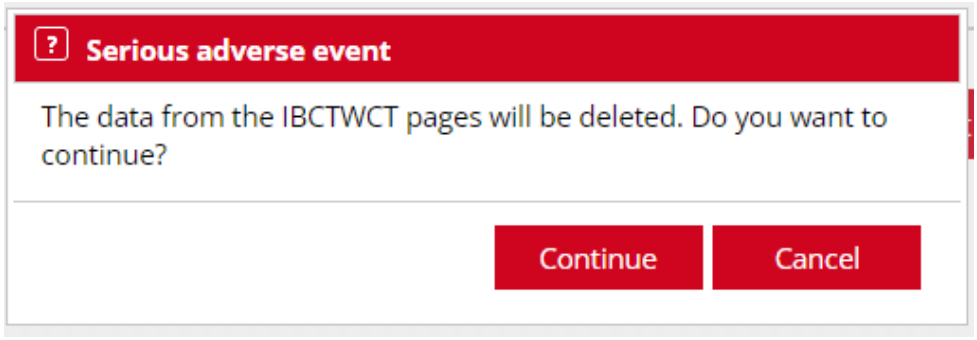


7. Click ‘Continue’ and click ‘Next page’ twice to continue to answer the ADU incident questions.

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

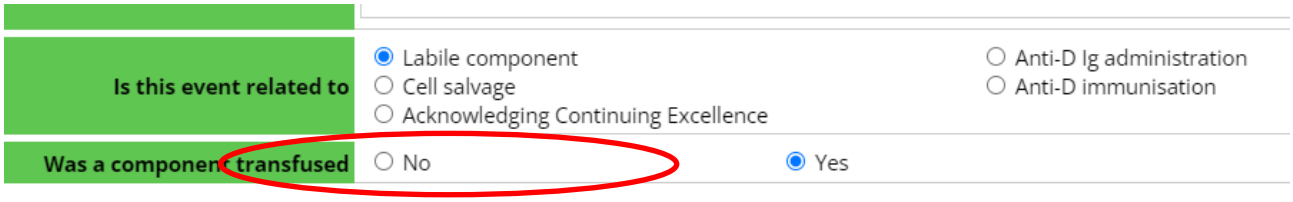
1. Starting from the ***Transfusion event*** page, **click** the ‘Change’ button next to ‘IBCT – Wrong component transfused’ to de-select it.

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

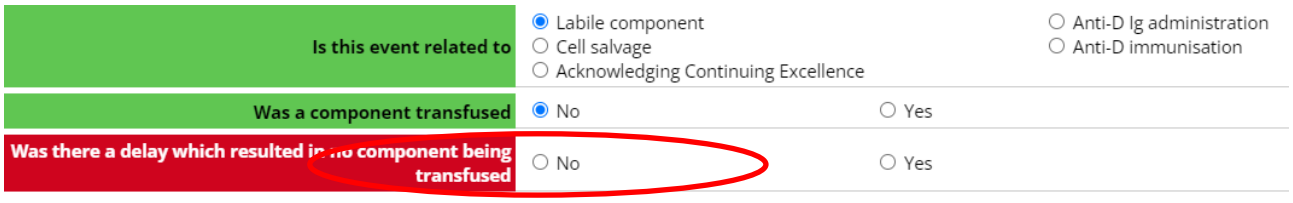


3. Click ‘Continue’ then navigate back to the ***Registration details*** page. (Either by clicking on the ‘Previous page’ button or by using the drop down list of pages at the top.)

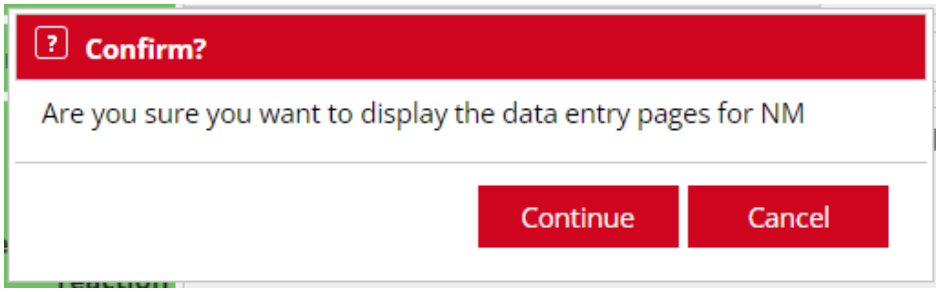
4. Click ‘No’ to change the answer to the question ‘Was a component transfused’



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



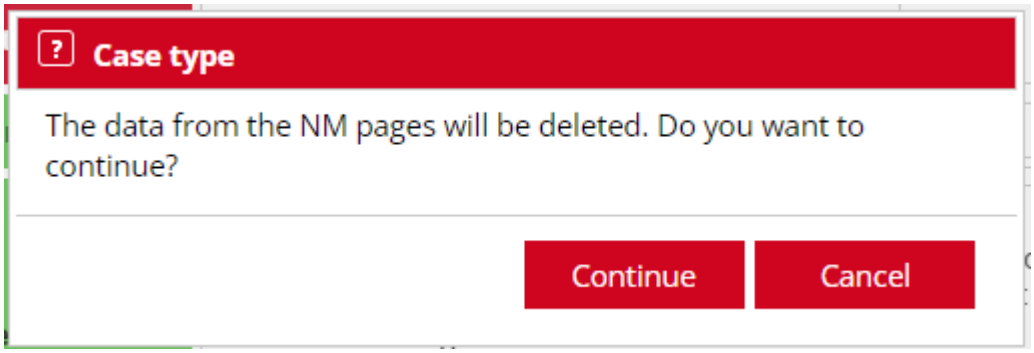
6. Click ‘Continue’ and click ‘Next page’ to continue to answer the near miss incident questions.



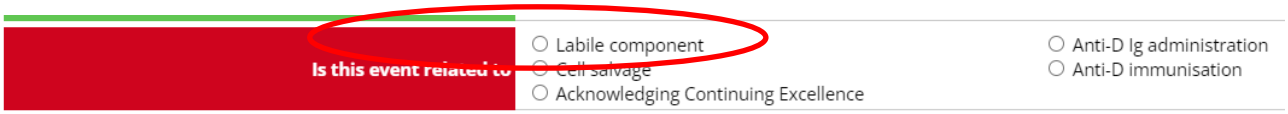
7.3 Example 3: Changing from Near Miss to a Labile component category (i.e. SAE or SAR where a component was transfused)

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

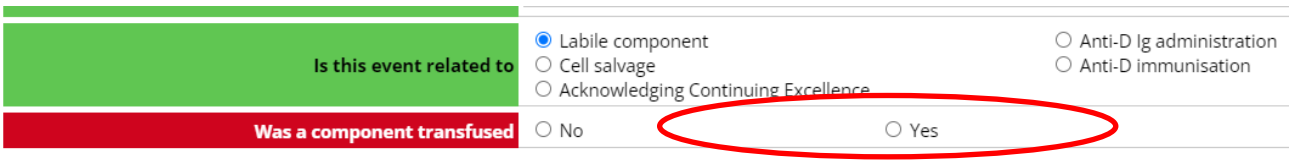
2. This will produce a warning message from the system to inform you that any data entered in the NM pages will be deleted.



3. Click once on 'Labile component'



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.



8. Imputability, Mortality and Morbidity

8.1 Imputability

When assessing imputability. i.e. what was the relationship between the adverse reaction and the transfused component, please use the imputability criteria in the table below.

N/A Not assessable	When there is insufficient data for imputability assessment
0 Excluded or Unlikely	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to causes other than the blood or blood components or where the evidence is clearly in favour of alternative causes
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 / probable	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

8.2 Mortality

When assessing mortality. i.e. what was the relationship between the adverse reaction and the death of the patient, please use the mortality criteria below.

- Death directly and solely caused by the transfusion (imputability 3)
- Death probably related to the transfusion (imputability 2)
- Death possibly related to the transfusion (imputability 1)
- Death unrelated to the transfusion (imputability 0)
- Patient recovered and survived

8.3 Morbidity

Morbidity should initially be assessed as ‘Major morbidity’, ‘Minor or moderate morbidity’ or ‘No clinical reaction’. When assessing major morbidity. i.e. what was the relationship between the adverse reaction and the level of morbidity suffered by the patient, please use the morbidity criteria below.

8.4 Major Morbidity

- Admission to intensive care, high dependency, or coronary care unit and/or ventilation
- Dialysis and/or renal impairment
- Major haemorrhage from transfusion induced coagulopathy
- Evidence of acute intravascular haemolysis e.g. haemoglobinaemia
- Persistent viral infection
- Acute symptomatic confirmed infection
- Reaction resulting in low or high haemoglobin level of a degree sufficient to cause risk to life unless there is immediate medical intervention
- Life-threatening acute reaction requiring immediate medical intervention
- Sensitisation to D and K in a female of childbearing potential