

***SUBMITTING A  
REPORT OF A NEAR  
MISS SAE  
OCCURRING IN THE  
HOSPITAL BLOOD  
BANK TO THE  
NATIONAL  
HAEMOVIGILANCE  
OFFICE***

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## **Introduction**

This document will provide guidance on reporting near miss SAE occurring in the hospital blood bank (HBB) i.e. the hospital transfusion laboratory.

### ***Near Miss SAE***

Near miss events are those which undetected, could result in the determination of a wrong blood group, issue, collection or administration of an incorrect, inappropriate or unsuitable component, but which were recognised before a blood component was transfused (SHOT, 2009)

An adverse event (AE) is categorised as a near miss event SAE when the blood component has not been transfused.

From beginning of 2010, it is mandatory to report all near miss events occurring in the HBB to the NHO. Near miss events occurring in the clinical area are not reportable to the NHO. It is recommended these are reviewed at local level in the hospital.

## **Submitting a report to NHO**

1. Evaluate incident at hospital level to ascertain if it is reportable as a Near Miss SAE. (See Appendix 1& 2).
2. Submit report to National Haemovigilance Office (NHO).
3. You may choose to submit the notification (BT 471-1) and confirmation reports (BT 472-1) separately or at one time.
4. Please ensure all questions are answered. Where questions are not answered, you will receive follow-up calls from staff at National Haemovigilance Office

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5. Reporting establishment is the name of the reporting hospital
6. Near Miss SAE are classified by the part of the work process in which the error occurs and the specification or cause of the error. (See Appendix 3)

7. Please assign identical report identifier to both the notification and confirmation forms. It is recommended that you include the name of your hospital in the local identifier. The NHO does not want or need patient identifiers (e.g. patient hospital numbers). Traceability of reports should be maintained at hospital level by this report identifier.

The NHO will assign a number to each report received to the office; HV /NM/Sequence / Year e.g. HV/NM/001/10.

8. Further details: You should include a short summary of error in this section

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9. Root Cause Analysis- Use of the root cause codes adopted by National Haemovigilance Office from Mers –TM is suggested (Please refer to National Haemovigilance Office Guidance on report forms 2008, available at; [http://www.giveblood.ie/Clinical\\_Services/Haemovigilance/NHO\\_Forms\\_2008\\_guidance\\_information.pdf](http://www.giveblood.ie/Clinical_Services/Haemovigilance/NHO_Forms_2008_guidance_information.pdf) accessed on-29/1/2010).
10. Corrective measures taken – Include a short description of actions taken to correct the error.

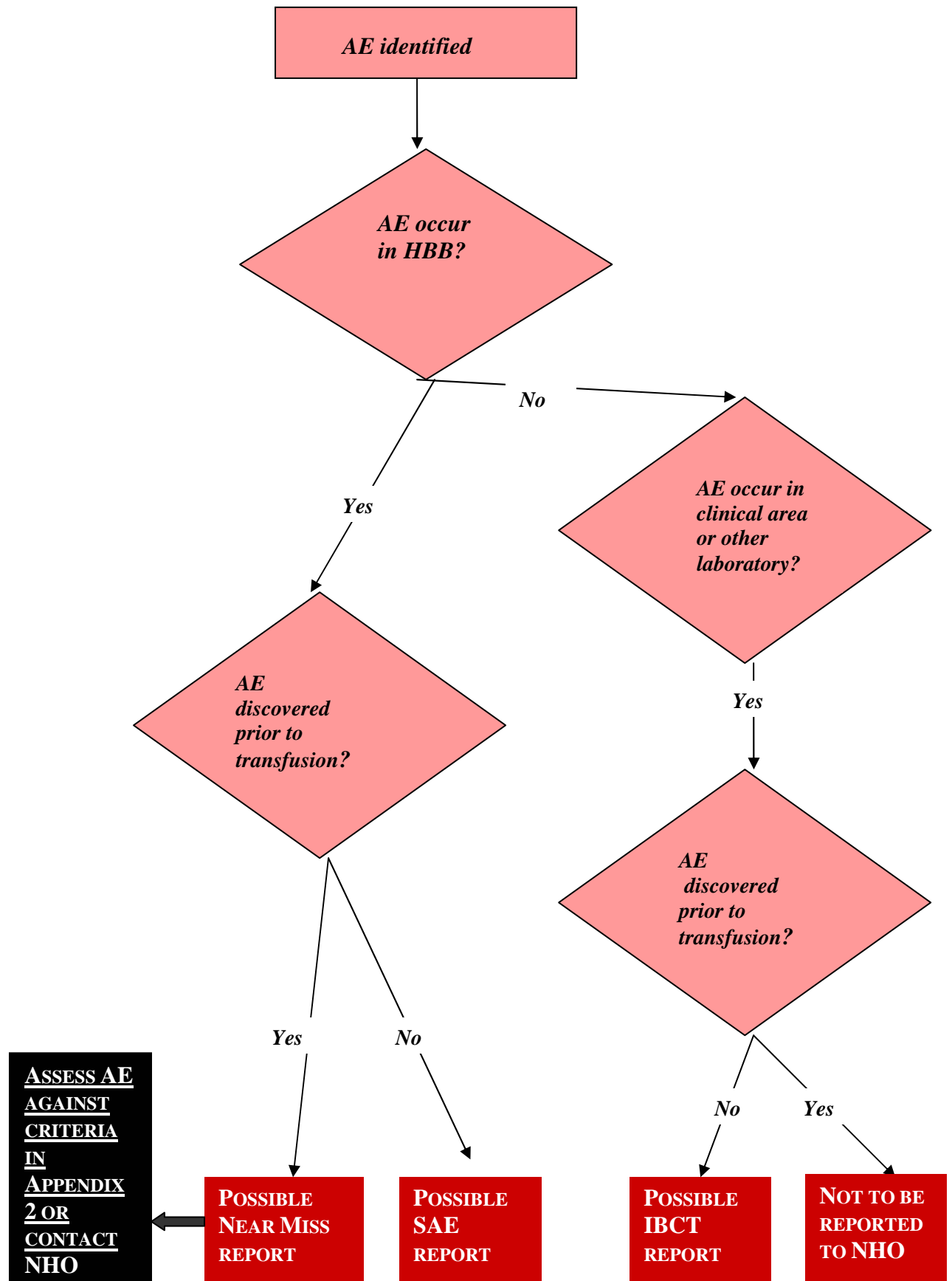
***The NHO will review each report and;***

11. You will receive an email from the NHO when your report has been processed.
12. All near miss SAE reports accepted by the NHO must be reported on ANSAE at end of reporting year

Sample forms are included in Appendix 4.

If you have any queries on reporting, please contact the NHO at 01-4322890/ 94 or at [haemovigilance@ibts.ie](mailto:haemovigilance@ibts.ie)

# Appendix 1: Flow-chart on reporting from hospitals to NHO



AE – Adverse Event

## Appendix 2: Evaluating when to report a near miss SAE occurring in a hospital blood bank.

Not all these events are adverse; nor are all adverse events serious. It is important to clarify when an adverse event becomes serious and reportable to NHO.

The following table will assist you to categorise an AE as a near miss SAE.

<p><i>Deviations from Standard Operating Procedures in hospital blood banks or other adverse events, which have implications for the quality and safety of blood components, should be reported to NHO when one or more of the following criteria applies:</i></p>
<ul style="list-style-type: none"><li>• <i>Inappropriate blood/blood components have been <b>issued</b>/distributed for clinical use, even if not used;</i></li><li>• <i>The adverse event resulted in loss of any irreplaceable autologous blood / blood component (e.g. rare group blood) or any highly matched (i.e. recipient specific) allogeneic blood/blood component;</i></li><li>• <i>The adverse event resulted in the loss of a significant quantity of unmatched blood or blood components;</i></li><li>• <i>The adverse event could have implications for other patients because of shared practices, services, supplies or donors (Repeated event inside or outside the HBB);</i></li><li>• <i>The adverse event could significantly impact the blood transfusion system jeopardising the confidence of blood donors or recipients in the system (EC, 2009)</i></li></ul>

If a report can satisfies any of these, criteria, it should be reported to the NHO as a near miss SAE.

### Appendix 3: Reporting Near Miss SAE from the work process

- **Testing of donations** - Compatibility testing is considered to fall within the term “testing of donations”. These include errors made
  - at sub-sampling resulting in wrong sample tested,
  - in unit selection
  - in grouping
  - made in unit labelling.

Where these AEs could potentially result in patients receiving

- incorrect ABO, Rh D or other antigen component ( not detectable in cross-match),
- blood components where special requirements not met (e.g. CMV, Irradiated, HLA matched)
- blood components which are incorrectly labelled.

Where such AEs occur and are detected prior to transfusion, these are reportable as near miss events.

These AE are caused by testing failures, failure of equipment, human error (EC, 2009).

Report to NHO as IBCT	Not reportable to NHO
Where the AE occurs in the clinical area resulting in an ABO incompatible transfusion e.g. error at time of sampling patient, This is <u>not</u> a mandatory SAE or Near Miss SAE, but should be reported as IBCT	Where the AE occurs in the clinical area e.g. at sampling and this error is detected prior to transfusion. This is a clinical near miss event, and therefore not reportable.

- **Storage** – Where an AE involves the cold chain in the HBB and where medical scientists are involved in the AE, these are mandatory reports. Where AEs occur and are detected prior to transfusion, these are reportable as near miss events
- **Distribution** – This is the act of delivery of blood and blood components to other blood establishments, hospital blood banks and manufacturers of blood and plasma derived products (Directive 2002/98/EC). Distribution does *not* include the issuing of blood or blood components for a patient for transfusion from the hospital blood bank.

Where AEs associated with distribution occurring in HBB are detected prior to transfusion, these are reportable as near miss events.

- **Materials** - A HBB should report SAEs relating to a deviation in materials in association with testing, storage and distribution. Where AEs occur and are detected prior to transfusion, these are reportable as near miss events

- **Other** – Other SAEs which affect the quality and safety of the blood or blood component not covered by the above categories, but occurring within the HBB. Examples include e.g. issue of expired components i.e. red cells, platelets transfused, where transfusion is commenced after expiry time due to an error in the HBB.  
Where such AEs occur and are detected prior to transfusion, these are reportable as near miss events

## Appendix 4: Completed sample forms

### Hospital Blood Bank: Notification of a Near Miss Event to the National Haemovigilance Office

Reporting establishment <i>Name of the reporting hospital</i>				
Report identification <i>Local hospital identifier – include hospital name</i>				
Reporting date (year/month/day) <i>Date adverse event reported in hospital</i>				
Date of serious event (year/month/day) <i>Date adverse event occurred</i>				
Serious adverse event, which may affect quality and safety of blood component due to a deviation in:	Specification <i>Tick appropriate cell</i>			
	Product defect	Equipment failure	Human error	Other (specify)
Testing of donations				
Storage				
Distribution				
Materials				
Others (specify)				

Further Details: *A short description of the adverse event can be included*

Signed: *Name of person submitting report* Date: \_\_\_\_\_

Email address: \_\_\_\_\_

*For National Haemovigilance Office use only*

HV No	HV/NM/Sequence/Year HV/NM/001/10	Date received	27/1/2010	Signature	M Cronin
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## Hospital Blood Bank: Confirmation of a Near Miss Event to the National Haemovigilance Office

<b>Reporting Establishment</b> <i>Name of the reporting hospital</i>	
<b>Report Identification</b> <i>Local hospital identifier – include hospital name.</i>	
<b>Date of Serious Adverse Event</b> <i>Date adverse event occurred</i>	
<b>Root cause analysis (details)</b> <i>Cause of adverse event</i> <i>Use of the root cause codes adopted by National Haemovigilance Office from Mers –TM is suggested</i>	
<b>Corrective measures taken (details)</b> <i>Include a short description of actions taken to correct the adverse event.</i>	
<i>For National Haemovigilance Office use only</i> <b>Confirmation date (year/month/day)</b>	

**Signed:** *Name of person submitting report*

**Date:** \_\_\_\_\_

**Email address:** \_\_\_\_\_

*For National Haemovigilance Office use only*

HV No	HV/NM/Sequence/Year <b>HV/NM/001/10</b>	Date received	<b>27/1/2010</b>	Signature	<b>M Cronin</b>
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