

**National Haemovigilance Office**

**Guidance on**

**REPORT FORMS**

**2008**

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## **Introduction**

The National Haemovigilance Office has launched revised report forms. The Initial Report Form is available on the website at [www.giveblood.ie](http://www.giveblood.ie), follow the file path -Clinical Services / National Haemovigilance Office/ Reporting to the NHO. Detailed forms are only sent to you on receipt of an Initial Report Form at the National Haemovigilance Office. They will continue to be issued from the National Haemovigilance Office database, and will be sent to you by email or post, based on your requirements. Please refer to the Haemovigilance Handbook: Reporting Serious Adverse Reactions and Serious Adverse Events to the National Haemovigilance Office for reporting protocols.

This document provides guidance on the revised report forms. It includes information on the use of each individual form, and details changes to the forms.

### **Completing the report forms**

All fields should be completed. All forms should be completed by hand. Writing should be legible. Abbreviations should never be used in completion of forms except laboratory tests, which can be abbreviated on accompanying typed reports. If designating a time, the 24-hour should be used.

## **1. Initial Report Form**

The initial form should be used to notify the National Haemovigilance Office of all Serious Adverse Reactions, Serious Adverse Events and Incorrect Blood Components Transfused.

Some changes have been made through out the form, such as Question 1, Age- Years /Months / Days. Insert an appropriate age. The appropriate denominator should be selected e.g.

46 years for an adult,

or 8 months for a child,

or 3 days for a neonate.

It is not required to calculate the patient's age in years months and days.

Question 10 should only be completed for reports of SAE.

The area which has been revised on this form is the classification of events and reactions. This has been done principally to ensure compliance with Commission Directives 2002/98/EC and 2005/61/EC.

### **1.1 Serious Adverse Events**

This section aims to identify the errors; Serious Adverse Events (SAE) and Incorrect Blood Components Transfused (IBCT) by outcome e.g. incorrect ABO group transfused –with no reaction or delay in giving the product. The National Haemovigilance Office will determine the level of the event.

### **1.2 Serious Adverse Reactions**

This section classifies serious adverse reactions (SAR) using the classification of Commission Directive 2005/61/EC. While reporting hospitals should determine imputability of the reaction i.e. the likelihood the

reaction can be attributed to the actual transfusion, this can be reviewed by the Director of the National Haemovigilance Office. Any change will be notified to the hospital.

## **2. Incorrect Blood Component Transfused Form**

This form is used to collect details on serious adverse events where blood components and specific products i.e. Solvent Detergent Plasma are implicated. It has undergone significant revision.

### **2.1 Discovery information (questions 1-5)**

This section seeks details surrounding the *Discovery* of the error, it asks where, what, when and how the error was discovered in addition to who was involved in the discovery. Question 3 asks you to select from a list of specific descriptors, each of which is further broken down and which best describes what was discovered. Question 4 asks you to select at what step of the work process the error was discovered. Question 5 asks you to describe in free-text how the error was discovered e.g. errors can be discovered through routine haemovigilance audit, routine cross-checking of laboratory work on call.

### **2.2 Occurrence information (questions 6-11)**

This section asks the reporter for details surrounding the actual *Occurrence*. It looks at where and how the error occurred and who was involved.

Question 6 asks you to select the step in the work process where the error *first* occurred e.g. the first site of error.

Questions 7 & 8 are self explanatory.

The data you provide us with in question 9 is particularly important as this data may be used by the NHO to carry out a root causes analysis (RCA). An

accurate RCA can only be carried out if all the details of *how and why* the error occurred (including contributory factors) are included. Contributory factors can be described as circumstances surrounding the event that you feel contributed to the error. Examples of contributory factors could include; short staffing, busy workload, lack of clear SOPs in place or lack of support from management for providing haemovigilance education & training.

Providing a detailed account of *what occurred* without details of *why* the error occurred will not enable a RCA to be carried out. RCA allows us to learn from error enabling improvements to be made, preventing future recurrence and improving the overall safety of transfusion. In addition, the cause of error is required for confirmation of SAE (Commission Directive 2005/61/EC ).

Question 9 also asks you to select the cause / causes of the error from a list of human & system failures. Many events involve both human and system failures therefore multiple selections can be made here. If the cause of error does not appear on the list then 'other' should be selected and a brief explanation should be given.

The National Haemovigilance Office has adopted the categorisation for human and system failures from the medical event reporting system for transfusion medicine (Mers-TM) these are outlined as follows;

## **Human Failure**

**Verification:** Errors which occur following incomplete assessment of a situation including related conditions of the patient / donor and materials to be used before beginning a task. Examples would be failure to obtain positive patient ID at the bedside, failure to verify most recent test results prior to prescribing and failure to verify current results against historical results where applicable.

**Knowledge:** An error occurs when the individual is unable to apply their existing knowledge to a novel situation .examples would be a trained Medical

Scientist who is unable to solve a complex antibody issue, or a trained nurse who fails to take into account the patient's blood group prior to commencing a transfusion.

**Co-ordination /Communication:** An error occurs due to a lack of communication or co-ordination within a team for example where an intention to cancel a prescription is not communicated resulting in the patient receiving an inappropriate transfusion.

**Failure to adhere to policies /procedures:** Errors which occur where trained staff does not follow policies.

**Carrying out task incorrectly;** Errors which occur where trained staff does not carry out tasks correctly, despite the availability of policies and having attended training.

**Monitoring:** Errors occur where there is a failure to monitor a process or patient status. Examples include; failure to monitor rate of transfusion leading to patient being transfused too quickly / slowly or a trained Medical Scientist operating an automated instrument and not realising that the pipette dispensing the reagent is clogged.

**Slip:** Errors occur where there is a failure in the performance of highly developed skills for example e.g. computer entry error or simple mind slip leading to failure to complete a task.

**Trip:** Failures in whole body movement, for example dropping a blood bag which splits and is wasted.

**Patient Related:** Errors which occur directly as a result of actions or characteristics of patients, and which are not within the control of the health care team. Examples include; where a patient gives wrong information about their patient details or where patients remove their own ID band.

**Unclassifiable;** Errors which arise and cannot be classified in any of the current categories.

## **System Failures**

**Design:** Errors which arise due to inadequate design of equipment, software or materials e.g. design of workspace, software packages, or label design.

**Materials:** Errors which arise due to deficits in materials e.g. defects in label adhesive, or ink smears on pre-printed labels or forms.

**Construction:** Errors which occur following poor construction e.g. incorrect set-up of blood pumps / laboratory equipment or installation of equipment in an inaccessible area.

**Management Priorities:** Errors which occur as result of organisational management prioritisation of other issues over safety e.g. decisions on staffing levels, limited or absent phlebotomy services, no provision for medical record numbers out of hours (Lundy et al)

### ***Policies and procedures;***

Errors which occur due to unclear / outdated or absent SOPs. Policies / procedures should be current, understandable well presented and accessible to all staff.

**Culture:** Errors which arise from a collective approach to safety and risk. Groups may establish their own modes of function as opposed to following prescribed methods e.g. not paging a manager / doctor out of hours to review a result /decision, as it is not usual practice.

Question 10 asks you to select what action was taken in relation to the transfusion in response to the error.

The final question in this section (question 11) seeks information on clinical and clerical investigations conducted to investigate this error. You should provide results with dates, where tests have been conducted. If 'other' is selected please explain and also include results where available.

### **2.3 Section 1 (questions 12-29)**

This section has not significantly changed. It should only be completed in event of ABO, RH D or other antigen incompatibility.

### **2.3 Sequelae (Questions 30-36)**

The most notable changes in this section relate to Questions 33 and 36. An explanation for answering Question 33 is provided in Section 4.5.

Question 36 relates to action taken following the SAE / IBCT. This arises directly from Commission Directive 2005/61/EC and is required for confirmation of the SAE. It is essential this field is completed.

## **3. Incorrect Product Administration or Omission Form**

This form is used to collect detailed information on SAE where Anti D and Factor Concentrates are implicated. This form now incorporates questions on error classification (questions 9 and 10), as previously described in 2.2.

## **4. Transfusion Reaction Detailed Form**

This form is used to collect detailed information on the following SAR where blood components and SD plasma are implicated;

- Immunological haemolysis due to ABO incompatibility
- Immunological haemolysis due to other allo-antibody (Acute < 24 hours)
- Immunological haemolysis due to other allo-antibody (Delayed > 24 hrs)
- Non-immunological haemolysis
- Anaphylaxis/hypersensitivity
- Febrile Non Haemolytic Transfusion Reaction
- Hypotensive transfusion reaction
- Transfusion associated dyspnoea
- Transfusion related acute lung injury (TRALI)
- Transfusion Associated Circulatory Overload
- Previously undescribed complication of transfusion (PUCT)
- Unclassified complication of transfusion.

#### **4.1 Section A (Questions 1 – 6)**

This section must be completed when reporting all reactions. The design surrounding question 6 has been slightly altered. Results of investigations should be included, where these are available.

#### **4.2 Section 1 (Questions 7-23)**

This section should be completed when reporting the following SAR:

- Immunological haemolysis due to ABO incompatibility
- Immunological haemolysis due to other allo-antibody (Acute < 24 hours)
- Immunological haemolysis due to other allo-antibody (Delayed > 24 hrs)
- Non-immunological haemolysis
- Febrile Non Haemolytic Transfusion Reaction
- Previously undescribed complication of transfusion (PUCT)
- Unclassified complication of transfusion.

There are no significant changes within this section.

#### **4.3 Section 2 (Questions 24-30)**

This section should be completed when reporting the following SAR:

- Transfusion related acute lung injury (TRALI)
- Transfusion Associated Circulatory Overload
- Transfusion associated dyspnoea
- Previously undescribed / unreported complication of transfusion (PUCT)
- Unclassified complication of transfusion.

There are no significant changes within this section.

#### **4.4 Section 3 (Questions 31)**

This section should be completed when reporting the following SAR:

- Transfusion related acute lung injury (TRALI)

There are no changes within this section.

#### **4.5 Sequelae (Questions 32 -41)**

The most notable changes in this section relate to Questions 35. This relates to Clinical Outcome and arises directly from Commission Directive 2005/61/EC. This information is required for confirmation of the SAR and therefore, it is essential these fields are completed. The National Haemovigilance Office has developed a definition of clinical outcome, and an explanation for the classification for the categories laid out in the Directive.

#### **Definition**

The Clinical Outcome refers to the effect of the precipitating SAR on the patient's clinical condition.

<b>Classification</b>	<b>Explanation</b>
Complete recovery	Patient develops signs and/or symptoms which resolve spontaneously without treatment.
Minor Sequelae	Patient develops signs and/or symptoms that resolve following symptomatic treatment, e.g. mild hypersensitivity effects responsive to antihistamines.
Serious Sequelae	Patient develops signs and/or symptoms which are life-threatening or are associated with significant persistent effects requiring ongoing treatment and intervention, are permanently disabling or prolong hospitalisation.
Death	Definitely related to transfusion Probably related to transfusion Possibly related to transfusion Unknown relationship to transfusion Not assessable

This section also includes questions on whether this reaction was caused by an erroneous transfusion (questions 38-39). This will enable the National Haemovigilance Office to identify where reactions occur, following error. The error classification is identical to that used in the Incorrect Blood component Transfused Form (See 2.2).

## **5. Suspected Transfusion Transmitted Bacterial Infection Form**

This form is used to collect detailed information on SAR on where bacterial contamination of the blood component is suspected to have caused the reaction.

## **5.1 Questions 1-4**

These questions seek information of the investigation of both the patient and the implicated component. A new question has been introduced asking if the results have been reviewed by a Consultant Microbiologist within the hospital, and if the results are considered clinically significant.

## **5.2. Sequelae (Questions 5-10)**

Changes to this section relate to question 7 only – Clinical Outcome and this is directly as a result of the EU Directive.

## **5.3 Error Details (Questions 11-12)**

While this is a new section to this questionnaire, it is identical to that used in the Incorrect Blood component Transfused Form (See 2.2).

## **6. Suspected Transfusion Viral Infection Form**

This form is used to collect detailed information on SAR on where a confirmed viral infection is suspected to have been caused by blood transfusion. Please refer to the National Haemovigilance Office Handbook on criteria for reporting Suspected Viral Transmitted Transfusion Infection. There are some minor changes to this form.

Question 4 seeks information on viral markers. This has been divided into three categories,

- Screening
- Confirmation
- PCR

Each category has a positive and a negative option. Where a positive option is selected, further details are required e.g. type of test, date of test. This

question also contains a section to indicate other viral infection and the confirmatory investigations.

While the format of question 11 has not changed, it has more options available e.g. CMV. This question will only be completed by a Supply Centre and where there is donor tracking unit to facilitate the investigations.

## **6. Suspected Transfusion Parasitological /Other Infection Form**

This form is used to collect detailed information on SAR on where a confirmed parasitological, prion or other infection is suspected to have been caused by blood transfusion. This is a new questionnaire. The format is similar to the questionnaire on a suspected viral infection.

Questions 1-6 seek information on the type of infection, clinical symptoms and investigations. Questions 7 and 8 looks at other risk factors for the infection. A pre-prepared list has been prepared for some infections such as Malaria, Chagas disease, Toxoplasmosis. Question 9 is on Clinical Outcome and this is directly as a result of the EU Directive.

## **7. Post Transfusion Purpura Form**

This form is used to collect detailed information on cases of post transfusion purpura. There are no significant changes to this form, except the inclusion of the error questions outlined in 2.2.

## **8 Transfusion Associated Graft Versus Host Disease Form**

This form is used to collect detailed information on cases of transfusion-associated graft versus host disease. There are no significant changes to this form, except the inclusion of the error questions outlined in 2.2.

## **9. Autologous Pre-deposit Donor Incident Form**

This form is used to collect information on pre-deposit autologous donor incidents. While the questions within the questionnaire have not changed, the sequence has been altered. The questionnaire is organised under the following headings.

- Section 1: Background to the donation
- Section 2: Patient history
- Section 3: Donation incident
- Section 4: Sequelae
- Section 5: Post operative transfusion
- Section 6: Criteria for donation
- Section 7: Follow-up action.

## References

Lundy, D. Laspina, S. Kaplan, H., Rabin-Faustman, B and Lawlor, E. (2007) Seven hundred and fifty-nine (759) chances to learn: a 3-year pilot project to analyse transfusion-related near-miss events in the Republic of Ireland, Von Sang. In press.

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