सत्यमेव जयते

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

Azadi Ka Amrit Mahotsav

HAEMOVIGILANCE NEWSLETTER

Haemovigilance Programme of India

Dr. Mansukh Mandaviya, Union Health Minister, Ministry of Health & Family Welfare, Government of India was the chief guest for the conference & addressed the First National Conference on Haemovigilance organized by National Institute of Biologicals (NIB), NOIDA From 09th-11th December, 2021 via (Online Mode)

Haemovigilance Newsletter Vol. No. 10 Issue 19, January-June, 2022

03 Haemovigilance Programme of India-Milestones

04 Online Webinar/ CME under HvPI

07 First National Conference on Haemovigilance

"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 Products' Administration Practices"

Table of Contents

Haemovigilance Programme of India-Milestones.....3
Online webinar/CME under Haemovigilance Programme.....4
Institutional representation under HvPI.....5
First National Conference on Haemovigilance.....7
New Members Enrolled under Haemovigilance Programme of India.....10
How to Enroll your Centre under HvPI.....15

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 Mandate' s 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 data to 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 as per the direction issued.

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

Online Webinar/CME under Haemovigilance Programme of India (HvPI)

1. Federation of Blood Donor Organizations of India in association with National Institute of Biologicals supported by Mani Trust Kalimpong organized a National Webinar on Voluntary Blood Donation (VBDS), Haemovigilance Programme on 24th July, 2021 (Online Mode).

❖ About **60 participants** from **19 states** all across the country attended the said online webinar.

2. An online webinar for participating centres on Validation of Donor Adverse Reaction Severity Grading Tool (SGT) study was organized by Haemovigilance Division of National Institute of Biologicals on 27th July, 2021.

❖ About 60 officials from blood centres of different part of the country participated in the said webinar.

3. Virtual Continuing Medical Education (CME) on Haemovigilance Programme of India was organized by National Institute of Biologicals in collaboration with CDSCO, East Zone Office, Ministry of Health & Family Welfare Government of India on 16th September, 2021.

Objective of the CME was to enrol & encourage reporting by the blood centres under HvPI in the respective states/ UTs

Salient Features

- A Total of 1258 registered delegates attended this virtual CME.
- The Director NIB gave welcome address which was followed by technical sessions.
- The Opening Remarks & Presentation on New G.S.R 166 (E) on Blood Centres and Its Importance in Safe Blood Transfusion Practices.

Lectures :

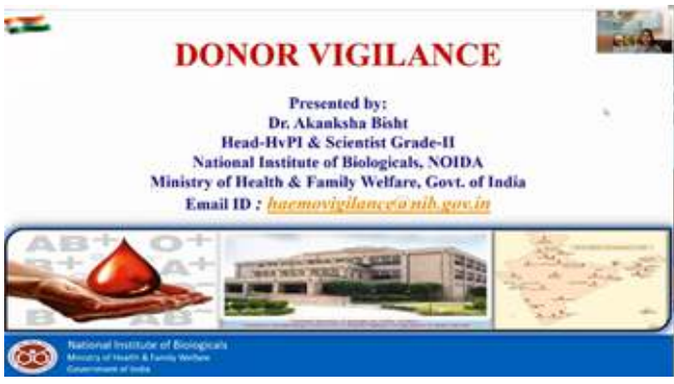
- Update on Haemovigilance Programme of India (HvPI) including Haemovigilance Software Demonstration.
- Classification, Definition, Severity of Blood Transfusion Reactions & Scope in HvPI.
- Blood Donor Haemovigilance under HvPI Scope, Terms, Definitions.
- Analysis of Haemovigilance Data & Recommendations.
- Analysis of Donor Data & Recommendations followed by Panel Discussion & Question Answer Session.

Institutional representation under Haemovigilance Programme of India (HvPI)

1. Presentation on the topic of Haemovigilance Programme of India by Head HvPI on 14th August, 2021 in National Workshop on Clinical Pharmacology and Therapeutics (NWCPT) organised by Department of Pharmacology, Postgraduate Institute of Medical Education & Research, Chandigarh held on 09th - 14th August, 2021 via online mode.

2. Head- HvPI virtually attended inaugural ceremony of National Pharmacovigilance Week from 17th-23rd September, 2021 held on 17th September, 2021 at National Coordination Centre-Pharmacovigilance Programme of India, Indian Pharmacopoeia Commission, Ghaziabad.

3. Talk on "DONOR VIGILANCE" delivered by Head HvPI in the World Health Organization, South-East Asia Region Training Series "Towards 100 percent Voluntary Blood Donation - Understanding Challenges and Barriers in the South-East Asia" organized on virtual platform by the Department of Transfusion Medicine, PGIMER, Chandigarh, on 08th October, 2021.



Blood Cell-National Health Mission & National Institute of Biologicals Organized "Two days Online and three days' residential hands on Training Programme on Training of Trainers for Strengthening of Blood Services" For Blood Bank Officials

S.No.	State	Date of training programmes
1.	Haryana	07th, 14th, 28th July, 2021 & 4th August, 2021
2.	Chhattisgarh	27th October, 2021 & 17th November, 2021

- One session during these training programmes were kept for Haemovigilance Programme of India.
- About 68 blood centres' officials & lab technicians of Haryana & Chhattisgarh participated in these said training programmes.
- During the HvPI session participants were apprised about Haemovigilance Programme of India followed by hands on training.

Haryana

Chhattisgarh

National Skill Development & Hands-on Training Programme on Quality Control of Biologicals for M.Sc. Biotechnology Students

The students from Vinoba Bhave University, Hazaribag, Jharkhand were apprised about Haemovigilance Programme of India, followed by Hands-on training on Haemovigilance Software during this National Skill Development & Hands-on Training Programme on Quality Control of Biologicals from 22nd November to 03rd December, 2021.

First National Conference on Haemovigilance organized by NIB, from 09th – 11th December, 2021 (Online Mode)

Haemovigilance Programme of India entered into 10th year on 10th December, 2021 & on this occasion the First National Conference on Haemovigilance via online mode was organized by NIB for 3 days from 9th-11th December, 2021.

The conference was organized with the following objectives:

- To create awareness about the HvPI.
- To encourage reporting under HvPI.
- To sensitize and train the Blood Centre officials w.r.t. guidelines, definitions.
- Improving quality of data submitted by the centres.
- To promote voluntary blood donations & promote safe blood donations.
- To strengthen blood services in the country.

Inaugural Ceremony: Dr. Mansukh Mandaviya, Union Health Minister, Ministry of Health & Family Welfare, Government of India was the chief guest for the conference & addressed the fraternity about utmost significance of Haemovigilance Program and urged for 100% enrollment by the Blood Centres to NIB so as to report the adverse reactions on Blood Donations & Transfusions. He also stressed upon that NIB along with other stakeholders should design some training module in medical course on Haemovigilance so, that to inculcate the culture of understanding reporting & preventing the occurrence & recurrence of adverse reactions and aid to strengthening blood safety in the country.

The other guests who were the part of the inaugural ceremony & addressed the gathering were Shri. Rajesh Bhushan ji, Secretary, Ministry of Health & Family Welfare, Government of India; Dr. Mandeep Kumar Bhandari, Joint Secretary (R), Ministry of Health & Family Welfare, Government of India; Dr. V. G. Somani, Drugs Controller General (I), CDSCO, New Delhi and Dr. Rajeev Singh Raghuvanshi , Secretary-cum-Scientific Director, IPC, Ghaziabad.

Dr. Anup Anvikar, Director NIB welcomed the dignitaries & the participants.

Salient Features of the First National Conference on Haemovigilance

- A well-structured 3 days program was organized which includes technical sessions on National Haemovigilance Programme, Recipient Haemovigilance, Donor Haemovigilance, Blood Safety with multiple discussions, debates and competitions.
- The conference was conducted virtually through online platform.
- A total of 47 experts which included 13 Chairpersons, 20 speakers, 8 selected abstract presenters & 6 Jury Members (for reviewing the abstracts submitted) actively participated for the said conference from all across the country.
- An overwhelming response to this conference is evident from fact that about 2763 number of registrations were done for the conference & about 70 abstracts were submitted for the conference. Apart from online platform many participants participated the conference through the live streaming on you tube channel of the First National Conference on Haemovigilance.

❖ **The best Abstracts selected for the oral presentations during the conference:-**

S. No.	Donor Category Selected Abstracts	Authors Name	Institute Name
1.	Study of Plateletpheresis Donor Hemovigilance and Materialovigilance in a Quaternary Care Centre in South India.	Deepti Sachan, Deepthi Krishna G, Kuralarasi Priyadarshini, Sheik Barith	Dr. Rela Institute & Medical Centre, Chennai
2.	Analysis of frequency and risk factors of vaso-vagal reaction in whole blood donors.	Radheshyam Meher, Gopal K Patidar, Rahul Chaurasia, Hem Chandra Pandey, Anzali Hazarika, Vidushi	AIIMS, New Delhi
3.	Effective implementation of 'Donor Safety Culture' strategies to monitor and minimize Donor Adverse Reactions in a tertiary care hospital Blood Centre.	Dr Lincy Jacob, Dr Akshata Parab, Jayashree Nawar, Manish Yadav	Dr L H Hiranandani Hospital, Powai, Mumbai
4.	Experience of donor adverse reactions at Regional Blood Transfusion Centre.	Dr. Abhay Jhaveri Dr. Sumit Bharadva	Surat Raktadan Kendra and Research Centre, Gujarat

S. No.	Recipient Category Selected Abstracts	Authors Name	Institute Name
1.	Posterior Reversible Encephalopathy Syndrome (PRES).	Preeti Budania, Saket Yadav, Madhu Mathur, Priya Marwah	Mahatma Gandhi Hospital, Jaipur
2.	Are we missing reverse-TRALI?	Debapriya Basu, Suvro Sankha Dutta, Sabita Basu	Tata Medical Center, Kolkata
3.	Delayed Hemolytic Transfusion Reaction with Compatible Blood– An Interesting Case Report.	Deeksha Singh, Sangeeta Pahuja, Geetika Sharma, Ram Vilash	Lady Hardinge Medical College & associated hospitals, New Delhi
4.	Is crossmatch compatible blood enough to prevent Hemolysis? Two eye-opening incidents reported at a tertiary care center in Eastern India.	N Datta, S Mukherjee, S Prakash, A Sahu, N Das, A Bose	AIIMS, Bhubaneswar

A glance from the First National Conference on Haemovigilance showing various Chairpersons, Speakers & Jury Members.

FIRST DAY (09th December, 2021)

SECOND DAY (10th December, 2021)

THIRD DAY (11th December, 2021)

JURY MEMBERS

Meeting

- Meeting of the Experts to Analyse Donor Data Submitted via Donor- Vigil Software for year 2018-2019 under National Blood Donor Vigilance Programme (NBDVP) was held on 29th- 30th September, 2021 from 10:30 am to 05:30 pm at Haemovigilance Division, Administrative Block, 2nd Floor, National Institute of Biologicals (NIB).

New Members Enrolled under Haemovigilance Programme of India (59)

Andhra Pradesh

1. Blood Centre, All India Institute of Medical Sciences, Mangalagiri, Guntur
2. Doctors Blood Bank, Vijaywada, Krishna

Assam

1. Dr. B. Borooah Cancer Institute, Dist- Kamrup (M)

Bihar

1. Prathama Blood Centre, Patna

Chhattisgarh

1. District Hospital Blood Bank, Balod

Gujarat

1. Sardar Vallabhbhai Patel Blood Bank, Surat

Haryana

1. Regional Blood Transfusion Centre, Karnal

Himachal Pradesh

1. Bhagwan Buddha Charitable Blood Centre, Kangra

Jharkhand

1. Raj Hospitals Blood Centre, Ranchi
2. Maa Ram Pyari Super Speciality Hospital Blood Centre, Ranchi

Karnataka

1. Manipal Hospital Jayanagar, Bangalore
2. Sagar Blood Centre, (A unit of Sagar Health Care and Diagnostic Services Pvt. Ltd.), Bangalore
3. Aster CMI Hospital Blood Centre, Bangalore
4. Manipal Hospital, Whitefield Bangalore
5. ESIC Medical College & PGIMSR, Rajajinagar, Bangalore
6. Ranebennuru Blood Bank, Haveri Dist.

Kerala

1. Almas Hospital Blood Bank, Kottakkal
2. Al-Azhar Medical College Super Speciality Hospital, Iddukki
3. Muthoot Health Care Private Limited, Kozhencherry
4. Aster Medcity Hospital, Blood Centre, Kochi
5. Indo American Hospital, Kottayam
6. Gimcare Hospital Blood Centre, Kannur
7. Mar Sleeva Medicity Hospital, Koottayam
8. Sunrise Institute of Medical Sciences, Kochi
9. High Range Hospital, Munnar
10. Polakulath Narayanan Renai Medicity, Kochi
11. Avitis Super Speciality Hospitals Pvt. Ltd., Palakkad

Ladakh

1. Distt. Hospital, Kargil
2. 153 General Hospital, Leh

Maharashtra

1. Rao Nursing Home, Pune
2. Riddhivinayak Hospital Services Public Charitable Trust, Palghar
3. M/s MIMER Medical College and Dr. Bhausaheb Sardesai Talegaon Rural Hospitals Garware Blood Bank, Pune
4. KEM Hospital, Pune Mathurabai Vashistha Blood Centre, Pune
5. Tata Memorial Hospital, Mumbai
6. Jain Social Federation's AnandrishiJi Blood Centre, Ahmednagar

Odisha

1. Saheed Laxman Nayak Medical College & Hospital, Koraput

Punjab

1. Grecian Super Speciality Hospital, Mohali

Rajasthan

1. Nahar Blood Centre, Bhinmal

Tamil Nadu

1. K.Govindasamy Naidu Medical Trust- K. G Hospital Blood Bank, Coimbatore
2. Government Medical College Hospital, Virudhunagar
3. MIOT Hospitals Blood Centre, Chennai
4. Annai Teresa Blood Bank & Apheresis Centre, Chennai
5. Kumaran Hospital Blood Bank, Chennai
6. Chennai Blood Centre, Chennai
7. VS Hospitals, Chennai
8. International Centre For Cardio Thoracic and Vascular Diseases (A unit of Frontier Lifeline Hospital), Chennai
9. Meenakshi Mission Hospital & Research Centre-Regional Blood Transfusion Centre, Madurai

Telangana

1. KIMS Hospital Blood Bank, Hyderabad
2. Thumbay Hospital Blood Centre, Hyderabad

Uttar Pradesh

1. Prakash Hospital Blood Bank, NOIDA
2. Prayag Hospital & Research Centre Pvt. Ltd., NOIDA
3. Heritage Hospitals Blood Centre, Varanasi
4. Bhagwan Buddha Charitable Blood Bank, Vasundhara, Ghaziabad

West Bengal

1. Medica Superspecialty Hospital Blood Bank (A Unit of Medical Hospital Pvt. Ltd.), Kolkata
2. Siliguri Terai Lions Charitable Trust Blood Bank, Siliguri
3. North Bengal Medical College and Hospital Blood Centre, Darjeeling
4. Maharaja Jitendra Narayan Medical College and Hospital, Cooch Behar
5. Ashok Laboratory Centre for Transfusion Medicine and Clinical Research, Kolkata
6. Rashmi Blood Centre, A Unit of S. S. S. S, Bardhaman

सत्यमेव जयते

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 *: _____

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

Sex *_____ (Male/Female/Other)

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

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

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

Site of Donation*_____ (Blood Centre/Camp)

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

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* _____

Volume Collected (ml)* _____

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

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_____

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

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

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

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

Venipuncture Site* _____(Left/Right/Both)

Injury* _____ (Yes/No)

Venipuncture* _____(1/2/>2)

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

NATIONAL BLOOD DONOR VIGILANCE PROGRAMME

(Haemovigilance Programme of India)

Adverse Blood Donor Reaction Reporting Form

Version 2

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 ☐					

TRANSFUSION REACTION REPORTING FORM (TRRF VERSION-2)

सत्यमेव जयते

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

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

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_____
☐ Restlessness					
☐ Vomiting			☐ Other_____		

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)										
☐	Buffy coat depleted PRBC										☐ Repeat 1 to 10
☐	Leucofiltered PRBC										
☐	Random Donor platelets/ pooled										
☐	Apheresis Platelets										☐ Repeat > 10
☐	Fresh Frozen Plasma										
☐	Cryoprecipitate										
☐	Any Other _____										

Add 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

TRANSFUSION REACTION REPORTING FORM (TRRF VERSION-2)

(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			
☐	Non Immunological Haemolysis			☐ 2. Recovered
☐	Hypotensive Transfusion Reaction			
☐	Transfusion Related Acute Lung Injury (TRALI) Definite ☐ Possible ☐			
☐	Transfusion Associated Dyspnoea (TAD)			
☐	Transfusion Associated Circulatory Overload (TACO)			
☐	Transfusion Transmitted Bacterial Infection			☐ 3. Recovered with Sequelae
☐	Transfusion Transmitted Parasitic Infection (Malaria)			
☐	Post Transfusion Purpura			
☐	Transfusion Associated Graft versus Host Disease (TAGvHD)			☐ 4. Unknown
☐	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 website:- 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

ACKNOWLEDGEMENT

NCC-HvPI acknowledges the contribution by Ms. Ruchi Rao (Technical Consultant), Mr. Akash Chaudhary (Bench Biologist),Ms.Sangeeta Yadav & Mr. Sushant Panchal (Data Entry Operators) of Haemovigilance Division, NIB for their contribution in bringing out this issue of HvPI Newsletter.

National Institute of Biologicals

Ministry of Health and Family Welfare, Government of India
A-32, Sector-62, Near NH-24, Noida - 201309, Uttar Pradesh
NIB website: **http://nib.gov.in/**
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**

Designed & Printed by : www.censer.in (Ph) 9810213218