SABRE Communication October 2008

Useful Hints and Tips

MHRA were delighted to have been involved with presenting at the 2008 SHOT annual update meeting. It gave us an opportunity to feedback to you some key messages on reporting and how to report. We are aware that not all SABRE reporters were present at the meeting so, having received much favourable feedback on the content of the presentation, we would like to share with you the "helpful hints and tips" mentioned.

Email tips

Not active	Please check your current log-in details. Verify that the name of the account holder is still valid and that the email address used is active. If you have recently undergone change in the structure of your email address, e.g. *@bupa.com* has become *@spirehealthcare.com*; this may result in SABRE emails not being delivered.
Blocked by firewalls	Please verify that SABRE emails are not being "recognised" as spam by your local network, and that they are not being rejected due to the attachment of Word, Excel or PDF documents.
Not monitored	Please check your inbox regularly. We may send communications other than Confirmation reminders and Annual Summaries that require action. If it is impractical to regularly check the dedicated SABRE inbox, ensure you have emails forwarded to an email address that is monitored.
Table in Annual Summary report not received/returned in a readable format	We are unsure why this happens to some tables included in emails. Some problems with tables can be overcome simply by "forwarding" the email and entering the information into the table. Otherwise, please contact the SABRE Helpdesk and we can send you an Excel spread sheet version instead.

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Not returned to the correct email address	If a SABRE email has been automatically forwarded to you by a "forwarding rule" or by a colleague, ensure that you send your reply back to the SABRE inbox. Simply clicking "reply" to the email will only send it back to the sender (from where it was forwarded) and not to the MHRA.
Ignored/not actioned	Although we accept that you might not be able to respond immediately, taking no action is not acceptable. Ensure that you make arrangements to action the email at a later date, or send it to someone who can action it.

Reporting tips

We are often asked to produce a definitive list of reactions and events which are reportable as this would help reporters decide what to report and what not to report. Although this would be helpful, it is impossible to do. Other than the reaction types already listed as being reportable in the legislation, there is no way of being able to identify types of incident that are definitely reportable.

What makes it impossible is that for each type of incident, there are so many variables that can influence assessment of the seriousness of the event. Factors such as where the error was made, where the error was discovered, how the error was discovered, which staff was involved affect whether an event is reportable or not. What you should do is look at the event in the context of both the definition and the reporting requirements. The flow diagram on page 7 of the Background and Guidance on reporting Serious Adverse Events and Serious Adverse Reactions was designed to help this.

Although we have presented some examples in this document, they are only a general guide. The events and reactions you have to deal with will almost certainly differ in some way. It is for you to assess the seriousness of an incident and to judge whether it is reportable.

Only report "serious" adverse events and reactions	The intention of the EU Blood Safety and Quality Directive is not to have you report every single event or reaction, but only "serious" ones, as defined in the legislation. Defining "serious" in the context of a report might not always be easy. Consider whether a patient was, or might have been harmed or incapacitated. Consider, also, whether the incident resulted in hospitalisation or morbidity or whether hospitalisation or morbidity was prolonged. For example, a patient suffering a minor rash only, or a slight rise in temperature does not constitute a serious reaction and should not be reported. However, severe shortness of breath or vomiting might be an example of disabling or incapacitating conditions. Any reaction treated with medicine, other than medicine used to treat mild symptoms (like paracetemol or antihistamines) is reportable since the additional treatment indicates that morbidity resulted or was prolonged and that hospitalisation was also prolonged (even if they were an "in-patient" and their overall length of stay might not be affected). Similarly, for adverse events, if a unit of red cells is left out for over 30 minutes, identified immediately as being unsuitable for transfusion, and arrangements made for its disposal, and this is a genuine "one-off", this is not necessarily serious and should not be reported. However, if the loss of this unit delays treatment of the patient, their hospitalisation has been increased then this should be reported.
Report "as soon as is known"	The legal requirement is that you report a serious adverse event or serious adverse reaction *as soon as is known*. You should not wait until your local investigation is complete. After your investigation, should it become apparent that the serious adverse event or reaction was not related to the quality or safety of the blood, then this must be indicated in the Confirmation report.
Choose the correct category	The majority of the event categories concern activities in a Blood Establishment; *Blood collection* refers to the collection of donor whole blood. It does not refer to the collection of blood from an issue fridge in a hospital. *Processing* only refers to processing of donor blood. It is not intended to be used for events involving the "processing" of patient samples.

	Testing of donations only covers the testing of donor blood and not patient samples. *Storage* is to be used whenever a component is not stored under optimal conditions, not just for units lost during equipment failure. Units lost after a fridge failure, stored in the wrong place and transported under incorrect conditions are all examples of storage errors. *Distribution* only refers to the physical act of moving components between two distinct sites, such as a hospital and a blood establishment or two different hospitals. Distribution does not cover the act of moving blood between departments within the same organisation. It is recognised that there is some overlap between these categories. Blood that goes out of temperature while being transported between two hospitals could be a storage failure or a distribution failure. In these cases use whatever category seems most sensible. The category of *Other* should be used as a last resort. In practice a hospital blood bank is only going to be reporting incidents within the categories of storage and distribution. If it doesn't fit one of these categories then use "Other" rather than trying to make it fit one of the alternatives.
Use clear, unambiguous language and grammar	The majority of the reports received are clearly written and unambiguous; however there are some which are quite difficult to follow. As a general rule, try to be concise while including all the relevant information. Try to avoid writing long stories, including irrelevant facts. Simply state what went wrong, what led up to this and why you have assessed this to be a serious adverse event or reaction. The "Root Cause" section should be used to state what caused the event, and the "Corrective Measures" section should be used to state what was done to correct the problem and prevent it recurring in the future. Avoid using local abbreviations and jargon and recognise that someone totally unconnected with the incident needs to read and understand exactly what happened.
Do not report clinical events	The Directive does not cover clinical events. In short, this means that, if the serious adverse event is the result of an error by a doctor, nurse, phlebotomist etc, these should *not* be reported. What should still be

involving the medical use of blood	reported is if the blood bank had a system for spotting these sorts of errors, but didn't. For example, a doctor collecting a sample from the wrong patient is not a reportable event. However, if the sample is tested in the blood bank, and the historical record is not checked and the error not identified, the event is reportable. We hope to see further clarity concerning "clinical" events emerge from the EU Working Group.
Do not report events involving blood products	Blood products such as anti-D, clotting factors, immunoglobulins, and solvent/detergent treated fresh frozen plasma such as Octaplas are licensed medical products and are not, therefore, covered by the Blood Safety and Quality regulations. Events and reactions involving these should not be reported. Adverse reactions to licensed medicinal products should be reported using the MHRA's *Yellow Card* Scheme.
Always submit a Confirmation report	Always submit a confirmation report when your investigation is completed. If it turns out that the event reported was not serious, or if the reaction reported wasn't a transfusion reaction related to the blood, you can indicate this in your Confirmation report. This is the correct place to add this information, not a Footnote. Footnotes are designed for additional information which comes to light after a notification or confirmation is submitted. Things to remember in your Confirmation report; • Identify the Root Cause. This is not just a repeat of the details of the event. Identify exactly what caused the event to occur. If the event involves a unit of red cells not packaged correctly for transport, the Root Cause is not "failure to pack the box correctly". Identify *why* the box was not packed correctly. This could be a distraction from the task due to lone working, lack of packing materials/resources, failure to follow SOP, lack of training, etc. Identifying an appropriate Root Cause will then help you to apply appropriate Corrective Measures • Identify appropriate Corrective Measures. Your Corrective Measures should not only correct the event you're reporting, but also prevent similar events from occurring in the future. It is possible that the Corrective Measure is simply to re-train a member of staff or re-iterate the existing SOP. However simple or obvious the Corrective Measures are, they must be documented, otherwise there will be no evidence that you have taken the appropriate Corrective Measures.

	• Choose the correct Reaction Type. Sometimes when you investigate a reaction, it turns out that the reaction may not be the reaction type originally stated in the Notification. Before simply applying an Imputability of "0", consider whether to select a different Reaction Type. For example, if your TRALI turns out not to be a TRALI, consider changing the Reaction Type to "anaphylaxis/hypertension" or "other" and indicating that it was, for example, a TACO or allergic reaction. • Select the appropriate Clinical Outcome. You should state the clinical outcome of the *reaction*, and not the overall clinical outcome for the patient. For example, the SAR was reported as "Immunological haemolysis due to other allo-antibody", but the patient died as a result of their original condition (*not* the reaction). In this case, you should not select "Death" as the Clinical Outcome, but one that is appropriate to the reaction.
Emailed reminders for Confirmations	Please remember, these are only reminders. They are not requests for you to put in a Confirmation report if you are not ready to submit one. Some investigations take longer to complete than others. Do not submit a Confirmation report stating that "Corrective Measures will follow". Updates to the progress of the investigation should be added as Footnotes.

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