



**GUIDANCE DOCUMENT  
FOR  
REPORTING ADVERSE TRANSFUSION  
REACTIONS IN BLOOD TRANSFUSION  
SERVICES**

**HAEMOVIGILANCE PROGRAMME OF INDIA  
(HvPI)**

**National Institute of Biologicals  
(National Coordinating Centre)  
Ministry of Health and Family Welfare  
Government of India  
2019**

## 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 a key to introduce required changes in the applicable policies, improve standards, system 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 Core 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: 02/07/2019

## PREFACE





The contents of this document are designed on the basis of various functional Haemovigilance systems in developed countries and modified as per the Indian scenario by Prof. Neelam Marwaha, Chairperson, National Executive Committee- Haemovigilance Programme of India (HvPI) & Former Head, Department of Transfusion Medicine, Post Graduate Institute of Medical Education & Research (PGIMER), Chandigarh, Prof. Debasish Gupta, Member, National Executive Committee- HvPI & Head, Department of Transfusion Medicine, Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Thiruvananthapuram, Prof. Ravneet Kaur, Member, Core Group- HvPI & Head, Department of Transfusion Medicine, Government Medical College and Hospital (GMCH), Chandigarh, Dr. Akanksha Bisht, Head-HvPI & Scientist Grade-II, National Institute of Biologicals (NIB), NOIDA and also the inputs given by the Reporting Centres under HvPI during two days residential national training workshop for the Blood Bank officials of the Reporting Centres under HvPI held in batches of two in the month of February & March, 2019 at NIB, NOIDA.

These guidelines are intended for reporting the Adverse Reactions related to Blood Transfusion by the Centres under HvPI.

These guidelines are not to be quoted as a reference in any official communication except in the communication with the National Coordinating Centre (NCC) for Haemovigilance Programme of India, NIB.

It is the intent of NIB which is the National Coordinating Centre (NCC) for Haemovigilance Programme of India 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 the requirements, after obtaining necessary approval from the competent authority.

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## **LIST OF ABBREVIATIONS**

ALT	Alanine Aminotransferase
AST	Aspartate Aminotransferase
BT	Blood Transfusion
CBC	Complete Blood Count
CDSCO	Central Drugs Standard Control Organization
CNS	Central Nervous System
CVS	Cardio Vascular System
DAT	Direct Antiglobulin Test
DCGI	Drugs Controller General India
DTM	Department of Transfusion Medicine
EDTA	Ethylene Diamine Tetra-acetic Acid
FFP	Fresh Frozen Plasma
GIT	Gastro Intestinal Tract
HvPI	Haemovigilance Programme of India
IHN	International Haemovigilance Network
ISBT	International Society of Blood Transfusion
LPRBC	Leukocyte-Poor Red Blood Cell
MoH&FW	Ministry of Health & Family Welfare
NCC	National Coordinating Centre
PRBC	Packed Red Blood Cells
PRP	Platelet-Rich Plasma
TRRF	Transfusion Reactions Reporting Form
TR-TD	Transfusion Reaction-Traceability Document
WB	Whole Blood

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## **1. INTRODUCTION**

Transfusion of blood and blood products is not without risks and it can lead to complications. The primary aim of the centralized Haemovigilance Programme is to improve transfusion safety and quality by collecting, collating, analysing and disseminating information on a commonly agreed upon set of 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 Programme has enrolled various centres including Medical Colleges/ Institutes/ Hospitals/ Blood Centres all across the Country and have an oversight by the Haemovigilance Advisory Committee so that it can achieve its goals and objectives.

Haemovigilance Programme of India is now a part of the International Haemovigilance Network (IHN) which provides a global forum for sharing best practices and benchmark of Haemovigilance data.

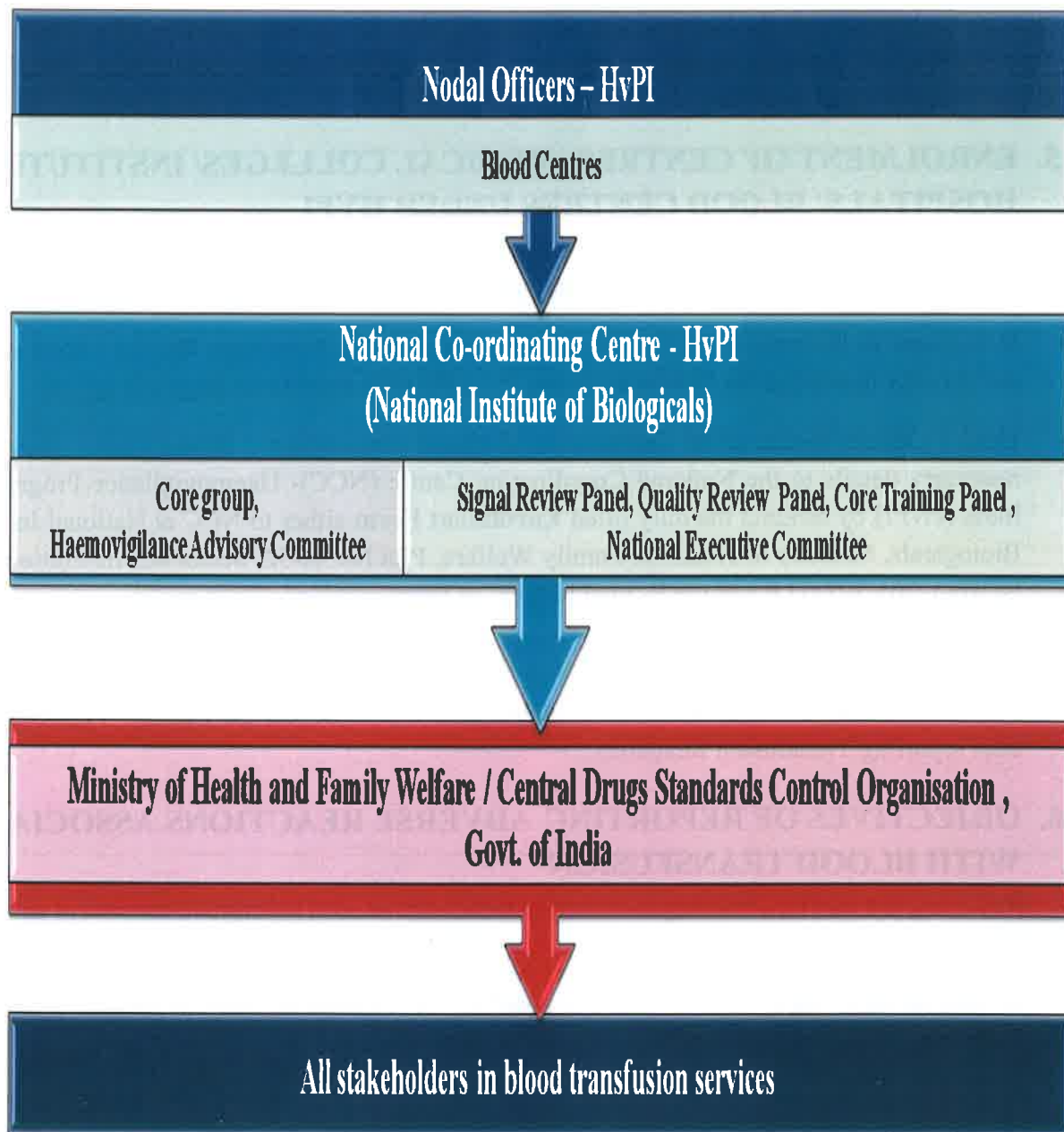
## **2. HAEMOVIGILANCE**

- Haemovigilance is a continuous process of data collection and analysis of Blood 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, 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 for the continual improvement of the quality and safety of blood products and the transfusion process.

### 3. HAEMOVIGILANCE PROGRAMME OF INDIA – ORGANOGRAM



#### Organizational structure for flow of HvPI information





#### 4. CENTRES UNDER HVPI

Those Blood Banks of Medical College/Institute/Hospitals and Stand-alone Blood Centres in India that are registered with the National Coordinating Centre for Haemovigilance Programme of India for reporting the Adverse Reactions that occur during Blood/ Blood Component Transfusion or Blood Product Administration.

#### 5. ENROLMENT OF CENTRES (MEDICAL COLLEGES/ INSTITUTES/ HOSPITALS/ BLOOD CENTRES UNDER HVPI

- Head / Officer-in-charge of Transfusion Medicine Department / Blood Centre sends request via email to NCC at [haemovigilance@nib.gov.in](mailto:haemovigilance@nib.gov.in)
- In response to the request NCC sends the Enrolment Form (**Annexure I**) to the Centre or Centre can directly download the Enrolment Form from the NIB website i.e. <http://nib.gov.in>
- Head / Officer-in-charge of Transfusion Medicine Department / Blood Centre provides the necessary details to the National Coordinating Centre (NCC)- Haemovigilance Programme of India (HvPI) by sending the duly filled **Enrolment Form** either to NCC at National Institute of Biologicals, Ministry of Health & Family Welfare, Plot No. A-32, Sector-62, Institutional Area, NOIDA-201 307 (U.P.) or via E- mail to NCC at [haemovigilance@nib.gov.in](mailto:haemovigilance@nib.gov.in)
- NCC verifies the received details.
- After verification NCC issues the User Id and Password to access the Haemo- Vigil Software to start reporting Transfusion Reactions.

#### 6. OBJECTIVES OF REPORTING ADVERSE REACTIONS ASSOCIATED WITH BLOOD TRANSFUSION

- Reporting is a tool for obtaining information which can be used to improve the patient and product safety.
- A national reporting system therefore can usefully be regarded as a tool to advance public policy concerning patient safety.
- Reporting can help in identify hazards, 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.
- WHO advocates 'Medication without harm' and blood safety is an important component of its strategic objective.

## **7. HAEMO-VIGIL SOFTWARE**

It is a Software which is being used for HvPI to collect & collate Transfusion Reaction Reports from Centres under HvPI for onward transmission of data to NCC. This software was indigenously developed by IT Team, NIB & was launched on 24<sup>th</sup> Jan, 2013.

## **8. PRIVACY AND SECURITY OF DATA**

It is the intention of NIB, Coordinating Centre for Haemovigilance Programme of India that the reports received will be held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public.

## **9. DOCUMENTATION & REPORTING OF ADVERSE REACTIONS ASSOCIATED WITH BLOOD & BLOOD PRODUCTS TRANSFUSION**

Documentation and reporting of Transfusion Reactions associated with Blood Transfusion service involve many aspects and interrelationships:

- Responsibilities of the Medical Colleges/ Institutes/ Hospitals/ Blood Centres under HvPI
- Responsibilities of Medical and other healthcare workers of the Centres under HvPI
- Responsibilities of the Department of Transfusion Medicine/ Blood Centres under HvPI
- Responsibilities of the Hospital Transfusion Committee of the Centres under HvPI
- Responsibilities of NIB, National Co-coordinating Centre - HvPI
- Responsibilities of Ministry of Health & Family Welfare (MoH&FW), Govt. of India
- Responsibilities of Central Drugs Standard and Control Organization (CDSCO), New Delhi

### **9.1 RESPONSIBILITIES OF THE BLOOD CENTRES OF MEDICAL COLLEGE/ INSTITUTE/ HOSPITALS AND STAND-ALONE BLOOD CENTRES IN INDIA THAT ARE REGISTERED WITH NCC- HVPI**

- To enter the information regarding Transfusion Reactions in Haemo-Vigil Software for onward transmission of data to NIB, NCC-HvPI.

## **9.2 RESPONSIBILITIES OF MEDICAL AND OTHER ATTENDING BEDSIDE HEALTHCARE STAFF OF THE CENTRES UNDER HVPI**

Bedside healthcare staff attending the patients having Suspected Transfusion Complications should perform the following documentation and reporting functions:

- 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 it in the patient's file.(**Annexure II**)
- Send the details of the Transfusion Reaction to the Department of Transfusion Medicine/ Blood Centre in the **Form No. 2 (Annexure III)**
- Protocol for the investigation of Acute Transfusion Reaction at the Patient Bedside is given at **Annexure-IV**.
- Assess the Imputability levels of the Adverse Reactions in coordination with the Department of Transfusion Medicine/ Blood Centre.(**Annexure V**)
- Maintain records of the complications in the patient's medical record, including the report of the investigation completed by the Department of Transfusion Medicine/ Blood Centre.

## **9.3 RESPONSIBILITIES OF THE DEPARTMENT OF TRANSFUSION MEDICINE/ BLOOD CENTRE**

The Department of Transfusion Medicine/ Blood Centre is responsible for several aspects of documentation and reporting of Transfusion Reactions and Complications. These include:

- Reporting the details of the clinical and laboratory investigations to the respective medical ward and/or to the Hospital Transfusion Committee as per institutional policy.
- To do the investigations as per the Transfusion Reaction Investigation Form (**Annexure VI**) and documenting the results in the Transfusion Reaction Investigation Form.
- To enter the necessary details as per the documentation required in the Transfusion Reaction-Traceability Document (TR-TD) Record. (**Annexure VII**)
- To assess the Imputability levels of the adverse reactions in coordination with the attending Physician and/or as per institutional protocol. (**Annexure V**)
- Custodian of the Transfusion Reaction-Traceability Document (TR-TD) Record (**Annexure VII**)
- To assure the completeness of the Transfusion Reaction-Traceability document (TR-TD) Record (**Annexure VII**)
- Report the details of transfusion as per the TRRF Form in the Haemo-Vigil Software. (**Annexure VIII**)
- Report the monthly details of the Component(s) units issued as per the Monthly Denominator Reporting Form. (**Annexure VIII**)

#### **9.4 RESPONSIBILITIES OF HOSPITAL TRANSFUSION COMMITTEE**

- To review the Reported Transfusion Reactions for improving Hospital Transfusion Practices as per institutional policy and terms of reference of Hospital transfusion Committee.

#### **9.5 RESPONSIBILITIES OF NIB, NATIONAL CO-ORDINATING CENTRE-HVPI**

- Collection, collation & analysis of Haemovigilance data and forward it to MoH&FW.
- Compilation of data and flagging major issues for deliberation by the Haemovigilance Advisory Committee.
- To monitor the functioning of the Centres under HvPI & quality of the data received from the Centres under HvPI.
- Review completeness, quality check, causality assessment.
- Preparation of SOPs, Guidance Documents and Training Manuals e.g. Software Manual etc.
- Providing training to the Centres under HvPI.
- Publication of Haemovigilance Newsletter.
- Communicate recommendations of Haemovigilance Advisory Committee to MoH&FW.

#### **9.6 RESPONSIBILITIES OF MOH&FW**

- Forward recommendations of Haemovigilance Advisory Committee to MoH&FW.

#### **9.7 RESPONSIBILITIES OF CDSCO**

- Formulate safety related regulatory decisions.
- Communication of Blood and Blood Products Transfusion Safety related decisions to Stakeholders.

## 10.DEFINITIONS

- **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. (<http://www.ihn-org.net>)
- **Adverse event**  
Undesirable and unintended occurrence before, during or after transfusion. It may be the result of an error or an incident and it may or may not result in a reaction.
- **Incident**  
Where the patient is transfused with a blood component which did not meet all the requirements for a suitable transfusion for that patient, or that was intended for another patient. It may or may not lead to an adverse reaction.
- **Near miss**  
Error or deviation from SOPs or policies that is discovered before the start of the transfusion and could have led to a wrongful transfusion or to a reaction in a recipient
- **Adverse reaction**  
An undesirable response or effect in a patient temporally associated with the administration of blood or blood component.
- **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.
- **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.



## 11. REFERENCES

- WHO draft guidelines for Adverse Event Reporting and Learning Systems.
- Serious Adverse Blood Reactions and Events (SABRE): User Guide for Mandatory Haemovigilance Reporting in UK; *December 2010*.
- ISBT working party on Haemovigilance; proposed standard definition for surveillance of non-infectious adverse transfusion reaction; *July 2011*.
- Haemovigilance Module, Biovigilance component. National Healthcare Safety Network. Centers for Disease Control and Prevention USA.

[http://www.cdc.gov/nhsn/PDFs/hemovigModuleProtocol\\_current.pdf](http://www.cdc.gov/nhsn/PDFs/hemovigModuleProtocol_current.pdf)

## ANNEXURE I



### Haemovigilance Programme of India Centre Enrolment Form

Name of the Medical College/Institute/Hospital/Blood Centre	
Address of the Medical College/Institute/Hospital/Blood Centre	
Centre recognised as:- (a) Hospital Based (Government) Blood Centre (b) Hospital Based (Private/Charitable/Trust) Blood Centre (c) Standalone Blood Centre	
License Number (Blood Centre)	
Name and address of the nursing homes / hospitals/ to which your blood Centre issues blood units (if any)	
Name (Head / Incharge of Transfusion Medicine Department /Blood Centre)	
Contact Number	
Email Address	

\_\_\_\_\_  
Signature & Stamp

(Head / Incharge of Transfusion Medicine Department /Blood Centre)

**\* Please Note:** Duly Filled Enrolment Form may be forwarded to National Coordinating Centre -HvPI, NIB, NOIDA via e-mail at [haemovigilance@nib.gov.in](mailto:haemovigilance@nib.gov.in) OR by post as mentioned below:  
National Institute of Biologicals, A-32, Sector-62, NOIDA, Uttar Pradesh -201309

Document Name: HvPI Enrolment Form	
Effective from Year: 2019	Validity: Till further addition

## ANNEXURE II

### FORM No.1 (Sample Form)

#### WHOLE BLOOD/ BLOOD COMPONENT/ BLOOD PRODUCT (RECORD OF BLOOD PRODUCTS ISSUED)

(Name of hospital.....)

(To be retained in patient's file)

#### 1.0 PATIENT DETAILS

S. No. \_\_\_\_\_ Date \_\_\_\_\_  
Name of Pt. \_\_\_\_\_  
Age/Sex \_\_\_\_\_  
C.R. No. \_\_\_\_\_  
Blood Group \_\_\_\_\_ Rh \_\_\_\_\_  
Hosp. \_\_\_\_\_ Wd \_\_\_\_\_ Bed \_\_\_\_\_

#### 2.0 PRODUCT DETAILS:

##### 2.1 BLOOD/COMPONENTS

1. WB
2. PRBC
3. LPRBC
4. PC
5. PRP
6. FFP
7. Cryo Poor Plasma
8. Cryo Precipitate
9. Blood Product (Name).....  
Batch No..... Manufacturer  
..... Expiry.....

Bag No(s) Centre	Date	Blood
1.		
2.		
3.		
4.		

Doctor/Technologist

# ANNEXURE III

## FORM No. 2(Sample Form)

### TRANSFUSION REACTION NOTIFICATION FORM FOR CLINICIANS

(Name of Hospital)					
<b>Transfusion Reaction Notification Form</b>					
(To be filled by Clinician and sent to Department of Transfusion Medicine/Blood Centre after transfusion)					
<b>(A) Patient Details</b>			<b>Clinician In-Charge:</b>		
Name of Pt.		CR No.	Age/ Sex		
Bed No./Ward/ Hospital		Blood Group			
Primary diagnosis					
Indication of Transfusion: Anaemia/ Bleeding/ Surgery/ Other:					
Previous H/o Transfusion/ pregnancy: Yes/NO Detail if yes:					
Medication Detail:					
<b>(B) Transfusion Details</b>					
Blood bag unit no.		Blood group:			
Type of component (Please Circle): WB / PRBC/FFP/PC/SDAP/Cryoprecipitates					
Transfusion Started at:			Transfusion Completed/Stopped at:		
Rate of Transfusion:			Quantity of blood transfused (ml)		
Detail of Blood component transfused just before this unit (if any):					
Was the patient under anaesthesia during transfusion: Yes/No if Yes type : GA/Spinal/LA					
Transfusion was given : Pre-Op/ Intra-Op/ Post-Op					
<b>(C) Transfusion Reaction Details</b>					
Pre-transfusion Vitals:		Temp:	Pulse:	BP:	RR: SPO2
Vitals at the time of reaction:		Temp:	Pulse:	BP:	RR: SPO2
Please tick mark the relevant signs and symptoms listed below					
<b>Generalised</b> <input type="checkbox"/> Fever <input type="checkbox"/> Anxiety <input type="checkbox"/> Chills <input type="checkbox"/> Nausea <input type="checkbox"/> Rigors <input type="checkbox"/> Vomiting <input type="checkbox"/> Itching <input type="checkbox"/> Jaundice <input type="checkbox"/> Urticaria <input type="checkbox"/> Flushing <input type="checkbox"/> Restlessness <input type="checkbox"/> Edema (Site) _____		<b>Pain</b> <input type="checkbox"/> Chest Pain <input type="checkbox"/> Abdominal Pain <input type="checkbox"/> Back/Flank Pain <input type="checkbox"/> Infusion Site Pain  <b>Renal</b> <input type="checkbox"/> Hematuria <input type="checkbox"/> Hemoglobinuria <input type="checkbox"/> Oliguria		<b>Circulatory</b> <input type="checkbox"/> Tachycardia <input type="checkbox"/> Hypertension <input type="checkbox"/> Hypotension <input type="checkbox"/> Raised JVP <input type="checkbox"/> Arrhythmias  <b>Respiratory</b> <input type="checkbox"/> Dyspnoea <input type="checkbox"/> Wheeze <input type="checkbox"/> Cough <input type="checkbox"/> Hypoxemia <input type="checkbox"/> Bilateral <input type="checkbox"/> Infiltrates on Chest X-ray  Any Other _____	
<b>(d) Investigations undertaken at bedside</b>					
<b>Sample sent to blood bank</b>					
<input type="checkbox"/> Post-transfusion 2ml EDTA sample		<input type="checkbox"/> Blood bag along with BT Set			
<b>Investigations sent to other labs</b>					
<input type="checkbox"/> Complete blood counts		<input type="checkbox"/> Plasma Hub	<input type="checkbox"/> Urine Hb	<input type="checkbox"/> Coagulation Screen	
<input type="checkbox"/> RFT (Urea / Creatinine/ Electrolyte)		<input type="checkbox"/> LFT (Bilirubin/ AST/ ALT)		<input type="checkbox"/> Chest X-ray	
<input type="checkbox"/> Blood Culture of Patient		<input type="checkbox"/> Blood culture of blood bag			
<b>( E ) Management Details:</b>					
Whether blood transfusion support will be required in next 24 hours. Yes/No					
<b>(F) Out come of Reaction: Recovered / Recovered with Sequelae / Death / Unknown</b>					
Name of Reporting Physician:			Signature / Date		
Contact No:					

## ANNEXURE IV

### PROTOCOL FOR THE INVESTIGATION OF ACUTE TRANSFUSION REACTION AT THE PATIENT BEDSIDE

#### Investigating Acute Transfusion Reactions

- Take immediate note and inform Blood Centre
- Seek help immediately from skilled anaesthetist 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 and Blood Bag with BT Set (if available) to the Blood Centre for:**

- i. Repeat ABO & Rh (D) Grouping
- ii. Repeat Antibody Screen and Cross Match
- iii. Direct Antiglobulin Test

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

- iv. Complete Blood Count (CBC)
- v. Plasma Haemoglobin
- vi. Urine Haemoglobin
- vii. Coagulation Screen

**Send clotted Blood sample to Biochemistry Lab for:**

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

**Send Blood culture in special blood culture bottles to Microbiology Lab.**



## ANNEXURE V

### IMPUTABILITY LEVELS

Imputability means the likelihood that an Adverse Reaction in a recipient can be attributed to the Blood or Blood Component transfused. The Imputability levels are given below:

Term	Assessment Scale
<b>Definite (Certain)</b>	When there is conclusive evidence beyond reasonable doubt that the adverse event can be attributed to the transfusion.
<b>Probable (Likely)</b>	When the evidence is clearly in favour of attributing the adverse event to the transfusion.
<b>Possible</b>	When the evidence is indeterminate for attributing the adverse event to the transfusion or an alternate cause.
<b>Unlikely (Doubtful)</b>	When the evidence is clearly in favour of attributing the adverse event to causes other than the transfusion.
<b>Excluded</b>	When there is conclusive evidence beyond reasonable doubt that the adverse event can be attributed to causes other than the transfusion.

## ANNEXURE VI

S. No.

## TRANSFUSION REACTION WORK-UP FORM

(Name of the Hospital.....)

**Patient Details**

Name: .....Hospital.....

CR No.....Ward/Bed No.....

Age/Sex:.....Unit In charge.....

Primary Diagnosis: .....

Indication for Transfusion: .....

Clinical Status of Patients:

Respiratory system:

Renal:

CVS:

GIT:

CNS:

Liver:

H/o Previous Transfusion, Pregnancy, Transplantation: Yes/No, details if  
yes.....**Previous Transfusions**☐ First time☐ Repeat 1-10☐ Repeat > 10.....

H/o Drug intake Medication History:

.....

Medical History: .....

Any other infusion through B.T. set: .....

**Transfusion Reaction details:**

Was the patient under anaesthesia during transfusion: Yes/No

If yes: type: GA/spinal/LA

Transfusion given: preop/introp/postop

Vitals: Both pre transfusion vitals and vitals at the time of reaction (in tabulated form) ; temperature,  
Pulse, B.P, Respiratory rate and SpO2

Signs and symptoms (please select the relevant signs and symptoms)

<b>Generalized</b> <input type="checkbox"/> Fever <input type="checkbox"/> Chills <input type="checkbox"/> Rigors <input type="checkbox"/> Itching (pruritus) <input type="checkbox"/> Edema Site _____ <input type="checkbox"/> Nausea <input type="checkbox"/> Vomiting <input type="checkbox"/> Flushing <input type="checkbox"/> Urticaria <input type="checkbox"/> Anxiety <input type="checkbox"/> Restlessness <input type="checkbox"/> Jaundice <input type="checkbox"/> Others : _____	<b>Pain</b> <input type="checkbox"/> Chest pain <input type="checkbox"/> Abdominal pain <input type="checkbox"/> Back/flank pain <input type="checkbox"/> Infusion site pain <input type="checkbox"/> Others : _____	<b>Respiratory</b> <input type="checkbox"/> Dyspnoea <input type="checkbox"/> Wheeze <input type="checkbox"/> Cough <input type="checkbox"/> Hypoxemia <input type="checkbox"/> Bilateral Infiltrates on Chest X-ray <input type="checkbox"/> Others : _____
	<b>Renal</b> <input type="checkbox"/> Haematuria <input type="checkbox"/> Haemoglobinuria <input type="checkbox"/> Oliguria <input type="checkbox"/> Others : _____	<b>Circulatory</b> <input type="checkbox"/> Tachycardia <input type="checkbox"/> Hypertension <input type="checkbox"/> Hypotension <input type="checkbox"/> Raised JVP <input type="checkbox"/> Arrhythmias <input type="checkbox"/> Others : _____

Details of Transfusion:					
Date and time of issue	Date and time of transfusion	Rate of Transfusion	Date and time of transfusion reaction	Date and time of transfusion completion	Recovery with date and time
					<input type="checkbox"/> Death <input type="checkbox"/> Recovered with sequelae <input type="checkbox"/> Recovered <input type="checkbox"/> Unknown
Management/ Any other relevant Detail :					

**(C) TRANSFUSION PRODUCT(S) DETAILS**

**Blood Component :** PRBC ☐ Buffy coat depleted PRBC ☐ Leucofiltered PRBC ☐ (pre/post storage) FFP  
☐ Random donor platelets/ pooled ☐ Apheresis platelets ☐ Cryoprecipitates ☐ Any other ☐ \_\_\_\_\_

**Date of crossmatch :** \_\_\_\_\_. **Type of crossmatch :** 1. ☐ Immediate Spin ☐ AHG 2. ☐ Tube ☐ Gel ☐ SPRCA

Unit no. transfused	Blood group	Volume transfused	Date of Collection	Date of Expiry	Manufacturer of blood bag	Lot no.	Tube No.	Date of Mfg.	Date of expiry

**Received:**

Reaction from (duly filled): .....

Blood Bag/Bags along with transfusion set: .....

Post transfusion sample: .....

**ANNEXURE VI****(Page 2/4)****TRANSFUSION REACTION WORK-UP FORM****(Name of the Hospital.....)****S. No.**

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

Amount of Blood/Blood Component transfused: .....

**Investigation:**

Identification of Patient:

Rechecking of Records:

Cross match file.....

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:**

	<b>Major (RT)</b>	<b>Major (37<sup>0</sup>) AHG phase</b>	<b>Minor (RT)</b>
PreTx Sample			
PostTx Sample			



**TRANSFUSION REACTION WORK-UP FORM**

(Name of the Hospital.....)

S No.

Evidence of Haemolysis:

Plasma Haemoglobin:..... Haemoglobin: Pre Tx.....

Serum Bilirubin:..... Post Tx: .....

Urine Haemoglobin: .....

Urine Hemosiderin: .....

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 DetailsCross match details

Where was blood kept during that interval: .....

Was blood warmed before transfusion, if yes; by what method: .....

## ANNEXURE VI

(Page 4/4)

### TRANSFUSION REACTION WORK-UP FORM

(Name of the Hospital.....)

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

S No.

Date of Cx Match	Date/time of Issue	Date of Receive Back

#### 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 Medical Officer/Nodal Officer



## ANNEXURE VII

### TR-TD (TRANSFUSION REACTION-TRACEABILITY DOCUMENT) RECORD TO BE MAINTAINED BY THE DEPARTMENT OF TRANSFUSION MEDICINE/ BLOOD CENTRE

S No	TRRF No.	Patient Reg No. of hospital	Adverse Reaction	Blood/ Blood component/ Blood Product transfused	Batch No/ Bag No. Mfg. date/ Expiry date	Indications for transfusion	Date & Time of start and completion of transfusion	Date & time of observed adverse reaction	Clinical features of the adverse reaction observed	Laboratory findings	Imputability Level	Final outcome of the transfusion reaction /

## ANNEXURE VIII

### TRANSFUSION REACTION REPORTING FORM (TRRF)

	<b>National Institute of Biologicals</b> Ministry of Health & Family Welfare, Govt. of India (National Coordinating Center) <b>HAEMOVIGILANCE PROGRAMME OF INDIA</b>										
<b>Transfusion Reaction Reporting Form (TRRF) For Blood &amp; Blood Components &amp; Plasma Products</b>											
<b>(A) Patient Information</b> <span style="float: right;">* Mandatory Field</span>											
Hospital Code No.: _____											
Patient Initials*: _____ Gender*: _____ Blood Group*: _____											
Hospital Admission No.*: _____ Age/Date of Birth*: _____ Yrs _____ Month _____ Days _____ Hrs _____ Mins											
Primary Diagnosis*: _____											
Medical History: _____											
<b>(B) Transfusion Reaction Details*</b>											
Was the patient under anaesthesia during transfusion: Yes/No If Yes type : GA/Spinal/LA											
Pre-transfusion Vitals: _____ Temp: _____ Pulse: _____ BP: _____ RR: _____ SPO2: _____											
Vitals at the time of reaction: _____ Temp: _____ Pulse: _____ BP: _____ RR: _____ SPO2: _____											
Please tick mark the relevant signs and symptoms listed below											
<b>Generalised</b> <input type="checkbox"/> Fever <input type="checkbox"/> Chills <input type="checkbox"/> Rigors <input type="checkbox"/> Nausea <input type="checkbox"/> Urticaria <input type="checkbox"/> Flushing <input type="checkbox"/> Restlessness <input type="checkbox"/> Vomiting	<b>Pain</b> <input type="checkbox"/> Anxiety <input type="checkbox"/> Itching (Pruritus) <input type="checkbox"/> Edema (Site) <input type="checkbox"/> Jaundice <input type="checkbox"/> Other _____ <input type="checkbox"/> Chest Pain <input type="checkbox"/> Abdominal <input type="checkbox"/> Back/Flank Pain <input type="checkbox"/> Infusion Site Pain <input type="checkbox"/> Other _____	<b>Respiratory</b> <input type="checkbox"/> Dyspnoea <input type="checkbox"/> Wheeze <input type="checkbox"/> Cough <input type="checkbox"/> Hypoxemia <input type="checkbox"/> Bilateral Infiltrates on Chest X-ray <input type="checkbox"/> Other _____									
<b>(C) Transfusion Product(s) Details*</b>											
Select*	Select Component	Select Indication	Date & Time of Issue of Blood Component	Date & Time of onset Transfusion	Unit Id (Transfused)	Blood Group	Volume Transfused (ml)	Expiry date of Blood Component	Manufacturer of Blood Bag	Batch / Lot No. of the Blood Bag	1st time/ repeat Transfusion
<input type="checkbox"/>	Whole blood										<input type="checkbox"/> 1st Time  <input type="checkbox"/> Repeat 1 to 10  <input type="checkbox"/> Repeat > 10
<input type="checkbox"/>	Packed Red blood cells (PRBC)										
<input type="checkbox"/>	Buffy coat depleted PRBC										
<input type="checkbox"/>	Leucofiltered PRBC										
<input type="checkbox"/>	Random Donor platelets/pooled										
<input type="checkbox"/>	Apheresis Platelets										
<input type="checkbox"/>	Fresh Frozen Plasma										
<input type="checkbox"/>	Cryoprecipitate										
<input type="checkbox"/>	Any Other										
<b>Add New Plasma Product</b>											
Select	Plasma Product	Indication	Date of Administration	Manufacturer	Expiry Date of the Plasma Product	Batch No. / Lot No.	1st Time / Repeat				
							<input type="checkbox"/> 1st Time <input type="checkbox"/> Repeat 1 to 10 <input type="checkbox"/> Repeat > 10				

(D) Investigations				
<input type="checkbox"/> Clerical Checks		Specify Error Found if any: _____		
Investigation	Pre-transfusion sample	Post-transfusion sample		
<input type="checkbox"/> Visual Check				
* <input type="checkbox"/> Repeat Blood Grouping	O+ /A+ /B+ /AB+ /O- /A- /B- /AB- /Others/Not Done	O+ /A+ /B+ /AB+ /O- /A- /B- /AB- /Others/Not Done		
* <input type="checkbox"/> Repeat Crossmatch	<input type="checkbox"/> Compatible <input type="checkbox"/> InCompatible <input type="checkbox"/> Not Done	<input type="checkbox"/> Compatible <input type="checkbox"/> InCompatible <input type="checkbox"/> Not Done		
* <input type="checkbox"/> Repeat Antibody screen	<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Not Done	<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Not Done		
<input type="checkbox"/> Antibody Identification				
* <input type="checkbox"/> Direct antiglobulin test	<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Not Done	<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Not Done		
<input type="checkbox"/> Hemoglobin				
<input type="checkbox"/> Plasma Hemoglobin				
<input type="checkbox"/> Urine hemoglobin				
<input type="checkbox"/> Bilirubin (Total/conjugated)				
<input type="checkbox"/> Platelet count				
<input type="checkbox"/> PT/INR				
* <input type="checkbox"/> Blood culture of Blood Bag	<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Not Done	Specify Organism if positive: _____		
* <input type="checkbox"/> Blood culture of Patient	<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Not Done	<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Not Done Specify Organism if positive: _____		
<input type="checkbox"/> Chest X-ray of the patient in case of suspected TRALI				
<b>In case of Non-immune hemolysis (which of the following was the case?)</b>				
<input type="checkbox"/> Hemolysis due to freezing of PRBC Units				
<input type="checkbox"/> Hemolysis due to inappropriate warming of PRBC Units				
<input type="checkbox"/> Hemolysis due to infusion of any other fluid through same BT set. Specify Fluid: _____				
<input type="checkbox"/> Mechanical damage				
<b>In Case of ABO Mismatch (which of the following was the case?)</b>				
<input type="checkbox"/> Wrong Blood in tube				
<input type="checkbox"/> Grouping error				
<input type="checkbox"/> Labelling error				
<input type="checkbox"/> Wrong unit transfused				
(E) Nature of Adverse Reaction(s)*				
Select	Reaction	Date & Time of Onset of Reaction	Date & Time of Recovery	Outcome
<input type="checkbox"/>	Febrile Non Haemolytic Reactions (FNHTR) 1° C rise in temperature <input type="checkbox"/> 2° C rise in temperature <input type="checkbox"/> Only Chills & Rigors <input type="checkbox"/>			<input type="checkbox"/> 1. Death following the Adverse Reaction(s)
<input type="checkbox"/>	Allergic reaction			<input type="checkbox"/> 2. Recovered
<input type="checkbox"/>	Anaphylaxis			
<input type="checkbox"/>	Immunological Haemolysis due to ABO incompatibility			
<input type="checkbox"/>	Immunological Haemolysis due to other Allo-Antibodies			
<input type="checkbox"/>	Non Immunological Haemolysis			
<input type="checkbox"/>	Hypotensive Transfusion Reaction			
<input type="checkbox"/>	Transfusion Related Acute Lung Injury (TRALI) Definite <input type="checkbox"/> Possible <input type="checkbox"/>			<input type="checkbox"/> 3. Recovered with Sequelae
<input type="checkbox"/>	Transfusion Associated Dyspnoea (TAD)			
<input type="checkbox"/>	Transfusion Associated Circulatory Overload (TACO)			
<input type="checkbox"/>	Transfusion Transmitted Bacterial Infection			
<input type="checkbox"/>	Transfusion Transmitted Parasitic Infection (Malaria)			
<input type="checkbox"/>	Post Transfusion Purpura			
<input type="checkbox"/>	Transfusion Associated Graft versus Host Disease (TAGvHD)			<input type="checkbox"/> 4. Unknown
<input type="checkbox"/>	Other Reaction (s) Add New <input type="text"/>			
<b>IMPUTABILITY ASSESSMENT</b>				
(F) Imputability Assessment*				
S. No.	Reaction Term	Transfusion Product/ Component	*Imputability Assessment (Please mention from the below list)	
*Imputability: 1. Definite (Certain), 2. Probable (Likely), 3. Possible, 4. Unlikely (Doubtful), 5. Excluded, 6. Not Assessed				
Monthly Denominator Reporting Form *				
Hospital Code :		Month/Year:		
Blood Component		No. of Units Issued		
1) Fresh Frozen Plasma				
2) Whole Blood				
3) Packed Red Blood Cells (PRBC)				
4) Buffy Coat Depleted PRBC				
5) Leucofiltered PRBC				
6) Random Donor Platelets/ Pooled				
7) Apheresis Platelets				
8) Cryoprecipitate				
9) Any Other				

## ANNEXURE IX

### FLOW CHART FOR REPORTING ADVERSE REACTIONS ASSOCIATED WITH BLOOD TRANSFUSION





## ANNEXURE X

### TRANSFUSION REACTIONS

**Transfusion Reactions:** Any untoward event or incident with a temporal relationship to blood transfusion is called a transfusion reaction.

#### Classification

##### 1. Non -infectious Transfusion Reactions

#### Haemolytic Transfusion Reactions

- Acute hemolytic transfusion reaction
- Delayed hemolytic transfusion reaction
- Delayed serological transfusion reaction

- **Non-Haemolytic Transfusion Reactions**

- Febrile non hemolytic transfusion reactions
- Allergic transfusion reaction
- Transfusion associated-Graft versus host disease
- Transfusion related acute lung injury
- Transfusion associated dyspnoea
- Transfusion associated circulatory overload
- Post -transfusion purpura
- Hypotensive transfusion reactions

- **Other Transfusion Reactions**

- Hemosiderosis, Hyperkalemia
- Unclassifiable Complication of Transfusion

- **Errors and Incidents**

- IBCT, Handling and Storage errors,
- Near miss events

##### 1. Infectious Transfusion Reactions

- a. Transfusion transmitted bacterial infections
- b. Transfusion transmitted viral infections
- c. Transfusion transmitted parasitic infections

Table: Classification of transfusion reactions based on their time of onset

Acute transfusion reactions	Onset during or within	Type of reaction
	1 hour	TAH
	4 hours	FNHTR, Allergic reaction
	6 hours/12 hours	TRALI, /TACO
	24 hours	HTR, TAD
Delayed transfusion reactions	Onset between	Type of reaction
	24 hrs-28 days	DHTR, DSTR
	5-12 days	Post transfusion Purpura
	7-42 days	TA-GVHD

## DEFINITIONS AND DIAGNOSIS

### 1. Hemolytic transfusion reaction:

A hemolytic transfusion reaction is characterized by clinical and laboratory signs of increased red cell destruction produced by blood transfusion. Hemolysis can occur intravascularly or extravascularly and can be acute or delayed.

#### Case Definitions:

- 1.1 **Acute hemolytic transfusion reaction (AHTR):** It has its onset during or within 24 hours of transfusion.
  - 1.1.1 **Immune AHTR:** AHTR is immune if there is positive serology with ABO incompatible transfusion, incompatible crossmatch, and direct antiglobulin test positive with or without positive antibody screen.
  - 1.1.2 **Non – Immune:** if the serology is negative and mechanical/thermal/toxic cause of red cell hemolysis is present.

**Clinical signs of red cell destruction:**

- Fever
- Chills/rigors
- Chest pain
- Facial Flushing
- Abdominal pain
- Back/flank pain
- Nausea/Vomiting
- Diarrhoea
- Hypotension
- Pallor
- Jaundice
- Oligo/anuria
- Diffuse Bleeding
- Dark urine (Cola colored)

**Laboratory features of red cell destruction**

1. Increased Plasma Hb
2. Hemoglobinuria
3. Decreased serum haptoglobin
4. Unconjugated hyperbilirubinemia
5. Increased LDH/AST levels
6. Decreased Hb
7. Decreased fibrinogen, presence of FDPs
8. Spherocytes on blood film
9. Deranged renal function tests, serum electrolytes

*Not all clinical or laboratory features are present in cases of hemolytic transfusion reactions.*

**GRADES OF SEVERITY:**

**Grade 1 (Non Severe):** the recipient may have required medical intervention (e.g. symptomatic treatment) but lack of such would not result in permanent damage or impairment of a body function

**Grade 2 (Severe):** the recipient required in-patient hospitalization or prolongation of hospitalization directly attributable to the event OR persistent or significant disability or incapacity OR Medical or surgical intervention required to preclude permanent damage or impairment of a body function.

**Grade 3 (Life threatening):** the recipient required major intervention following the transfusion (vasopressors, intubation, transfer to intensive care) to prevent death.

**Grade 4 (Death):** the recipient died following an adverse reaction and the death is possible, probably or definitely related to transfusion.

*If the recipient died of another cause, the severity of the reaction should be graded as 1, 2 or 3*

### **1.2 Delayed hemolytic transfusion reaction (DHTR):**

Definitive: It usually manifests between 24 hours and 28 days after a transfusion.

- Clinical and laboratory features of red cell destruction are usually present but are less severe
- It may manifest as an inadequate rise of post-transfusion hemoglobin level or unexplained fall in hemoglobin after a transfusion or an unconjugated hyperbilirubinemia.
- Blood group serology usually shows positive direct antiglobulin test and positive antibody screen either due to newly formed alloantibody or preexisting alloantibody missed on pre transfusion testing.

**Grades of severity:** Same as AHTR

**1.3 DSTR:** It is characterized by demonstration of clinically significant alloantibodies against red blood cells which were previously absent (as far as is known) with absence of clinical and laboratory features of hemolysis.

**Severity:** DSTR reactions are not severe as there are no clinical signs and symptoms.

## **2. Cardio-respiratory Transfusion reactions:**

Predominantly pulmonary symptoms; Pulmonary transfusion reactions are characterized by respiratory distress or pulmonary edema due to pulmonary damage produced by blood transfusion. These reactions which includes TRALI and TAD are considered as primary pulmonary reactions.

Secondary pulmonary reactions occur in the wake of another transfusion reactions in which lung is not the mainly affected tissue. These include anaphylactic reactions, hemolytic transfusion reactions and TTBI.

Grades of severity of all pulmonary transfusion reactions is similar to AHTR

### **2.1 TRALI**

**2.1.1 Definite TRALI:** In patients with no evidence of acute lung injury (ALI) prior to transfusion, TRALI is diagnosed if a new ALI is present (all five criteria should be met):

- Acute onset
- Hypoxemia
  - $PaO_2/FiO_2 < 300$  mm Hg or
  - Oxygen saturation is  $< 90\%$  on room air or
  - Other clinical evidence
- Bilateral infiltrates on frontal chest radiograph
- No evidence of left atrial hypertension (i.e. circulatory overload)

- No temporal relationship to an alternative risk factor for ALI, during or within 6 hours of completion of transfusion

Alternate risk factors for ALI are:

- |                      |                        |                          |
|----------------------|------------------------|--------------------------|
| • Direct Lung Injury | • Indirect Lung Injury | • Acute pancreatitis     |
| • Aspiration         | • Severe sepsis        | • Cardiopulmonary Bypass |
| • Pneumonia          | • Shock                | • Drug Overdose          |
| • Toxic inhalation   | • Multiple trauma      |                          |
| • Lung contusion     | • Burn Injury          |                          |
| • Near drowning      |                        |                          |

**2.1.2 Possible TRALI:** If there is presence of temporal relationship of TRALI to an alternate risk factor for Acute Lung Injury (as described above), TRALI should be termed as Possible TRALI

**Imputability:**

**Definite:** If it meets the criteria for Definite TRALI

**Probable:** N/A

**Possible:** if it meets the criteria for possible TRALI

**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.

**2.2 Transfusion Associated Circulatory overload: Transfusion Associated Circulatory overload:**

**TACO reporting criteria\* (IHN/ISBT Working party on Haemovigilance and AABB) April 2017**

Patients classified with a **TACO (surveillance diagnosis)** should have acute or worsening respiratory compromise during or up to 12 hours after transfusion and should exhibit two or more of the criteria below:

- Evidence of acute or worsening pulmonary oedema based on:
  - clinical physical examination (see Note 1), *and/or*
  - radiographic chest imaging and/or other non-invasive assessment of cardiac function e.g. echocardiogram (see Note 2)
- Evidence for cardiovascular system changes not explained by the patient's underlying medical condition, including development of tachycardia, hypertension, jugular venous distension, enlarged cardiac silhouette and/or peripheral oedema (see Note 3)

- Evidence of fluid overload including any of the following: a positive fluid balance; response to diuretic therapy combined with clinical improvement; and change in the patient's weight in the peri-transfusion period (see Note 4)
- Elevation in B type natriuretic peptide (NP) levels (e.g., BNP or NT-pro BNP) to greater than 1.5 times the pre-transfusion value. A normal post-transfusion NP level is not consistent with a diagnosis of TACO; serial testing of NP levels in the peri-transfusion period may be helpful in identifying TACO.

\*These criteria establish a surveillance definition based on a complete description of an event, including information that becomes available well after onset. This is for reporting and tracking purposes and the criteria do not constitute clinical diagnosis for the purpose of real-time clinical interventions.

### **Notes**

**1. Clinical findings** could include crackles on lung auscultation, orthopnea and cough, cyanosis and decreased oxygen saturation values in the absence of other specific causes.

### **2. Diagnostic radiographic imaging**

Findings consistent with pulmonary oedema from circulatory overload could include presence of new or worsening pleural effusions, progressive lobar vessel enlargement, peribronchial cuffing, bilateral Kerley lines, alveolar oedema with nodular areas of increased opacity and/or cardiac silhouette enlargement.

### **3. Blood pressure monitoring**

Often the arterial pressure is raised, often with widened pulse pressure; however hypotension may be a presenting feature, e.g. in patients in a state of acute cardiac collapse. Blood pressure should be monitored especially if multi-unit transfusions are given.

### **4. Change in the patient's weight**

Typically the patient's weight will increase. However there may be a decrease following diuretic therapy.

### **Imputability**

The imputability, the *causal* contribution of the transfusion, is assessed separately.



**2.3 Transfusion associated dyspnoea:** It is characterized by respiratory distress within 24 hours of transfusion that does not meet the criteria of TRALI, TACO, or allergic reaction. Respiratory distress should be the most prominent feature and should not be explained by the patient's underlying condition.

**2.4 Hypotensive transfusion reaction:** This reaction is characterized by hypotension defined as a drop in systolic blood pressure of more than or equal to 30 mm Hg occurring during or within one hour of completing transfusion and a systolic blood pressure less than or equal to 80 mm Hg and all other transfusion reactions presenting with hypotension are excluded.

Most reactions do occur very rapidly after the start of the transfusion (within minutes). This reaction responds rapidly to cessation of transfusion and supportive treatment. Hypotension is usually the sole manifestation but facial flushing and gastrointestinal symptoms may occur. It is more frequently seen in patients on ACE Inhibitors.

**Grades of severity :**

**Non-Severe :** The recipient required no more than discontinuation of transfusion and symptom management and no long term morbidity resulted from the reaction

**Severe :** Inpatient hospitalization or prolongation of hospitalization is directly attributable to hypotension, or hypotension led directly to long term morbidity (e.g. brain damage) AND Vasopressors were not required

**Life threatening:** the recipient required vasopressors

**Death :** The recipient died as a result of adverse transfusion reaction. Death should be used if death is possibly, probably or definitely related to transfusion.

**3. Systemic transfusion reactions :**

**3.1 Febrile Non-hemolytic transfusion reaction (FNHTR):**

There is a FNHTR in the presence of one or more of:

- fever ( $\geq 38^{\circ}\text{C}$  oral or equivalent and a change of  $\geq 1^{\circ}\text{C}$  from pretransfusion value),
- chills/rigors

This may be accompanied by headache and nausea. Occurring during or within four hours following transfusion without any other cause such as hemolytic transfusion reaction, bacterial contamination or underlying condition.

FNHTR could be present in absence of fever (if chills or rigors without fever).

### **Grades of severity**

#### **Grade 1:**

- Fever ( $\geq 38^{\circ}\text{C}$  oral and an increase of  $\geq 1^{\circ}\text{C}$  from pretransfusion value)
- Chills/rigors with or without fever
- May be accompanied by headache and nausea.

#### **Grade 2:**

- Fever ( $\geq 39^{\circ}\text{C}$  oral and increase of  $\geq 2^{\circ}\text{C}$  from pretransfusion value)
- With chills/rigors
- May be accompanied by headache and nausea.

**3.2 Allergic reaction:** An allergic reaction may present only with mucocutaneous signs and symptoms:

- Morbilliform rash with pruritus
- Urticaria (hives)
- Localized angioedema
- Edema of lips, tongue and uvula
- Periorbital pruritus, erythema and edema
- Conjunctival edema

occurring during or within 4 hours of transfusion. In this form it usually presents no immediate risk to life of patient and responds quickly to symptomatic treatment like antihistamine or steroid medications. This type of allergic reaction is called 'minor allergic reaction'.

***For the purpose of classification this type of allergic reaction would be graded as 1, i.e. non-severe.***

An allergic reaction can also involve respiratory and/or cardiovascular systems and present like an anaphylactic reaction. There is anaphylaxis when, in addition to mucocutaneous systems there is airway compromise or severe hypotension requiring vasopressor treatment (or associated symptoms like hypotonia, syncope). The respiratory signs and symptoms may be laryngeal (tightness in the throat, dysphagia, dysphonia, hoarseness, stridor) or pulmonary (dyspnoea, cough, wheezing/bronchospasm, hypoxemia). Such a reaction usually occurs occurring during or very shortly after transfusion.

**For the purpose of classification this type of allergic reaction would be graded as 2 (severe), 3 (life-threatening) or 4 (death) depending on the course and outcome of the reaction as details under grades of severity for AHTR.**

### **3.3 Post Transfusion Purpura (PTP)**

PTP is characterized by thrombocytopenia arising 5-12 days following transfusion of cellular blood components with findings of antibodies in the patient directed against the Human Platelet Antigen (HPA) system.

### **3.4 TA-GVHD: TA-GVHD is a clinical syndrome characterized by symptoms of fever**

- Characteristic rash : erythematous, maculopapular eruption centrally that spreads to extremities and may, in severe cases, progress to generalized erythroderma and haemorrhagic bullous formation
- Liver dysfunction
- Diarrhea
- Pancytopenia
- Characteristic histological appearance on biopsy

Occurring 1-6 weeks following transfusion with no other apparent cause. The diagnosis of TA-GVHD is further supported by the presence of chimerism.

#### **Grades of Severity :**

**Mild:** N/A

**Severe:** Patient had marked symptoms and responded to treatment

**Life-threatening:** Patient had severe symptoms and required lifesaving treatment (e.g., immunosuppression)

**Death:** The recipient died as a result of adverse transfusion reaction. Death should be used if death is possibly, probably or definitely related to transfusion.

#### **Imputability:**

**Definite:** WBC chimerism present in the absence of alternative diagnoses

**Probable:** WBC chimerism present BUT Other potential causes are present (e.g., stem cell transplantation)

**Possible:** WBC chimerism not present or not done OR Alternative explanations are more likely (e.g., solid organ transplantation)

**Doubtful:** evidence is clearly in favour of a cause other than the transfusion, but transfusion cannot be excluded.

**Ruled out:** there is conclusive evidence beyond reasonable doubt of a cause other than the transfusion.

**4.5 Transfusion transmitted Infection (TTI):** These transfusion reactions are characterized by laboratory evidence of a pathogen in the transfusion recipient. As per **UK Serious Hazards of Transfusion**.

**Definition:**

A report is classified as a transfusion-transmitted infection if, following investigations:

- The recipient had evidence of infection following transfusion with blood components and there was no evidence of infection prior to transfusion and no evidence of an alternative source of infection

and either:

- At least one component received by the infected recipient was donated by a donor who had evidence of the same transmissible infection

or:

- At least one component received by the infected recipient was shown to contain the agent of infection.

<https://www.shotuk.org/wp-content/.../12.-Transfusion-Transmitted-Infections-TTI.pd...>

Clinicians investigating suspected viral TTIs should explore all possible risk exposures in parallel with the Blood Transfusion Service investigations, in order to determine the patient's most likely source of infection.

**Hence diagnosis of a viral TTI requires the following;**

- Documentation of seronegativity of patient in the pre-transfusion sample
- Investigations in both patients and implicated donors
- Exclusion of other modes of transmission
- Viral genotyping in recipient and donor case of doubt /dispute.

