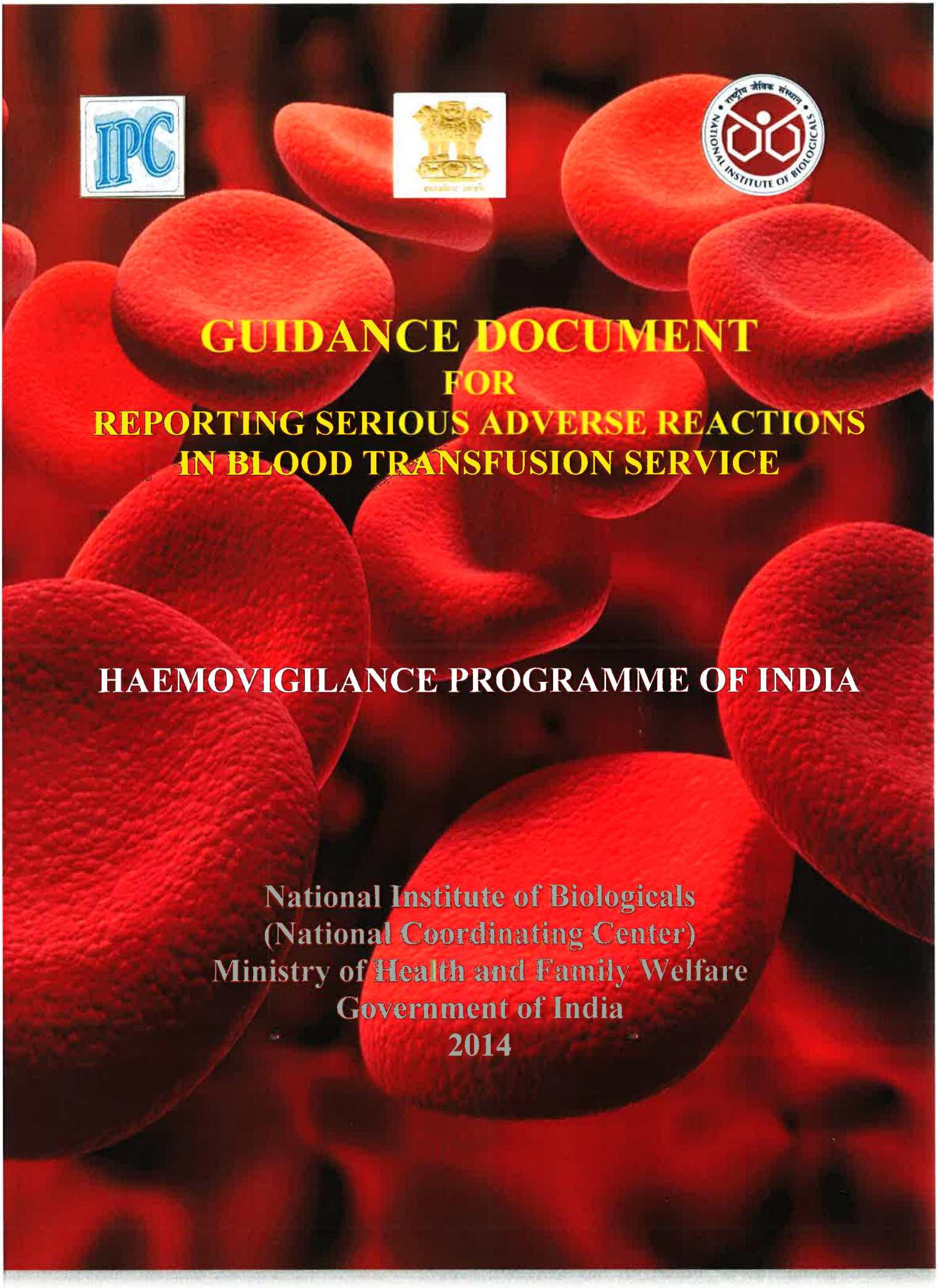

GUIDANCE DOCUMENT
FOR
REPORTING SERIOUS ADVERSE REACTIONS IN BLOOD TRANSFUSION SERVICE

HAEMOVIGILANCE PROGRAMME OF INDIA

National Institute of Biologicals
(National Coordinating Center)
Ministry of Health and Family Welfare
Government of India
2014

FOREWARD

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 preventing 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 April 2014

ACKNOWLEDGEMENTS

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PREFACE

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

These guidelines are intended for reporting the Serious Adverse Reactions related to Blood Transfusion by the Centers under Haemovigilance Programme of India (HvPI).

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

It is the intent of NIB which is the National Coordinating Center (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.

ABBREVIATIONS

ALT	Alanine Amino Transferase
AST	Aspartate Amino Transferase
CBC	Complete Blood Count
CDSCO	Central Drugs Standard Control Organization
CNS	Central Nervous System
CVS	Cardio Vascular System
DCGI	Drugs Controller General India
DCT	Discrete Cosine Transform
EDTA	Ethylene Diamine Tetraacetic Acid
FFP	Fresh Frozen Plasma
GIT	Gastro Intestinal Tract
HvPI	Haemovigilance Programme of India
IHN	International Haemovigilance Network
IPC	Indian Pharmacopoeia Commission
ISBT	International Society of Blood Transfusion
LPRBC	Leukocyte-Poor Red Blood Cell
NACO	National AIDS Control Organisation
NCC	National Coordinating Center
NIB	National Institute of Biologicals
PRBC	Packed Red Blood Cells
PRP	Platelet-Rich Plasma
PvPI	Pharmacovigilance Programme of India
SAR(s)	Serious Adverse Reaction(s)
SBTC	State Blood Transfusion Council
TRRF	Transfusion Reactions Reporting Form
TR-TD	Transfusion Reaction-Traceability Document
WB	Whole Blood

INDEX

1. INTRODUCTION

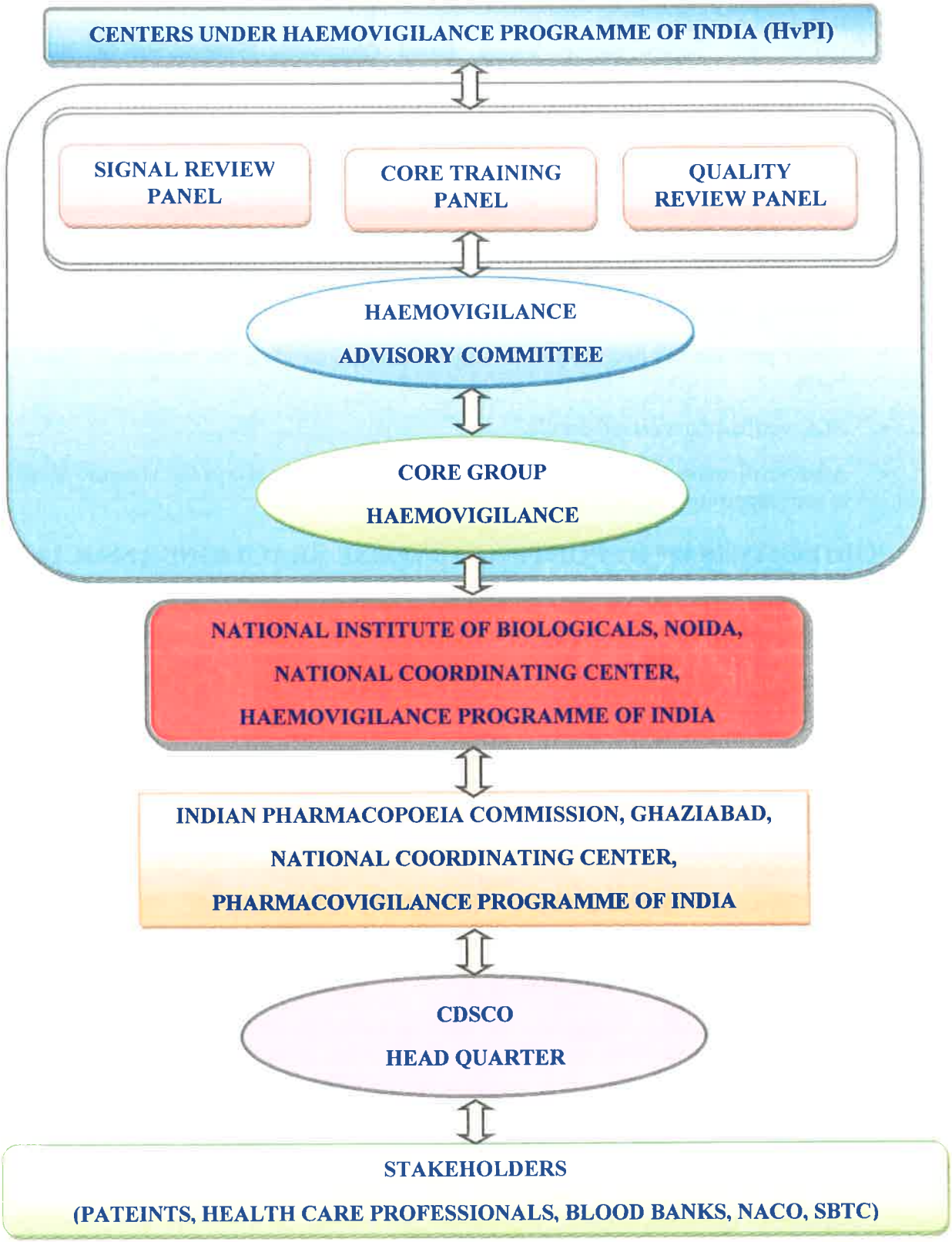
Transfusion of blood and blood products is not without risks and it can lead to complications. The primary aim of the centralized Haemovigilance Programme is to improve transfusion safety and quality by collecting, collating, analysing and disseminating information on a common set of Serious Adverse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

The ultimate goal of Haemovigilance Programme of India is to be 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



4. CENTERS UNDER HvPI

Those Medical Colleges/ Institutes/ Hospitals/ Blood Banks in India that are registered with the National Coordinating Center for Haemovigilance Programme of India for reporting the Adverse Reactions that occurs during Blood/ Blood Component Transfusion or Blood Product Administration.

5. ENROLMENT OF CENTERS (MEDICAL COLLEGES/ INSTITUTES/ HOSPITALS/ BLOOD BANKS) UNDER HvPI

- Head / Incharge of Transfusion Medicine Department / Blood Bank/ sends request via email to haemovigilance@nib.gov.in
- In response to the request NCC sends the Enrolment Form **(Annexure I)** to collect the necessary details of the Center.
- Center provides the necessary details to the NCC by sending the completely filled Enrolment Form.
- 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 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.

7. HAEMO-VIGIL SOFTWARE

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

8. PRIVACY AND SECURITY OF DATA

It is the intention of NIB, Coordinating Center 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 SERIOUS 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 Banks (Centers) under HvPI
- Responsibilities of Medical and Nursing Staff of the Centers under HvPI
- Responsibilities of the Department of Transfusion Medicine/ Blood Bank of the Centers under HvPI
- Responsibilities of the Hospital Transfusion Committee of the Centers under HvPI
- Responsibilities of NIB, National Co-coordinating Center - HvPI
- Responsibilities of IPC, National Co-coordinating Center - PvPI
- Responsibilities of Central Drugs Standard and Control Organization (CDSCO), New Delhi

9.1 RESPONSIBILITIES OF THE MEDICAL COLLEGES/ INSTITUTES/ HOSPITALS/ BLOOD BANKS UNDER 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 NURSING STAFF OF THE CENTERS UNDER HvPI

Physicians and nurses attending the 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 it in the patient's file. **(Annexure II)**
- Send the details of the Transfusion Reaction to the Department Transfusion Medicine/ Blood Bank in the **Form No. 2. (Annexure III)**

- Protocol for the investigation of an acute Transfusion Reaction is given at **Annexure-IV**.
- Assess the Imputability levels of the Adverse Reactions in coordination with the Department of Transfusion Medicine/ Blood Bank. **(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 Bank.

9.3 RESPONSIBILITIES OF THE DEPARTMENT OF TRANSFUSION MEDICINE/ BLOOD BANK

The Department of Transfusion Medicine/ Blood Bank 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 to the Hospital Transfusion Committee.
- To do the investigations as per the Work up Form **(Annexure VI)** and documenting the results in the work up form.
- To enter the necessary details as per the documentation required in the Transfusion Reaction-Traceability document (TR-TD) Record **(AnnexureVII)**
- To assess the Imputability levels of the adverse reactions in coordination with the attending Physician. **(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)**

9.4 RESPONSIBILITIES OF HOSPITAL TRANSFUSION COMMITTEE

- To review the Reported Transfusion Reactions for improving Hospital Transfusion Practices

9.5 RESPONSIBILITIES OF NIB, NATIONAL CO-ORDINATING CENTER-HvPI

- Collection, collation & analysis of Haemovigilance data and forward it to IPC.
- Compilation of data and flagging major issues for deliberation by the Haemovigilance Advisory Committee.
- To monitor the functioning of the Centers under HvPI & quality of the data received from the Centers 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 Centers under HvPI.
- Publication of Haemovigilance Newsletter.
- Communicate recommendations of Haemovigilance Advisory Committee to National Coordinating Centre, IPC, Ghaziabad.

9.6 RESPONSIBILITIES OF IPC, NATIONAL CO-ORDINATING CENTER-PvPI

Forward recommendations of Haemovigilance Advisory Committee to DCGI-CDSCO.

9.7 RESPONSIBILITIES OF CDSCO

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

10. IMPUTABILITY LEVELS

Imputability means the likelihood that a Serious Adverse Reaction in a recipient can be attributed to the Blood or Blood Component or Plasma 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 favour 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 favour 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.

11. 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.

- **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.

ANNEXURE I

Haemovigilance Programme of India

Centre Enrolment Form

Name of the Medical College/Institute/Hospital/Blood Bank	
Address of the Medical College/Institute/Hospital/Blood Bank	
License Number (Blood Bank)	
Name and address of the nursing homes / hospitals/ to which your blood bank issues blood units (if any)	
Name (Head / Incharge of Transfusion Medicine Department /Blood Bank)	
Contact Number	
Email Address	

Signature & Stamp

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

* ***Please Note:*** **Duly Filled Enrolment Form may be forwarded to National Coordinating Centre -HvPI, NIB, NOIDA via e-mail at** *haemovigilance@nib.gov.in* **OR by post as mentioned below:**

National Institute of Biologicals

A-32, Sector-62, NOIDA, Uttar Pradesh -201307

ANNEXURE II

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

DTM 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)	Date	Blood Bank
1.		
2.		
3.		
4.		

Doctor

ANNEXURE III

FORM No. 2

WHOLE BLOOD/ BLOOD COMPONENT /BLOOD PRODUCT TRANSFUSION REACTION FORM

(Name of hospital.....)

(To be sent to Department of Transfusion Medicine/ Blood Bank 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.

BLOOD/COMPONENTS/PRODUCTS

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.....
   Expiry.....
   Manufacturer .....

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

CLINICAL OBSERVATION:

General condition	Pre Transfusion	During Transfusion	Post Transfusion
Pulse			
Resp.			
Temp.			
B.P.			
Rigor			
Chills			
Myalgia			
Urticaria			
Other Observation			

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 IV

PROTOCOL FOR THE INVESTIGATION OF ACUTE TRANSFUSION REACTION

Investigating Acute Transfusion Reactions

- Take immediate note and inform blood bank
- 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 & Blood unit along with BT set to blood bank 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

Term	Assessment Scale
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 favour 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 favour 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.

ANNEXURE VI

TRANSFUSION REACTION WORK-UP FORM

(Name of the Hospital.....)

S No.

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

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

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

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 VI

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:

	Major (RT)	**Major (37^0) AHG phase**	**Minor (RT)**
PreTx Sample			
PostTx Sample			

ANNEXURE VI

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 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 VI

TRANSFUSION REACTION WORK-UP FORM

(Name of the Hospital.....)

S No.

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

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 Consultant/Senior Resident

Signature of Junior Resident

ANNEXURE VII

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

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 /

TRANSFUSION REACTION REPORTING FORM (TRRF)

Transfusion Reaction Reporting Form (TRRF) for Blood & Blood Products

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 COMPONENTS & PLASMA PRODUCTS
For reporting of Transfusion Reactions by Healthcare Professionals

* Mandatory Field

A) PATIENT INFORMATION

Patient initials* ..... DOB/Age in years * : ..... Blood Group * : ..... Diagnosis .....

Hospital Code No* ..... Hospital Admission No* ..... Sex: * F ☐ M ☐

Date * & Time of Transfusion ..... Date * & Time of reaction ..... Date & Time of recovery .....

B) TRANSFUSION PRODUCT DETAILS*

Components	Select Components	Unit Number (transfused)	Expiry Date of the Blood Component	Manufacturer of the Blood Bag	Batch Number	Indications	1st time / Repeat Transfusion (No. of Repeats)
Whole Blood							
Red Blood Cells							
Platelets Apheresis							
Platelets Pooled/ RDP							
Solvent detergent (SD) Plasma							
FFP							
Cryoprecipitate							
Any other							

Plasma Products (Please Specify)	Manufacturer of the Plasma Product	Batch Number	Expiry Date of the Plasma Product		

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 (HCV)	
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	Febrile Non Haemolytic Reactions(FNHTR)	
16	Transfusion Associated Dyspnea(TAD)	
17	Transfusion Associated Circulatory Overload (TACO)	
18	Other Reaction(s)	

D) OUTCOME OF THE ADVERSE REACTION (s)*

- 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)_____

Any other information .....

F) CAUSALITY ASSESSMENT*

Date of this report (DD/MM/YYYY)

TRANSFUSION REACTION REPORTING FORM (TRRF)

ADVICE ABOUT REPORTING

- Report adverse experiences with Blood Transfusion or Blood Products Administration
- Who Can Report?
  - >> Any health care professional (Doctors including Dentists, Nurses and Pharmacists)
- Where to Report?
  - >> Please send the completed form to the nearest Medical Colleges / Hospitals / Blood Banks / Institutes under Haemovigilance Programme of India or to National Coordinating Center-Haemovigilance Programme of India, NIB
  - >> A list of nationwide Medical Colleges / Hospitals / Blood Banks / Institutes under Haemovigilance Programme of India is available at: http://www.nib.gov.in
- What happens to the submitted information
  - >> The causality assessment is carried out at Medical Colleges/Hospitals/Blood Banks/Institutes under Haemovigilance Programme of India
  - >> The information collected in Transfusion Reaction Reporting Form (TRRF) will be forwarded to National Coordinating Centre-Haemovigilance Programme of India NIB, through a software (Haemo-Vigil) developed in house by NIB's IT division. This data will be collated & analyzed to identify trends, recommend best practices and interventions required to improve patient care & safety
  - >> These recommendations will be forwarded to IPC National Coordinating Centre, PvPI for onward transmission to Drugs Controller General (India), Central Drugs Standard Control Organization
  - >> These recommendations will be used to formulate safety related regulatory decisions on Blood & Blood Products Transfusion which will be communicated to various stakeholders.
  - >> The information will be submitted to the Advisory Committee of Haemovigilance Programme of India constituted by the Ministry of Health and Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required

TRANSFUSION REACTION REPORTING FORM (TRRF)

For VOLUNTARY reporting of Transfusion Reactions by health care professionals.

National Institute of Biologicals
National Coordinating Centre-Haemovigilance Programme of India
Directorate General of Health Services
Ministry of Health & Family Welfare, Government of India
A-32,Sector-62, NOIDA
http://www.nib.gov.in

Confidentiality

The patient's identity is 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.
Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

TRRF can be downloaded from the websites:
www.nib.gov.in • www.ipc.gov.in • www.cdsco.nic.in

ANNEXURE IX

FLOW CHART FOR REPORTING SERIOUS ADVERSE REACTIONS ASSOCIATED WITH BLOOD TRANSFUSION

Medical Ward: Adverse Reaction noted by the Physician / Nurse.

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Medical Ward: Documentation in Form No.1 **(Annexure II)**

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Medical Ward: Fill up Form No.2 **(Annexure III)**. Along with Form No.2 send Blood Bag, Transfusion Set, and Post-transfusion Sample to Department of Transfusion Medicine/ Blood Bank for further investigation including Repeat ABO & Rh (D) Grouping, Repeat Antibody Screen and Cross Match, Direct Antiglobulin Test.

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Medical ward: Send Post Transfusion Blood in special Blood Culture Bottles to Microbiology Lab.

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Medical ward: Send EDTA and Citrated Blood Sample and Urine Sample of the patient to Haematology Lab for Complete blood count (CBC), Plasma haemoglobin, Urine haemoglobin, Coagulation screen.

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Medical ward: Send clotted Blood Sample to Biochemistry Lab. for Renal Function Test (Urea, Creatinine and Electrolytes), Liver Function Tests (Bilirubin, ALT and AST).

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Department of Transfusion Medicine/ Blood Bank: 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

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Department of Transfusion Medicine/ Blood Bank: Assess the Imputability Level of the Transfusion Reaction in coordination with the attending Physician of the respective Medical

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Department of Transfusion Medicine/ Blood Bank: Enter the details in the Transfusion Reaction-Traceability Document (TR-TD). **(Annexure VII)**

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Haemo-Vigil Software: Enter the information as per the Transfusion Reaction Reporting Form for Blood & Plasma Products for onward transmission of data to NCC, NIB.

ANNEXURE X

ISBT TABLE OF REPORTABLE SERIOUS ADVERSE REACTIONS (SARS)

Serious Adverse Reactions	Clinical Features	Laboratory Features
Immunological Haemolysis due to ABO incompatibility	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	Haemoglobinuria, decreased serum haptoglobin, unconjugated hyperbilirubinaemia, increased LDH and AST levels. Blood group serology shows ABO incompatible mismatch between recipient and donor.
Immunological Haemolysis due to other allo-antibody	As above	As above but blood group serology shows either allo-antibodies to donor red cells or auto-antibodies in the recipient
Non-immunological haemolysis	As above	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.
Transfusion-transmitted bacterial infection. **Note** – MUST be reported	Fever, rigors and joint pain with no evidence of symptoms pre-transfusion or alternative source of infection.	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

Anaphlaxis/hypersensitivity	Mucocutaneous signs and symptoms including urticaria, rash, pruritus, localised angioedema, oedema of lips, tongue, uvula and conjuctiva 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 transfusion	Rising mast cell tryptase levels or IgA deficiency and/or anti- IgA in the recipient
Transfusion related acute lung injury	Hypoxaemia (PaO_2/FiO_2 < 300 mm Hg or O_2 sats < 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.	Evidence of anti-HLA or anti-HNA antibodies in recipient with incompatibility between donor and recipient.
Transfusion-transmitted viral infection (HBV)		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, PLUS either 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.

Transfusion-transmitted viral infection (HCV		As above
Transfusion-transmitted viral infection HIV 1& 2		As above
Transfusion-transmitted viral infection - other		As above
Post transfusion purpura	Bruising, severe haemorrhage, oozing wounds. Usually occurs 5-12 days post transfusion.	Thrombocytopenia (5-12 days post transfusion) and anti-HPA antibodies present
Graft versus host disease	Fever, rash, liver dysfunction, diarrhea. Usually occurs 1-6 weeks after transfusion.	Pancytopenia, characteristic histological appearances on bone marrow biopsy, bone marrow hypoplasia, chimerism

Other serious reaction(s) - Specify	E.g. Febrile non haemolytic transfusion reactions (FNHTR) where fever >= 39 °C oral or equivalent and a change of >= 2 °C from pretransfusion value, chills, rigors, headache, nausea. Usually occurs within 4 hours of transfusion and without any evidence of hemolysis, 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