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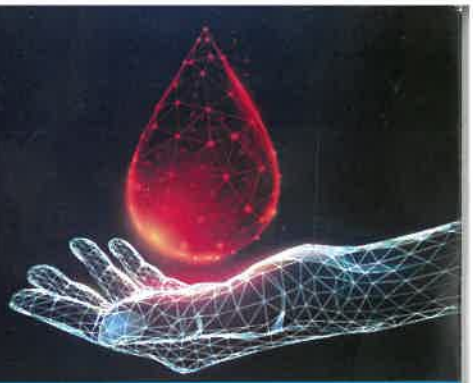
National Institute of Biologicals, NOIDA (NCC- HvPI)
Ministry of Health and Family Welfare, Govt. of India

HAEMOVIGILANCE NEWSLETTER

VOL. NO. 11 ISSUE 22 JULY-DECEMBER, 2023

Two Days Residential Training cum Workshop for the Blood Centre officials of the Reporting Centres under Haemovigilance Programme of India

"The aim of the newsletter is to disseminate information on Haemovigilance Programme of India so as to create awareness amongst healthcare professionals & other stakeholders on safe Blood Transfusion & Blood Donation Practices"



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Haemovigilance Programme of India - Milestones

Haemovigilance Programme of India was launched on 10th December, 2012 at the National level in 90 medical institutions across the country by National Institute of Biologicals (NIB), NOIDA, Ministry of Health & Family Welfare, Government of India as the National Coordinating Centre (NCC). The objective of this programme is to track Adverse Reactions associated with Blood Transfusion and Blood Donation.

Haemovigilance is defined as 'a set of surveillance procedures covering the whole transfusion chain from the collection of blood and its components to the follow-up of its recipients i.e. from the vein of the donor to the vein of the recipient. It is 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 and recurrence'. Haemovigilance is a tool to improve the quality of the blood transfusion chain, primarily focusing on safety.

1. The recipient's arm i.e. reporting of Adverse Reactions with respect to Blood Transfusion in the patient is being covered under **Haemovigilance Programme of India (HvPI)** with the launch of the programme on 10th December, 2012 in the country.
2. The donor's arm i.e. Reporting of Adverse Reactions associated with Blood Donations is being covered under **National Blood Donor Vigilance Programme (NBDVP)** which was launched on 14th June, 2015 on World Blood Donor Day at Science City Kolkata under the ambit of HvPI.
3. Reporting of Adverse Transfusion Reactions is done online via Haemo-Vigil software & reporting of Adverse Blood Donor Reactions is done via Donor-Vigil software available on NIB website www.nib.gov.in

Implementation and coordination of activities of Haemovigilance Programme of India became one of the Mandates of NIB as per its bye-laws 3.4.1 of the Institute as approved in the Governing Body meeting of NIB held under chairpersonship of Secretary (Health & F.W.)/ Chairman, Governing Body of NIB on 12th Dec, 2014

DCG (I) issued an office memorandum dated 4th December, 2015 w.r.t. enrolment of all licensed blood centres under HvPI. These licensed blood centres are required to obtain their user ID and password from NIB to uplink their adverse transfusion reaction datato Haemo-Vigil software under HvPI.

National Accreditation Board for Hospitals and Healthcare Providers (NABH) in its third edition of accreditation standards on Blood Centres and transfusion services issued in year 2016 has included enrolment by Blood Centres under National Haemovigilance Program of India and monitor adverse donor reactions and adverse transfusion reactions in compliance to the issued directives.

NCC-HvPI, NIB issues certificate of participation to the centres who are actively reporting under Haemovigilance Programme of India.

Continuing Medical Education (CMEs) Organized by NIB to create awareness about the Haemovigilance Programme of India(HvPI)

- A Continuing Medical Education (CME) on Haemovigilance Programme of India organised by National Institute of Biologicals (NIB), NOIDA in collaboration with Hind Institute of Medical Sciences (HIMS) Sitapur, Uttar Pradesh on 24th March, 2023 at HIMS Sitapur, Uttar Pradesh. Head HvPI gave the presentation on "Haemovigilance Programme in India & Networking" in the said CME.
- About 180 participants which included Blood bank officials, clinicians, technicians,nurses, PG students & officials from drugs control department attended the said CME.

- A Continuing Medical Education (CME) on Haemovigilance Programme of India organized by National Institute of Biologicals (NIB), NOIDA in collaboration with Punjab Institute of Medical Sciences (PIMS), Shrimann Superspeciality Hospital & Indian Medical Association (IMA) Jalandhar on 26th May, 2023 at PIMS, Jalandhar. Head HvPI gave the presentation on "Update on Haemovigilance Programme in India" in the said CME.
- About 200 participants attended the said CME.

पिम्स में श्रीमन सुपर स्पैशिलटी अस्पताल व आई.एम.ए. के सहयोग से सी.एम.ई. आयोजित

Two Days Residential Training cum Workshop for the Blood Centre officials of the Reporting Centres under Haemovigilance Programme of India on 29th & 30th May, 2023 at NIB, NOIDA

Objective

The objective of this training cum workshop was to sensitize and train the blood centre officials of reporting centres under HvPI w.r.t. latest updates, definitions, guidelines and reporting of adverse blood transfusion reactions with special emphasis to improve the quality of data being submitted under HvPI.

- Haemovigilance Division of National Institute of Biologicals (NIB) organized Two Days Residential Training cum Workshop for the Blood Centre officials of the Reporting Centres under Haemovigilance Programme of India on 29th & 30th May, 2023 at NIB, NOIDA.
- About 38 participants including blood centre officials, technical officials from 14 states of the country and 07 experts had participated in the said Training cum Workshop.

Registration

Inauguration

Group Photograph

Technical Session

Day 1

- Update on Haemovigilance Programme of India and its impact.
- Classification and Workup of Transfusion Reaction.
- FNHTRs & Allergic reactions -definitions, grading, imputability followed by case discussions.
- Introduction to adverse events with cardiorespiratory symptoms followed by Case /report discussions on TRALI, TACO, TAD, hypotensive transfusion reaction.
- Haemolytic transfusion reactions - Case /report discussions.



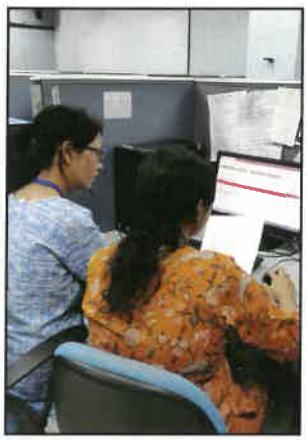
Day 2

- Donor Vigilance in India: Introduction & Experience of initial two years of implementation.
- Donor adverse reactions: Classification & Definitions.
- Severity Grading Tools in Donor adverse reaction.
- Uploading of Donor adverse reaction on Donor Hemovigil software: Challenges in Data Analysis.
- Case Discussion: Localised donor adverse reactions.
- Vaso Vagal Reactions: Case based approach & Prevention strategies.
- Discussion on Haemo-Vigil software(s)



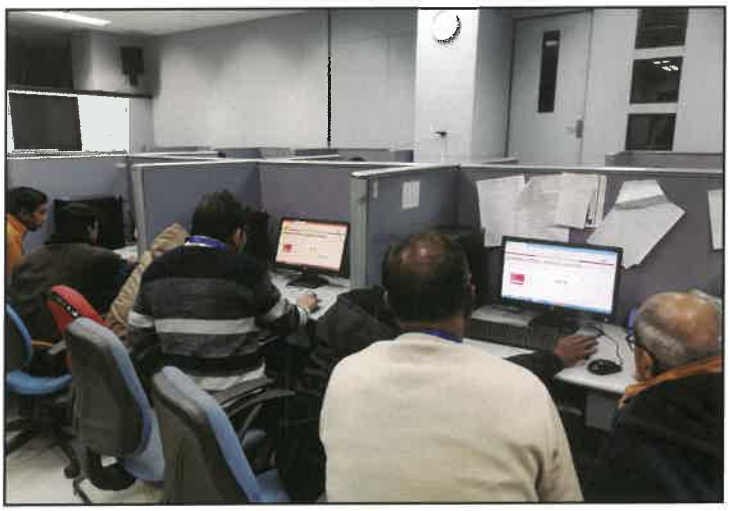
Visit to Immunodiagnostic Kit Laboratory-WHO collaborative centre


Offline Demonstration of Haemovigilance Software(s)

NIB- National Health Mission (NHM)
Collaborative Six Days Residential Training Programme for Strengthening of Blood Services for the state Chhattisgarh & Telangana

- The medical officials & lab technicians of the Chhattisgarh state participated in the aforesaid training. One session during this training programme was kept for Haemovigilance Programme of India on 10th January, 2023 & during this session about 41 participants were apprised about Haemovigilance Programme of India followed by hands on training. Head HvPI gave the presentation on Haemovigilance Programme of India and software demonstration on 10th January, 2023.



Chhattisgarh on 09th - 14th January, 2023

- The medical officials & lab technicians of the Telangana state participated in the aforesaid training. One session during this training programme was kept for Haemovigilance Programme of India on 13th May, 2023 & during this session about 40 participants were apprised about Haemovigilance Programme of India followed by hands on training. Head HvPI gave the presentation on Haemovigilance Programme of India and software demonstration on 13th May, 2023.

Telangana on 08th - 13th May, 2023

National Skill Development & Hands-on Training Programme on Quality Control of Biologicals for M.Sc. Biotechnology Students from 22nd May to 02nd June, 2023 at NIB, NOIDA

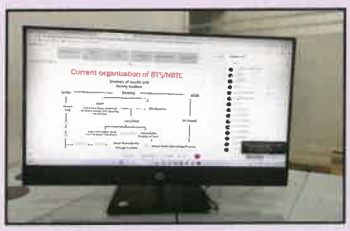
- The students from Guru Ghasidas Vishwavidyalaya, Bilaspur (Chattisgarh) participated in the said training programme. One day session during this training programme was kept for Haemovigilance Programme of India on 01st June, 2023. During this session about 30 students including 01 faculty were apprised about Haemovigilance Programme of India followed by hands on training.




Online Webinar meeting on the occasion of World Blood Donor Day

- Head HvPI attended the Online Webinar meeting on the occasion of World Blood Donor Day held on 07th June, 2023 organized by Blood Transfusion Services, Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India.






Meeting Organized by NIB

- An online meeting of the expert was held on 28th February, 2023 at Haemovigilance Division of NIB.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Pilot study to understand and compare challenges being faced in reporting of transfusion reactions in various types of blood banks enrolled under Haemovigilance Programme of India

Rayaz Ahmad Bhat, Vishal Tiwari, Satyajeet Singh, Ruchi Rao, Akash Chaudhary, Akanksha Bisht

Abstract:

BACKGROUND: Hemovigilance has become one of the important quality check systems of blood transfusion process, but under/non‐reporting of transfusion‐associated adverse reactions despite the presence of reporting systems emphasize the need to understand the challenges being faced in active reporting of adverse transfusion reactions.

AIM: To identify and document the possible factors leading to under‐reporting and impacting the quality of blood transfusion reactions being submitted under Haemovigilance Programme of India (HvPI).

SETTINGS AND DESIGN: This was a cross‐sectional, observational type study, carried out in six blood banks, two each of government, private, and stand‐alone sectors in Delhi National Capital Region enrolled under HvPI.

MATERIALS AND METHODS: The study was carried out for a period of 6 months with a‐month residence in each blood bank. During this period, data related to adverse transfusion reactions and their reporting were collected using a designed data collecting form and a validated questionnaire from all the six blood banks.

STATISTICAL ANALYSIS USED: MS Excel Ver. 2007 was used for compilation and descriptive analysis of collected data, and SPSS Ver. 25.0 was used for determining the Cronbach's alpha for the questionnaire which was statistically significant ($\alpha > 0.7$).

RESULTS: In a period of 6 months, a total of 5136 blood products were issued from these blood banks along with 5136 reaction reporting forms, but only 515 transfusion reaction report forms were returned to these blood banks. It was found that each blood bank faces some challenges with respect to identifying and reporting adverse transfusion reactions.

CONCLUSION: Addressing the gaps identified during this study will result in robust hemovigilance system in our country and having reliability of data being reported under HvPI.

Keywords:

Adverse transfusion reactions, blood banks, challenges, hemovigilance, reporting

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Introduction

Blood transfusion, indeed a life‐saving medical intervention, but a same life‐savior intervention, can be life‐threatening with many risks associated with this, ranging from mild allergic reactions to fatal anaphylactic reactions vis‐à‐vis transfusion‐transmitted infections.[1] The

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New Members Enrolled under Haemovigilance Programme of India (63)

Andhra Pradesh
1. New Vision Blood Bank (Unit of Rural and Urban Development Society), Prakasam District
2. M/s Udayananda Hospital Blood Centre, (A Unit of Udayananda Health Care Pvt. Ltd.), Noonepalli, Nandyal

Assam
1. S. M. Dev Civil Hospital Blood Centre, Silchar, Cachar
2. Hayat Hospital Blood Centre, Guwahati
3. Blood Bank Apollo Hospitals, Guwahati

Bihar
1. Jay Prabha Medanta Blood Center (Jay Prabha Medanta Hospital), Patna
2. Bharat Blood Centre, Patna

Chhattisgarh
1. SCCH Blood Centre, Raipur
2. M/s The Civil Surgeon Cum Chief Hospital Superintendent, District Hospital Blood Bank, District Hospital Ambikapur, Surguja

Gujarat
1. Nukem Blood Bank, Haria L.G. Rotary Hospital, Vapi
2. Polycab Social Welfare Foundation Blood Centre, Panchmahal
3. Blood Centre GMERS Medical College and Hospital, Dharpur, Patan
4. Kumarpal Gandhi Blood Centre, Ankleshwar

Haryana
1. Bhagwandas Hospital Blood Centre, Sonipat
2. Blood Centre FIMS, Sonipat
3. Mahatma Gandhi Blood Centre, Hisar
4. Signature Hospital, Blood Centre Park, Medicity (North) Private Limited, Gurugram
5. Amrita Institute of Medical Sciences, Faridabad
6. SGT Medical College, Hospital & Research Institute, Gurugram

Jammu & Kashmir
1. Govt. Medical College, Doda

Jharkhand
1. Paras HEC Hospital Blood Centre, Ranchi

Karnataka
1. Jindal Sanjeevani Multispeciality Hospital, Ballari District
2. BIMS Blood Centre, Belagavi
3. Sri Madhusudan Sai Institute of Medical Science & Research Blood Centre, Chikkaballapura

Kerala
1. Mothercare Blood Centre, Palakkad
2. Blood Centre District Hospital, Vatakara, Kozhikode

Madhya Pradesh
1. Bhandari Hospital & Research Centre (Mohit Blood Centre), Indore
2. Jabalpur Blood Centre, Jabalpur

Maharashtra
1. Bharati Vidyapeeth (Deemed Tobe University) Medical College & Hospital, Blood Center, Sangli
2. New Arpan Voluntary Blood Center, Ahmednagar
3. Symbiosis Medical College for Women, Pune
4. Plasma Diagnostic Laboratories and Blood Centre, Dombivli (E), Thane
5. Shri Satya Sai Blood Centre, Sambhajinagar
6. Jupiter Lifeline Hospital Blood Centre, Pune

Meghalaya
1. Nongstoin Civil Hospital Blood Centre, West Khasi Hills District

New Delhi
1. Blood Center, Jai Prakash Narayan Apex Trauma Center, AIIMS , Raj Nagar

Odisha
1. JP Blood Centre, Jai Prakash Hospital & Research Centre Pvt. Ltd., Sundargarh
2. Hi-Tech Medical College and Hospital, Rourkela

Punjab
1. M/s Karan Hospital Multispeciaty Centre, Samrala, Ludhiana
2. Civil Hospital, Khanna, Ludhiana
3. Red Cross Blood Centre, Ludhiana
4. Parkash Hospital, Amritsar
5. Blood Centre Civil Hospital, Batala
6. Oxford Hospital, Jalandhar
7. Smt Parvati Devi Hospital, Unit-2, Blood Centre, Amritsar
8. Park Hospital, A Unit of Park Medicity (World) Pvt. Ltd., Patiala
9. Blood Centre Guru Nanak Dev Superspeciality Hospital, Tarn-Taran

Tamil Nadu
1. Lions Blood Bank and Research Foundation Trust, Ambattur, Chennai
2. Dr. Kamakshi Memorial Blood Bank and Blood Component Research Centre, Chennai
3. Kauvery Regional Blood Centre (Kauvery Hospital), Chennai
4. Apollo KH Hospital, Melvisharam
5. Sri Narayani Hospital and Research Centre, Vellore
6. Maruthi Blood Centre Run by Maruthi Blood Bank & Research Foundation Trust, Krishnagiri

Telangana
1. Pranaam Blood Centre (A Unit of Jeevan Society), Ranga Reddy Dist.
2. Malla Reddy Narayana Multispeciality Hospital, Hyderabad
3. Yashoda Hospitals, Hitech City, Blood Centre, Ranga Reddy Dist.

Uttar Pradesh
1. Yagya Charitable Blood Bank, Lucknow
2. M/s Apollomedics Super Speciality Hospital (Blood Centre), Lucknow
3. Sri Sai Hospital & Blood Center, Moradabad
4. S.S.B. Trauma Centre, Firozabad
5. Jaswant Rai Speciality Hospital, Meerut

West Bengal
1. Sri Ramkrishna Institute of Medical Sciences & Sanaka Hospitals (A Unit of Sanaka Educational Trust) Blood Centre, Dist. Burdwan, Durgapur
2. CSDH Blood Centre, South 24 Parganas

National Institute of Biologicals
Ministry of Health & Family Welfare, Govt. of India
NATIONAL BLOOD DONOR VIGILANCE PROGRAMME
(Haemovigilance Programme of India)
Adverse Blood Donor Reaction Reporting Form

Version-2

A) Donor Information

Donor Id *: _____

Sex * _____ (Male/Female/Other)

Weight of Donor (kg) * _____ Height of Donor (cm)* _____

Age/ Date of Birth * Yrs: _____ Month: _____ Days: _____ OR _____

Pre-Donation Vitals* Pulse: _____ per min BP (Systolic): _____ mmHg

BP (Diastolic): _____ mmHg

Type of Donation* **(a)** Whole Blood **(b)** Apheresis__ (Platelets/Plasma/ Plasma + Platelets/RBC/Granulocyte/ Peripheral Blood Stem Cells/ COVID-19 Convalescent Plasma)

Donor Type* **(a)** Voluntary **(b)** Replacement **(c)** Family Donor **(d)** Autologous (First Time/Repeat)

Site of Donation* _____ (Blood Centre/Camp)

Date of Donation * _____

Time of Donation Hr _____ Min _____

B) Whole blood Details of Blood Collected/Apheresis Details of Blood Collected

(a) Whole Blood

Lot No. of Blood Bag* _____

Manufacturer of Blood Bag* _____ (Terumo Penpol Limited/Mitra Industries Pvt. Ltd/ HLL Lifecare Ltd/Fresenius Kabi AG/Fenwal Inc/Polymed/Other)

Volume Collected (ml)* _____

Expiry Date of Blood Bag* _____

(b) Apheresis

Lot No. Kit* _____

Volume Collected (ml)* _____

Expiry Date of Kit* _____

C) Adverse Reaction Details

Date and Time of reaction* _____ Hr____Min____

Vitals at the time of Reaction Pulse: _____ per min BP (Systolic): _____ mmHg BP (Diastolic): _____ mmHg

Venipuncture Site*_____ (Left/Right/Both)

Venipuncture* _____ (1/2/>2)

Type of Reaction*_____ (Localised/Generalized/Both/ Other Reactions)

Data Captured*_____ (Onsite/Call back by donor/ Call back by Blood Centre)

Reaction Time* _____ (Pre-Donation/During Donation/After Donation)

Injury* _____ (Yes/No)

Site of Reaction*_____(At Donation Site/ Outside Donation Site)

Donation Completed* _____ (Yes/No)

D) Type of Complications:*

Localised Complications

☐ **A1-Complications mainly characterized by the occurrence of blood outside the vessels**

(a) ☐ Haematoma (bruise)

(b) ☐ Arterial puncture

(c) ☐ Delayed(bleeding/Re-bleeding) ☐ (Within 30 minutes of Donation/After 30 minutes of Donation)

☐ **A2-Complications mainly characterized by pain**

(a) ☐ Nerve injury/irritation

(b) ☐ Other Painful arm

☐ **A3-Localised infection/inflammation along the course of a vein**

(a) ☐ Thrombophlebitis

(b) ☐ Cellulitis

☐ **A4- Allergy (local): Itching and redness at the** ☐ (Venipuncture Site/Medical Adhesive Medicated Tape/Skin Disinfection Area)

☐ **A5-Other major blood vessel injury -Serious conditions needing specialist medical diagnosis and attention**

(a) ☐ Deep venous thrombosis (DVT)

(b) ☐ Arteriovenous fistula

(c) ☐ Compartment syndrome

(d) ☐ Brachial artery pseudoaneurysm

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Generalized Complications

☐ **B1-Vasovagal reactions**

(a) ☐ Generalized Weakness (b) ☐ Anxiety (c) ☐ Dizziness (d) ☐ Nausea
(e) ☐ Vomiting (f) ☐ Pallor(skin and lips) (g) ☐ Rapid Pulse (h) ☐ Convulsions
(i) ☐ Cold extremities (j) ☐ Hyperventilation (k) ☐ Hypotension (l) ☐ Low Vol Pulse
(m) ☐ Feeling of warmth (n) ☐ Tetany (o) ☐ Loss of bowel or bladder control (p) ☐ Cyanosis
(q) ☐ Sweating (r) ☐ Loss of Consciousness(LOC) ☐ (<60 Sec/>60 Sec)

☐ **B2-Allergic reactions (Generalized)**

(a) ☐ Cyanosis (b) ☐ Wheezing (c) ☐ Flushing,swelling of eyes,lips or tongue
(d) ☐ Chest tightness (e) ☐ Cardiac a rrest

☐ **B3-Other serious complications related to blood donation**

(a) ☐ Acute cardiac symptoms(other than myocardial infarction or cardiac arrest) (b) ☐ Myocardial infarction(MI)
(c) ☐ Cardiac arrest (d) ☐ Transient Ischemic attack (TIA) (e) ☐ Death

Apheresis Complication Yes/No

☐ **C-Complications related to apheresis**

(a) ☐ Citrate reaction
☐ tingling/vibrations-lips,fingers ☐ light-headedness ☐ Metallic taste ☐ Muscle twitching
☐ Carpopedal spasm ☐ Shock ☐ Cardiac arrest ☐ Tetany
☐ Prophylactic Calcium given before reaction ☐ (Yes/No)

(b) ☐ Haemolysis during procedure
(c) ☐ Air embolism
(d) ☐ Unable to return red cell(>200ml)

Other Complication

☐ **D-Other Reactions** Please Specify _____

Outcome* ☐ Resolved on donation site ☐ Resolved on follow up ☐ Recovered with Sequelae
☐ Permanently disabled ☐ Death following the adverse reactions Unknown

Imputability* ☐ Definite (Certain) ☐ Probable (Likely) ☐ Possible
☐ Unlikely (Doubtful) ☐ Excluded

Any Other Information or Predisposing Factors for Submitted Reactions: ☐

Reporter..... **Date of Report**.....

Denominator Data about All Donor

Total Donation in the month (of reporting)

☐ **Whole blood** ☐

Volume of donation (Total)* No. of 350 ml bags ☐ No. of 450 ml bags ☐

☐ **Apheresis if apheresis** ☐ RBC ☐ Platelets ☐ Plasma ☐
Plasma+Platelets ☐ Granulocyte ☐ Peripheral Blood Stem Cells ☐
COVID-19 Convalescent Plasma ☐

Gender of Donor(Total)* Male ☐ Female ☐ Other ☐
Type of Donation(Total)* Voluntary ☐ Replacement ☐ Family Donor ☐ Autologous ☐
Donor Types(Total)* First-Time Donors ☐ Repeat Donors ☐
Site of Donation(Total)* Blood Centre ☐ Camp ☐

National Institute of Biologicals
Ministry of Health & Family Welfare, Govt. of India
(National Coordinating Center)
HAEMOVIGILANCE PROGRAMME OF INDIA

Transfusion Reaction Reporting Form (TRRF) For Blood & Blood Components & Plasma Products (Version-2)

* Mandatory Field

(A) Patient Information

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) Transfusion Reaction Details*

Was the patient under anaesthesia during transfusion: Yes/No if Yes type : GA/Spinal/LA

	Temp:	Pulse:	BP:	RR:	SPO2:
Pre-transfusion Vitals:					
Vitals at the time of reaction:					

Please tick mark the relevant signs and symptoms listed below

Generalised		Pain	Respiratory	Renal	Circulatory
☐ Fever	☐ Anxiety	☐ Chest Pain	☐ Dyspnoea	☐ Haematuria	☐ Tachycardia
☐ Chills	☐ Itching (Pruritus)	☐ Abdominal	☐ Wheeze	☐ Haemoglobinuria	☐ Hypertension
☐ Rigors	☐ Edema (Site)____	☐ Back/Flank Pain	☐ Cough	☐ Oliguria	☐ Hypotension
☐ Nausea	☐ Juandice	☐ Infusion Site Pain	☐ Hypoxemia	☐ Other_____	☐ Raised JVP
☐ Urticaria	☐ Other_____	☐ Other_____	☐ Bilateral Infiltrates on Chest X-ray		☐ Arrhythmias
☐ Flushing			☐ Other_____		☐ Other_____
☐ Restlessness					
☐ Vomiting					

Any Other(Specify) : .....

C) Transfusion Product(s) Details*

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
☐	Saline Washed Red Cells										☐ 1st Time
☐	COVID-19 Convalescent Plasma										
☐	Whole blood										
☐	Packed Red blood cells (PRBC)										☐ Repeat 1 to 10
☐	Buffy coat depleted PRBC										
☐	Leucofiltered PRBC										
☐	Random Donor platelets/ pooled										☐ Repeat > 10
☐	Apheresis Platelets										
☐	Fresh Frozen Plasma										
☐	Cryoprecipitate										
☐	Any Other _____										

dd New Plasma Product

Select	Plasma Product	Indication	Date of Administration	Manufacturer	Expiry Date of the Plasma Product	Batch No. / Lot No.	1st Time / Repeat
							☐ 1st Time ☐ Repeat 1 to 10 ☐ Repeat > 10

(D) Investigations

☐ Clerical Checks — Specify Error Found if any: _____

	Investigation	Pre-transfusion sample	Post-transfusion sample
☐	Visual Check		
* ☐	Repeat Blood Grouping	O+ /A+ /B+ /AB+ /O- /A- /B- /AB-	O+ /A+ /B+ /AB+ /O- /A- /B- /AB-
* ☐	Repeat Crossmatch	☐ Compatible ☐ InCompatible ☐ Not Done	☐ Compatible ☐ InCompatible ☐ Not Done
* ☐	Repeat Antibody screen	☐ Negative ☐ Positive ☐ Not Done	☐ Negative ☐ Positive ☐ Not Done
☐	Antibody Identification		
* ☐	Direct antiglobulin test	☐ Negative ☐ Positive ☐ Not Done	☐ Negative ☐ Positive ☐ Not Done
☐	Hemoglobin		
☐	Plasma Hemoglobin		
☐	Urine hemoglobin		
☐	Bilirubin (Total/conjugated)		
☐	Platelet count		
☐	PT/INR		
* ☐	Blood culture of Blood Bag	☐ Negative ☐ Positive ☐ Not Done	Specify Organism if positive_____
* ☐	Blood culture of Patient	☐ Negative ☐ Positive ☐ Not Done Specify Organism if positive_____	☐ Negative ☐ Positive ☐ Not Done Specify Organism if positive_____
☐	Chest X-ray of the patient in case of suspected TRALI		

In case of Non-immune hemolysis (which of the following was the case?)

☐ Hemolysis due to freezing of PRBC Units
☐ Hemolysis due to inappropriate warming of PRBC Units
☐ Hemolysis due to infusion of any other fluid through same BT set. — Specify Fluid:_____
☐ Mechanical damage

In Case of ABO Mismatch (which of the following was the case?)

☐ Wrong Blood in tube
☐ Grouping error
☐ Labelling error
☐ Wrong unit transfused

(E) Nature of Adverse Reaction(s)*

Select	Reaction	Date & Time of Onset of Reaction	Date & Time of Recovery	Outcome
☐	Febrile Non Haemolytic Reactions (FNHTR) 1° C rise in temperature ☐ 2° C rise in temperature ☐ Only Chills & Rigors ☐			☐ 1. Death following the Adverse Reaction(s)
☐	Allergic reaction			
☐	Anaphylaxis			
☐	Immunological Haemolysis due to ABO Incompatibility			
☐	Immunological Haemolysis due to other Allo-Antibodies			☐ 2. Recovered
☐	Non Immunological Haemolysis			
☐	Hypotensive Transfusion Reaction			
☐	Transfusion Related Acute Lung Injury (TRALI) Definite ☐ Possible ☐			
☐	Transfusion Associated Dyspnoea (TAD)			☐ 3. Recovered with Sequelae
☐	Transfusion Associated Circulatory Overload (TACO)			
☐	Transfusion Transmitted Bacterial Infection			
☐	Transfusion Transmitted Parasitic Infection (Malaria)			☐ 4. Unknown
☐	Post Transfusion Purpura			
☐	Transfusion Associated Graft versus Host Disease (TAGvHD)			
☐	Other Reaction (s) _____ _____ Add New			

IMPUTABITLITY ASSESSMENT

(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) Saline Washed Red Cells	
2) COVID-19 Convalescent Plasma	
3) Fresh Frozen Plasma	
4) Whole Blood	
5) Packed Red Blood Cells (PRBC)	
6) Buffy Coat Depleted PRBC	
7) Leucofiltered PRBC	
8) Random Donor Platelets/ Pooled	
9) Apheresis Platelets	
10) Cryoprecipitate	
11) Any Other_____	

How to Enroll your Centre under HvPI

Who can enrol?
Head/ In-charge of Transfusion Medicine Department / Blood Centre

How to enrol?

1) Head / Incharge 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 - 201 309 (U.P.) or via E-mail to NCC at haemovigilance@nib.gov.in

2) NCC verifies the details provided by the centre.

3) After verification, NCC issues the User Id and Password to the Head / Incharge of Transfusion Medicine Department / Blood Centre to access the (a) Haemo-Vigil Software (b) Donor-Vigil Software for onward Submission of Transfusion Reactions Reports and Adverse Blood Donor Reaction Reports to NCC.

Download Enrolment Form from the site:-http://nib.gov.in/media/Annexure7.pdf

How to Report?
Reporting of Adverse Transfusion Reactions via Haemo-Vigil Software & Adverse Blood Donor Reactions in donation via Donor-Vigil Software.

a) Centres enrolled under HvPI receives unique User Id & Password from NCC-HvPI, NIB.
b) User Id & Password is same for both the Softwares i.e. Haemo-Vigil (to report adverse transfusion reactions) & Donor-Vigil (to report adverse donor reactions).
c) Software(s) link is available at NIB website i.e. www.nib.gov.in under the tab of Haemovigilance Programme of India.
d) The adverse reaction reports can be uplinked and submitted online via the above mentioned software(s) to NCC-HvPI, NIB

National Institute of Biologicals- National Coordinating Centre-HvPI

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Email: haemovigilance@nib.gov.in

Tel: 0120-2400072, 0120-2593612 Fax: 0120-2403014,

Toll Free No. 1800-180-2588 [Mon to Fri (9:00 a.m. to 5:30 p.m.)] query related to Haemovigilance Programme of India.

For any other Information/ Suggestions/ Query related to Haemovigilance Programme of India kindly contact: Dr. Akanksha Bisht, Scientist Grade-II & Head-Haemovigilance Programme of India, NIB, NOIDA at: haemovigilance@nib.gov.in