IPC-NIB

GUIDANCE DOCUMENT FOR
REPORTING SERIOUS ADVERSE REACTIONS IN BLOOD TRANSFUSION SERVICE

National Institute of Biologicals
Ministry of Health and Family Welfare
Government of India
2012
FOREWORD

Haemovigilance is an urgent need of the country to identify and prevent occurrence or recurrence of transfusion related adverse reactions, so as to increase the safety & quality of blood transfusion and blood products administration.

This system includes monitoring, reporting, investigation, identification and analysis of adverse reactions related to transfusion and manufacturing. The information thus collected will facilitate corrective and preventive actions to be taken to minimize the potential risks associated with blood collection, processing and transfusion to patients. Such information is also key to introduce required changes in the applicable policies, improve standards, systems and processes and assist in the formulation of guidelines.

A centralized Haemovigilance system involves all relevant stakeholders and coordinates various activities between the blood banks, blood transfusion services, hospital health care professionals and transfusion committees, regulatory agencies and national health authorities. Extension of the Haemovigilance system to regional and global sharing of information by linking it to international Haemovigilance Network will further strengthen it. The members of Haemovigilance Advisory Committee, Core Group, Signal Review Panel, Quality Review Panel and Training Panel have an important role to play in achieving the above objectives.

I am happy that all the Scientists, Academicians, Transfusion Medicine Experts associated with this Haemovigilance Programme have given their valuable inputs to prepare this Guidance Document. I sincerely believe that this Guidance Document will be very much useful and an essential tool for the doctors, technicians and other healthcare professionals in the transfusion medicine practice and public health.

(Dr. Surinder Singh)

Director, NIB
Dated : 10th December, 2012
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</tbody>
</table>
PREFACE

The contents of this document are designed based on various functional Haemovigilance system in developed countries and also modified as per the Indian scenario as suggested by the Haemovigilance Advisory Committee –India during its first meeting on 29th November 2012 held at National Institute of Biologicals, Noida.

These guidelines are intended for reporting the serious adverse reactions in transfusion medicine by the Adverse Drug Reaction (ADR) Monitoring Centers of Pharmacovigilance Programme of India.

These guidelines are not to be quoted as a reference in any official communications except in the communications with the Coordinating Center for Haemovigilance at NIB.

It is the intent of NIB which is the Coordinating Center for Haemovigilance that Haemovigilance reports will contain no identifiable or re-identifiable data; that no patient, clinician, staff member or healthcare facility is identifiable from materials contained within the report.

This guidance document may be amended from time to time as per requirements after obtaining necessary approval from the competent authority.
INTRODUCTION:

Transfusion of blood and blood products is not without risks and it can lead to complications. The primary aim of the centralized Haemovigilance Program is to improve transfusion safety and quality by collecting, collating, analyzing and disseminating information on a common set of serious adverse reactions due to the transfusion of blood and blood products. Information obtained will be used to build better and safer systems, efficient use of valuable health resources and ultimately deliver better patient healthcare. The program currently has 60 medical colleges included in the network and has an oversight by the Haemovigilance Advisory Committee so that it achieves its goals and objectives. The number of the Medical Colleges under the ambit of this programme will be increased to 90 by March 2013.

This Haemovigilance Programme is being seen in the wider context of ‘Biovigilance’. The ultimate goal of this Haemovigilance programme of India is to be a part of the International Haemovigilance Network(IHN) which presently has 28 countries as its member and provides a global forum for sharing best practices and benchmarking of Haemovigilance data.
Haemovigilance- Organogram

INDIAN PHARMACOPOEIA COMMISSION, GHAZIABAD, NATIONAL COORDINATING CENTRE
PHARMACOVIGILANCE PROGRAMME OF INDIA

NATIONAL INSTITUTE OF BIOLOGICALS, COORDINATING CENTRE-
BIOVIGILANCE

CORE GROUP
HAEMOVIGILANCE

HAEMOVIGILANCE
ADVISORY
COMMITTEE

SIGNAL REVIEW
PANEL

CORE TRAINING
PANEL

QUALITY
REVIEW PANEL

MEDICAL COLLEGES
(TECHINCAL ASSOCIATE)
1.0 Haemovigilance:

- Haemovigilance is a continuous process of data collection and analysis of transfusion-related adverse reactions in order to investigate their causes and outcomes, and prevent their occurrence or recurrence.

- It includes the identification, reporting, investigation and analysis of adverse reactions and events in recipients and blood donors as well as incidents in manufacturing processes and, eventually errors and “near-misses”.

- A haemovigilance system is also an integral part of quality management in a blood system, triggering corrective and preventive actions, and for the continual improvement of the quality and safety of blood products and the transfusion process.
2.0 Objective of reporting adverse reactions and adverse reactions in transfusion

- Reporting is a tool for obtaining information which can be used to improve the product safety.
- A national reporting system, therefore, can usefully be regarded as a tool to advance public policy concerning patient safety.
- Reporting can help identify hazards and risks, and provide information as to where the system is breaking down.
- This can help target improvement efforts and systems changes to reduce the likelihood of injury to future patients.
- Reporting of suspected adverse reactions in a timely manner facilitates effective risk management.
- ADR Monitoring Centers: are those medical colleges & institutes / hospitals/ blood banks in India that are registered with the Pharmacovigilance National Co-coordinating Center for reporting the adverse reactions that occurs during blood/ component transfusion or Blood Product (plasma derived products) administration.

Privacy and security of data—

It is the intention of NIB (National Institute of Biologicals) which is the Coordinating Center for Haemovigilance that Haemovigilance reports will contain no identifiable or re-identifiable data; that no patient, clinician, staff member or healthcare facility is identifiable from materials contained within the report.
3.0 Documenting & Reporting of Serious Adverse reactions/ events in Blood & Blood products Transfusion

Documenting and reporting Transfusion Reactions in blood transfusion service involve many aspects and interrelationships:

- Responsibilities of Medical and Nursing Staff of the ADR Monitoring centers
- Responsibilities of the Transfusion Service department of the ADR Monitoring centers
- Responsibilities of the Hospital Transfusion Committee of the ADR Monitoring centers
- Responsibilities of the Head, Department of Transfusion of the ADR Monitoring centers
- Responsibilities of the technical Associate IPC -PvPI (Pharmacovigilance Programme of India) posted in the ADR Monitoring centers
- Responsibilities of Haemovigilance Center, National Institute of Biologicals (NIB)
- Responsibilities of PvPI National Co-coordinating Center, Indian Pharmacopoeia Commission
- Responsibilities of Central Drugs Standard and Control Organization, New Delhi
4.0 Responsibilities of Medical and Nursing Staff of the ADR Monitoring Centers

Physicians and nurses attending to patients having suspected transfusion complications should perform the following documentation and reporting functions:

- Attending nursing staff should report suspected transfusion reaction immediately to the attending physician
- Document the details of the patient as well as the implicated units/products in the Form No.1 and retain in the patient’s file.
- Send the details of the transfusion reaction to the Department Transfusion Medicine in the Form No. 2
- Protocol for the investigation of an acute Transfusion reaction is given at Annexure-I
- Assess the Imputability levels of the adverse reactions in coordination with the Department of Transfusion Medicine as given in Table : 2
- Maintain records of the complication in the patient’s medical record, including the report of the investigation completed by the Department of Transfusion Medicine.
FORM No.1
Whole Blood/ Blood Component/ Blood Product
(Compatibility Report)

(Name of hospital…………………………………………………………………………………………………………………………)
( To be retained in patient’s file)

1.0 PATIENT DETAILS

<table>
<thead>
<tr>
<th>DTM S.No.</th>
<th>Date</th>
<th>Name of Pt.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age/Sex</th>
<th>C.R. No.</th>
<th>Blood Group</th>
<th>Rh</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Wd</th>
<th>Bed</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2.0 PRODUCT DETAILS:

2.1 BLOOD/COMPONENTS

<table>
<thead>
<tr>
<th>No.</th>
<th>Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>WB</td>
</tr>
<tr>
<td>2</td>
<td>PRBC</td>
</tr>
<tr>
<td>3</td>
<td>LPRBC</td>
</tr>
<tr>
<td>4</td>
<td>PC</td>
</tr>
<tr>
<td>5</td>
<td>PRP</td>
</tr>
<tr>
<td>6</td>
<td>FFP</td>
</tr>
<tr>
<td>7</td>
<td>Cryo Poor Plasma</td>
</tr>
<tr>
<td>8</td>
<td>Cryo Precipitate</td>
</tr>
<tr>
<td>9</td>
<td>Blood Product (Name)</td>
</tr>
<tr>
<td></td>
<td>Batch No. Manufacturer Expiry</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Bag No.(s)</th>
<th>Date</th>
<th>Blood Bank</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Doctor
FORM No. 2
Whole Blood/ Blood Component / Blood product
TRANSFUSION REACTION FORM
(Name of hospital………………………………………………………………………………..)
(To be sent to Department of Transfusion Medicine after transfusion)

DTM S.No.__________ Date__________

Name of Patient________________________
C.R. No. ________ Group________Rh_____
Hospital__________Ward_____Bed No._____
Donor Units
Blood Bag No(s).
1: 
2. 
3. 
4. 

Transfusion started at _____ completed at _____
Rate of Transfusion _________ drops per minute
Actual quantity of blood transfused ________(ml)

CLINICAL OBSERVATION:

<table>
<thead>
<tr>
<th>General condition</th>
<th>Pre Transfusion</th>
<th>During Transfusion</th>
<th>Post Transfusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulse</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resp.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temp.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B.P.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rigor</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chills</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Myalgia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urticaria</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Doctor/ Nurse

Note: In any case of transfusion reaction, inform the blood bank staff immediately. Send blood bag, transfusion set, post-transfusion sample (EDTA)
Annexure –I

Investigating Acute Transfusion Reactions

➢ Take immediate note and inform blood bank
➢ Seek help immediately from skilled anesthetist or emergency team
➢ Complete the transfusion reaction form and appropriately record the following:-

- Type of transfusion reaction
- Time after the start of transfusion to the occurrence of reaction
- Unit No. of component transfused
- Volume of the component transfused

Send the following for lab investigations:

Send clotted and EDTA samples & Blood unit along with BT set to blood bank for:
a.i. Repeat ABO & Rh (D) grouping
a.ii. Repeat antibody screen and cross match
a.iii. Direct antiglobulin test

Send EDTA and citrated blood sample and urine sample to Hematology for:

a.iv. Complete blood count (CBC)
a.v. Plasma hemoglobin
a.vi. Urine hemoglobin
a.vii. Coagulation screen

Send clotted Blood sample to Biochemistry Lab. for:

a.viii. Renal function test (urea, creatinine and electrolytes)
a.ix. Liver function tests (bilirubin, ALT and AST)

Send Blood culture in special blood culture bottles to Microbiology Lab.
5.0 Responsibilities of the Department of Transfusion Medicine

The transfusion service is responsible for several aspects of documenting and reporting transfusion reactions and complications. These include documenting and reporting:

- Report the details of the clinical and laboratory investigation to the respective medical ward and to the Hospital Transfusion Committee
- To do the investigations as per the work up form at Annexure-2 and documenting the results in the work up form
- To enter the necessary details as per the documentation required at Table 1 in the Transfusion Reaction-Traceability document (TR-TD)
- To assess the Imputability levels of the adverse reactions in coordination with the attending physician as given in Table : 2
- Custodian of the Transfusion Reaction-Traceability document (TR-TD)
- To assure the completeness of the Transfusion Reaction-Traceability document (TR-TD)
- Report the details as per the TRRF Form to the technical associate PvPI
Transfusion Reaction Work-Up Form

Name:.................................................................Hospital:.........................................................
CR No............................................................Ward/Bed No......................................................
Age/Sex:..........................................................Unit Incharge:...................................................
Diagnosis:........................................................
Indication for Transfusion:.................................................................
Clinical Status of Patients:

Respiratory system: Renal:
CVS: GIT:
CNS: Liver:

H/o Previous Transfusion, Pregnancy, Transplantation:

H/o Drug intake:

Any other infusion through B.T. set:

Reaction details:

Received:

Reaction from (duly filled):

Blood Bag/Bags along with transfusion set:

Post transfusion sample:

Date/time at which Blood/ Blood component was transfused:

Date/time at which reaction occurred:

Date/time at which sample/reaction form were sent to blood bank:
**ANNEXURE-2 (Page 2/4)**

**(Name of the Hospital…………………………………………………………………………..)**

**Transfusion Reaction Work-Up Form**

Blood/Blood Component unit No.:…………………………………………………………………………

Amount of Blood/Blood Component transfused:………………………………………………………………………………………

**Investigation:**

Identification of Patient:

Rechecking of Records:

- Cross matchfile…………………………………………………………………………………………
- Issue Register…………………………………………………………………………………………
- Blood Grouping Register…………………………………………………………………………...
- Visual Examination of bag/transfusion set:…………………………………………………………

**Supernatant of Sample:**

Pre Tx Sample:
Post Tx Sample…………………………………………………………………………………………
Bag Sample…………………………………………………………………………………………

**Blood Group:**

Pre Tx Sample…………………………………………………………………………………………
Post Tx Sample…………………………………………………………………………………………
Bag Sample…………………………………………………………………………………………

**Direct Coombs Test (DCT):**

Post Tx Sample:  ........................................
Pre Tx Sample………………………………………………

Repeat cross match of Blood Bag Sample with:

<table>
<thead>
<tr>
<th></th>
<th>Major (RT)</th>
<th>Major (37°) AHG phase</th>
<th>Minor (RT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PreTx Sample</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PostTx Sample</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Transfusion Reaction Work-Up Form

### Evidence of Hemolysis:
- **Plasma Haemoglobin:** ..............................................................
  - Pre Tx: ..............................................................
- **Serum Bilirubin:** ..............................................................
  - Post Tx: ..............................................................
- **Urine Haemoglobin:** ...........................................................
- **Urine Haemosidrin:** ...........................................................

### Coagulation status:
- **PTI:** .............................................................................
- **Platelet count:** ..................................................................

### Blood Culture (Date/time at which culture was sent):
- **Blood Bag:** ..............................................................
- **Patient:** ..............................................................

### Peripheral Blood smear (Patient sample/ Blood Bag sample):
- **Leishman stain:** ..............................................................
- **Gram stain:** ................................................................
- **Unstained smear:** ..........................................................

### Blood Bag Details
- **Type of Blood Bag:** ..........................................................
- **Lot No.:** ..........................................................
- **Date of collection:** ..........................................................
- **Tube No.:** ..........................................................
- **Date of Expiry:** ..........................................................

### Cross match details
- **Date of Cx-match:** ..........................................................
- **Emergency/Routine:** ..........................................................
- **Name of Technical Staff who cross matched the unit:** ..........................................................
- **Date/time of Issue:** ..........................................................
- **Interval between issue and transfusion:** ..........................................................
- **Where was blood kept during that interval:** ..........................................................
- **Was blood warmed before transfusion, if yes; by what method:** ..........................................................

---

**ANNEXURE-2 (Page 3/4)**

(Name of the Hospital…………………………………………………..)
Transfusion Reaction Work-Up Form

If Blood bag has been previously Cx-matched/issued:

<table>
<thead>
<tr>
<th>Date of Cx Match</th>
<th>Date/time of Issue</th>
<th>Date of Receive Back</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Donor Details

Name:........................................................................................................... Age/Sex: ........................................
Address:....................................................................................................................
Phone:.....................................................................................................................
Date of Collection: .............................................. Place of Collection…………………
Name of Phlebotomist/Assistant:.................................................................
Type of Donor VD/RD..............................................................................................
Any special Investigation ..........................................................................................
Inference:
..........................................................................................................................
..........................................................................................................................
..........................................................................................................................

Signature of Consultant/Senior Resident                                Signature of Junior Resident
6.0 Responsibilities of Hospital Transfusion Committee

- To perform review of reported transfusion reactions for improving Hospital Transfusion Practices

7.0 Responsibilities of the technical Associate IPC -PvPI (Pharmacovigilance Programme of India) at the ADR centers

- To enter the information obtained from the Department of Transfusion Medicine of the ADR monitoring centers, in the TRRF form and forward it to NIB.

8.0 Responsibilities of Haemovigilance Center, NIB

- Collection, collation & analysis of Haemovigilance data and Forward the data to IPC
- Compilation of data and flagging major issues for deliberation by the Haemovigilance Advisory Committee
- To monitor the functioning & Quality of the data collected by the Adverse transfusion Reaction Reporting Centers i.e. ADR Monitoring Centers of Pharmacovigilance Programme of India (PvPI)
- Review completeness, quality check, causality assessment.
- Preparation of SOPs, guidance documents and training manuals.
- Training and feedback to medical colleges.
- Haemovigilance newsletter.
- Communicate recommendations of Haemovigilance advisory committee to National Coordinating Centre, IPC, Ghaziabad,
9.0 Responsibilities of PvPI National Co-ordinating Center, IPC

- Forward recommendations of Haemovigilance Advisory Committee to DCGI-CDSCO

10.0 Responsibilities of CDSCO

- Formulate safety related regulatory decisions
- Communication of Blood and Blood Products Transfusion safety related decisions to stake holders.
11.0 Table 1: TR-TD (Transfusion Reaction-Traceability Document) Record to be maintained by the Department of Transfusion Medicine with the following information

<table>
<thead>
<tr>
<th>Sl No.</th>
<th>TRRF ID of the patient</th>
<th>Patient Reg No. of hospital</th>
<th>Adverse Reaction/ Blood component/ Blood Product transfused</th>
<th>Batch No/ Bag No. Mfg date/ Expiry date</th>
<th>Indications for transfusion</th>
<th>Date &amp; Time of start and completion of transfusion</th>
<th>Date &amp; time of observed adverse reaction</th>
<th>Clinical features of the adverse reaction observed</th>
<th>Laboratory findings</th>
<th>Imputability Level</th>
<th>Final outcome of the transfusion reaction</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
</tr>
</tbody>
</table>
12.0 **Imputability levels:** Imputability means the likelihood that a serious adverse reaction in a recipient can be attributed to the blood or blood component or blood product transfused. The Imputability levels are given below:

- **Definite (certain):** when there is conclusive evidence beyond reasonable doubt that the adverse event can be attributed to the transfusion.
- **Probable (likely):** when the evidence is clearly in favor of attributing the adverse event to the transfusion.
- **Possible:** when the evidence is indeterminate for attributing the adverse event to the transfusion or an alternate cause.
- **Unlikely (doubtful):** when the evidence is clearly in favor of attributing the adverse event to causes other than the transfusion.
- **Excluded:** When there is conclusive evidence beyond reasonable doubt that the adverse event can be attributed to causes other than the transfusion.

After assessment of the adverse reaction by the Department of Transfusion Medicine and are satisfied that all the information provided is both correct and complete, submit the necessary details as in the TRRF form to the technical associate PvPI.
## 13.0 TRRF

**Indian Pharmacopoeia Commission – National Institute of Biologicals**  
Ministry of Health & Family Welfare – Govt. of India

**HAEMOVIGILANCE**  
(Pharmacovigilance Programme of India)

### TRANSFUSION REACTIONS REPORTING FORM FOR BLOOD & BLOOD PRODUCTS

For reporting of Transfusion Reactions by Healthcare Professionals

### A) Patient Information

<table>
<thead>
<tr>
<th>Information</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Initials</td>
<td>…………….</td>
</tr>
<tr>
<td>DOB/Age in years</td>
<td>…………….</td>
</tr>
<tr>
<td>Blood Group</td>
<td>…………….</td>
</tr>
<tr>
<td>Diagnosis</td>
<td>…………….</td>
</tr>
<tr>
<td>Hospital Code No.</td>
<td>…………….</td>
</tr>
<tr>
<td>Hospital Admission No.</td>
<td>…………….</td>
</tr>
<tr>
<td>Sex</td>
<td>F □ M □</td>
</tr>
<tr>
<td>Date &amp; Time of Transfusion</td>
<td>…………….</td>
</tr>
<tr>
<td>Date &amp; Time of reaction</td>
<td>…………….</td>
</tr>
<tr>
<td>Date &amp; Time of recovery</td>
<td>…………….</td>
</tr>
</tbody>
</table>

### B) Transfusion Product Details

<table>
<thead>
<tr>
<th>Blood Products</th>
<th>Unit Numbers</th>
<th>Indications</th>
<th>1st time / Repeat Transfusion (No. of Repeats)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole Blood</td>
<td>…………….</td>
<td>…………….</td>
<td>…………….</td>
</tr>
<tr>
<td>Red Blood Cells</td>
<td>…………….</td>
<td>…………….</td>
<td>…………….</td>
</tr>
<tr>
<td>Platelets Apheresis</td>
<td>…………….</td>
<td>…………….</td>
<td>…………….</td>
</tr>
<tr>
<td>Platelets Pooled/RDP</td>
<td>…………….</td>
<td>…………….</td>
<td>…………….</td>
</tr>
<tr>
<td>Solvent detergent (SD) Plasma</td>
<td>…………….</td>
<td>…………….</td>
<td>…………….</td>
</tr>
<tr>
<td>FFP</td>
<td>…………….</td>
<td>…………….</td>
<td>…………….</td>
</tr>
<tr>
<td>Cryoprecipitate</td>
<td>…………….</td>
<td>…………….</td>
<td>…………….</td>
</tr>
<tr>
<td>Any other</td>
<td>…………….</td>
<td>…………….</td>
<td>…………….</td>
</tr>
<tr>
<td>Blood Products (Please Specify)</td>
<td>Manufacturer</td>
<td>Batch Number</td>
<td>Expiry Date</td>
</tr>
<tr>
<td>----------------</td>
<td>--------------</td>
<td>-------------</td>
<td>-------------</td>
</tr>
</tbody>
</table>

### C) NATURE OF ADVERSE REACTIONS

| Reactions | Please Tick (

1. Immunological Haemolysis due to ABO incompatibility

2. Immunological Haemolysis due to other allo-antibodies

3. Non Immunological Haemolysis

4. Transfusion Transmitted Bacterial Infection

5. Anaphylaxis / Hypersensitivity

6. Transfusion Related Acute Lung Injury (TRALI)

7. Transfusion Transmitted Viral Infection (HBV)

8. Transfusion Transmitted Viral Infection (HGV)

9. Transfusion Transmitted Viral Infection (HIV-1/2)

10. Transfusion Transmitted Viral Infection, other (Specify)

11. Transfusion Transmitted Parasitic Infection (Malaria)

12. Transfusion Transmitted Parasitic Infection, other (Specify)

13. Post Transfusion Purpura

14. Transfusion Associated Graft versus Host Disease (TAGvHD)

15. Other serious reaction(s) – Specify (e.g., transfusion associated circulatory overload (TACO), transfusion associated dyspnea (TAD), febrile non-Haemolytic reactions (FNHTR) and uncategorized Unintended responses)

### D) Outcomes of the Adverse Reactions

- Death following the adverse reactions
- Recovered
- Recovered with sequelae
- Permanently disabled
- Unknown

### E) Reporter

- Name and professional Address: …………….  
- Pin Code: ……………. Email: …………….  
- Tel No. (with STD code): …………….  

### F) Causality Assessment

- Date of this report (DD/MM/YYYY)
14.0 **FLOW CHART FOR REPORTING SERIOUS ADVERSE REACTIONS IN BLOOD TRANSFUSION**

Medical Ward: Adverse reaction noted by the physician / Nurse

Medical Ward: Documentation in Form No.1

Medical Ward : Fill Up Form No.2 and forward the form and Send blood bag, transfusion set, post-transfusion sample to Department of Transfusion Medicine for further investigation including Repeat ABO & Rh (D) grouping, Repeat antibody screen and cross match, Direct antiglobulin test

Medical ward: Send EDTA and citrated blood sample and urine sample of the patient to Hematology Lab for Complete blood count (CBC), Plasma hemoglobin, Urine hemoglobin, Coagulation screen

Medical ward: Send clotted Blood sample to Biochemistry Lab. For Renal function test (urea, creatinine and electrolytes), Liver function tests (bilirubin, ALT and AST)

Medical ward: Send post transfusion Blood in special blood culture bottles to Microbiology Lab

Department of transfusion Medicine: To further investigate the transfusion reaction as per the Transfusion reaction Work Up Form, document the findings, Compilation of the reports from other departments and reporting results and inferences to the respective medical ward.

Department of transfusion Medicine: Assess the Imputability level of the transfusion reaction in coordination with the attending physician of the respective medical ward.

Department of transfusion Medicine: Enter the details in the Transfusion Reaction-Traceability Document & intimate the Technical associate PVPI

Technical associate PVPI: Enter the information as per the Transfusion Reaction Reporting Form for blood & Blood Products and submit it to Haemovigilance Center, NIB
<table>
<thead>
<tr>
<th>Serious Adverse Reactions</th>
<th>Clinical Features</th>
<th>Laboratory Features</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunological Haemolysis due to ABO incompatibility</td>
<td>Fever, chills/rigors, facial flushing, chest pain, abdominal pain, back/flank pain, nausea/vomiting, diarrhoea, hypotension, pallor, jaundice, oligoanuria, diffuse bleeding, dark urine, decreased haemoglobin levels. Reactions may occur within 24 hours (acute) or may not manifest for up to 28 days</td>
<td>haemoglobinuria, decreased serum haptoglobin, unconjugated hyperbilirubinaemia, increased LDH and AST levels. Blood group serology shows ABO incompatible mismatch between recipient and donor.</td>
</tr>
<tr>
<td>Immunological Haemolysis due to other allo-antibody</td>
<td>As above</td>
<td>As above but blood group serology shows either allo-antibodies to donor red cells or auto-antibodies in the recipient</td>
</tr>
<tr>
<td>Non-immunological haemolysis</td>
<td>As above</td>
<td>As above but due to non-immunological, possibly mechanical factors such as malfunction of a pump or blood warmer, or the use of hypotonic solutions etc.</td>
</tr>
<tr>
<td>Transfusion-transmitted bacterial infection</td>
<td>Fever, rigors and joint pain with no evidence of symptoms pre-transfusion or alternative source of infection.</td>
<td>Positive blood cultures from recipient and donor pack (matching organisms) or at least one component received by the infected recipient shown to contain the agent of infection</td>
</tr>
<tr>
<td>Note – MUST be reported</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anaphlaxis/hypersensitivity</td>
<td>Mucocutaneous signs and symptoms including urticaria, rash, pruritus, localised angioedema, oedema of lips, tongue, uvula and conjuntiva with airway compromise or severe hypotension requiring vasopressor treatment (or associated symptoms like hypotonia, syncope). Respiratory symptoms may be laryngeal (throat tightness, dysphagia, dysphonia, hoarseness, stridor) or pulmonary (dyspnoea, cough, wheezing/bronchospasm, hypoxemia) Usually occurs during or very shortly after</td>
<td>Rising mast cell tryptase levels or IgA deficiency and/or anti-IgA in the recipient</td>
</tr>
<tr>
<td>Transfusion related acute lung injury</td>
<td>Hypoxaemia (PaO$_2$/FiO$_2$ &lt; 300 mm Hg or O$_2$ sats &lt;90% on room air), bilateral infiltrates on frontal chest X-ray, no evidence of TACO, no temporal relationship to an alternative risk factor for ALI during or within 6 hours of completion of transfusion. Usually acute onset.</td>
<td>Evidence of anti-HLA or anti-HNA antibodies in recipient with incompatibility between donor and recipient.</td>
</tr>
</tbody>
</table>
### 15. B- ISBT of reportable serious adverse reactions table

<table>
<thead>
<tr>
<th>Serious Adverse Reactions</th>
<th>Clinical Features</th>
<th>Laboratory Features</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transfusion-transmitted viral infection (HBV)</td>
<td></td>
<td>Include if the recipient shows evidence of infection post-transfusion and there was no evidence of infection prior to transfusion or any alternative source of the infection, <strong>PLUS either</strong> at least one component received by the infected recipient was shown to contain the agent of infection or at least one component received was donated by a donor who has evidence of the same transmissible infection.</td>
</tr>
<tr>
<td>Transfusion-transmitted viral infection (HCV)</td>
<td></td>
<td>As above</td>
</tr>
<tr>
<td>Transfusion-transmitted viral infection HIV 1&amp; 2</td>
<td></td>
<td>As above</td>
</tr>
<tr>
<td>Transfusion-transmitted viral infection - other</td>
<td></td>
<td>As above</td>
</tr>
<tr>
<td>Post transfusion purpura</td>
<td>Bruising, severe haemorrhage, oozing wounds. Usually occurs 5-12 days post transfusion.</td>
<td>Thrombocytopenia (5-12 days post transfusion) and anti-HPA antibodies present</td>
</tr>
<tr>
<td>Graft versus host disease</td>
<td>Fever, rash, liver dysfunction, diarrhoea. Usually occurs 1-6 weeks after transfusion.</td>
<td>Pancytopenia, characteristic histological appearances on bone marrow biopsy, bone marrow hypoplasia, chimerism</td>
</tr>
<tr>
<td>Other serious reaction(s) - Specify</td>
<td>E.g. Febrile non haemolytic transfusion reactions (FNHTR) where fever &gt;= 39 °C oral or equivalent and a change of &gt;= 2 °C from pretransfusion value, chills, rigors, headache, nausea. Usually occurs within 4 hours of transfusion and without any evidence of haemolysis, bacterial contamination or underlying condition. E.g. Transfusion associated circulatory overload (TACO) – acute respiratory distress, tachycardia, increased blood pressure, acute or worsening pulmonary oedema on frontal chest x-ray, evidence of positive fluid balance. Usually occurs within 6 hours of completion of transfusion. E.g. Transfusion associated dyspnea (TAD) – respiratory distress occurring within 24 hours of transfusion but without the symptoms of TRALI, TACO or allergic reactions and not explained by any underlying condition.</td>
<td></td>
</tr>
</tbody>
</table>
16.0 Definitions

i) Haemovigilance: A set of surveillance procedures covering the whole transfusion chain (from the collection of blood and its components to the follow-up of recipients), intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence.

ii) Serious Adverse Reaction: An unintended response in a donor or in a patient that is associated with the collection, or transfusion of blood or blood components that is fatal, life-threatening, disabling or incapacitating, or which results in or prolongs hospitalization or morbidity.

iii) Serious Adverse event: Any untoward occurrence associated with the collection, testing, processing, storage and distribution, of blood or blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalization or morbidity.
17.0 References

i) WHO draft guidelines for Adverse Event Reporting and Learning Systems

ii) Serious Adverse Blood Reactions and Events (SABRE): User Guide for Mandatory Haemovigilance Reporting in UK; December 2010