सत्यमेव जयते

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

HAEMOVIGILANCE NEWSLETTER

Haemovigilance Programme of India

Virtual Continuing Medical Educations (CMEs) organized by National Institute of Biologicals (NIB) in collaboration with Drugs Control Departments of Kerala, Puducherry, Lakshadweep, Tamil Nadu & CDSCO, South Zone Office

Haemovigilance
Newsletter Vol. No. 9
Issue 18, July-December, 2021

"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

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

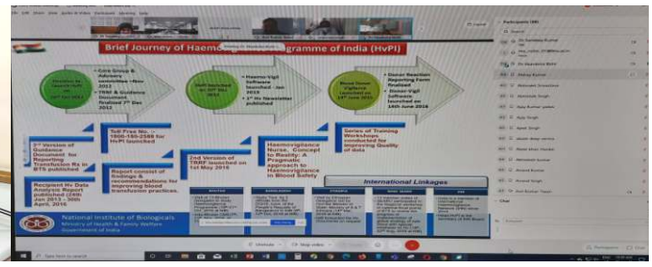
DCG (I) issued an office memorandum dated 4th December, 2015 w.r.t. enrolment of all licensed blood centres under HvPI. These licensed blood centres are required to obtain their user ID and password from NIB to uplink their adverse transfusion data to Haemo-Vigil software under HvPI.

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.

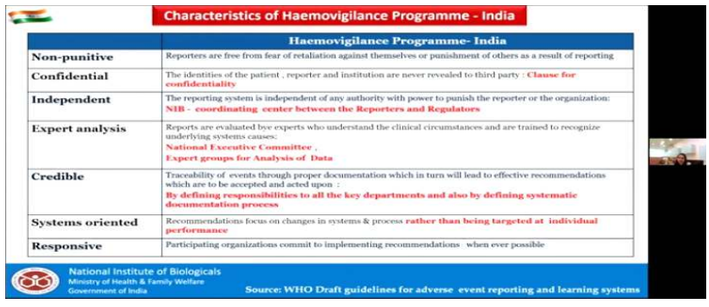
Institutional representation under Haemovigilance Programme of India (HvPI)

1. Presentation on "Haemovigilance" by Head HvPI during Virtual Training Programme for Blood Bank Lab Technicians & BCSU organised by Blood Bank Sir Sunder Lal Hospital, Institute of Medical Sciences Banaras Hindu University, Varanasi in collaboration with Uttar Pradesh State AIDS Control Society (UPSACS) held on 18th -22nd January, 2021.

2. Talk on "Keynote Address: Haemovigilance Programme of India" delivered by Head HvPI in CME on Haemovigilance organized by Department of Pathology, Government Institute of Medical Sciences, Greater Noida held on 06.04.2021.

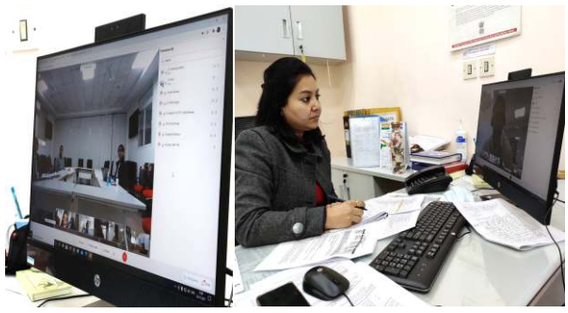

3. Presentation on "National Donor Vigilance Programme of India: An Update" by Head HvPI in an online educational event on the occasion of World Blood Donor Day 2021 organized by The Department of Transfusion Medicine at Super Speciality Paediatric Hospital and Post Graduate Teaching Institute (SSPH PGTI), Noida, Uttar Pradesh with National Health Mission (NHM) Blood Cell Uttar Pradesh held on 12th June, 2021.



4. Talk on "COVID-19 & Blood Donor Vigilance & Haemovigilance Programme" by Head HvPI in the webinar on the eve of World Blood Donor Day (WBDD) 2021 organized by member organization of Federation of Indian Blood Donors Organizations (FIBDO) held on 13th June, 2021.

Meetings of Expert Group of Haemovigilance Programme of India

Expert Group Meetings:-



28.01.2021

03.02.2021

17.02.2021-18.02.2021

30.06.2021

National Health Mission (NHM)

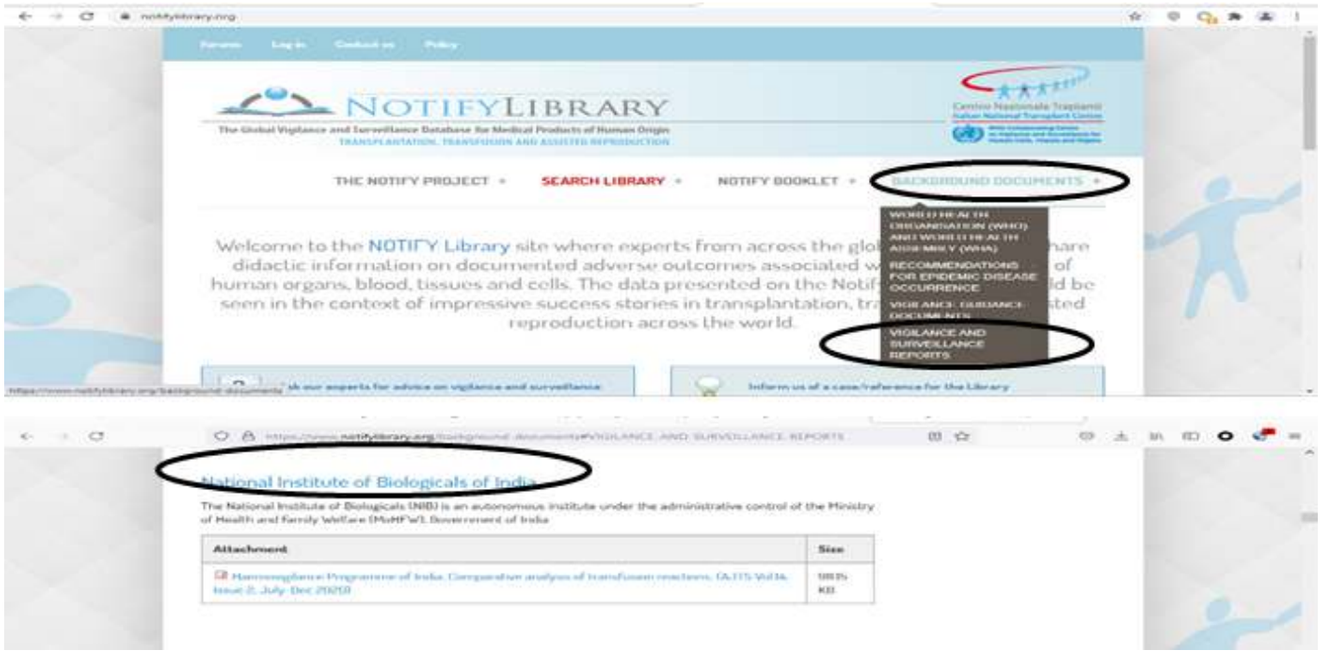
- Blood Cell-National Health Mission & National Institute of Biologicals Organized "Two days online and three days' residential hands on Training Programme on Training of Trainers for Strengthening of Blood Services" For Blood Centres Officials (State of Haryana) w.e.f. 18th March 2021.
  - ❖ One session during this training programme was kept for Haemovigilance Programme of India on 24th March, 2021 & 07th April, 2021.
  - ❖ About 20 blood centres' officials & lab technicians of Haryana participated in these said training programmes.
  - ❖ During the HvPI session participants were apprised about Haemovigilance Programme of India followed by hands on training.

NHM First batch on 24.03.2021

NHM Second batch on 07.04.2021

Global Recognition

Global Recognition:- A published report of HvPI titled Haemovigilance Programme of India: Comparative analysis of transfusion reactions reported over a 5-year period through two reporting formats and key recommendations for blood safety" has been accepted and posted in the WHO-NOTIFYLIBRARY wherein our institute name along with the aforesaid article is available on this website (**www.notifylibrary.org**) under the tab: Background Documents-Vigilance and Surveillance Reports.



IHN Teleconference

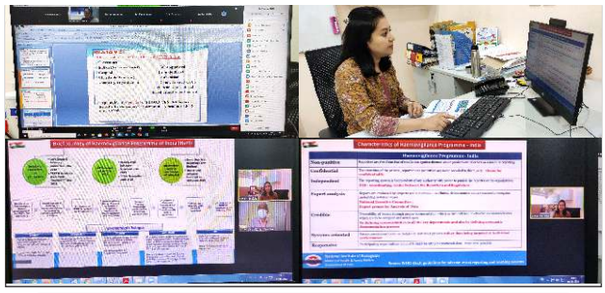
1. Head- HvPI & Secretary of International Haemovigilance Network (IHN) attended International Haemovigilance Network (IHN) Virtual Mini-conference: Haemovigilance in times of Covid-19 on 18th March, 2021 at 6:30 pm Indian Standard Time
2. Head- HvPI & Secretary of International Haemovigilance Network (IHN) attended teleconference of IHN Board on 16th June, 2021 at 7:30 PM of Indian Standard Time.

State wise Virtual CMEs/Trainings on Haemovigilance Programme of India organized by NIB

Objective

The objective of these CMEs were to sensitize the blood centres' officials of reporting centres under HvPI w.r.t. latest updates, definitions, guidelines and reporting of adverse reactions with special emphasis to improve the quality of data being submitted under HvPI. These CMEs are conducted regularly from time to time.

- Virtual CMEs on Haemovigilance Programme of India Organized by National Institute of Biologicals, Ministry of Health & Family Welfare, Government of India in collaboration with office of the Director of Drugs Control, Tamil Nadu & CDSCO, South Zone Office :-
  (a) CME for first batch held on 09.03.2021.
  (b) CME for second batch held on 11.03.2021.



CME on 09.03.2021

CME on 11.03.2021

- A Virtual Continuing Medical Education (CME) on Haemovigilance Programme of India Organized by National Institute of Biologicals, Ministry of Health & Family Welfare, Government of India in collaboration with Drugs Control Departments of Kerala, Puducherry, Lakshadweep & CDSCO, South Zone Office held on 07.04.2021

CME on 07.04.2021

About 421 participants participated above mentioned virtual CMEs.

Salient features of the CMEs

- Update on Haemovigilance Programme of India (HvPI) including Software Demonstration.
- Regulatory Requirements for functioning and operation of Blood Centres.
- Recipient Haemovigilance under HvPI Scope, Terms, Definitions.
- Blood Donor Haemovigilance under HvPI Scope, Terms, Definitions.
- Analysis of Haemovigilance Data & Recommendations.
- Panel Discussion & Question Answer Session.

Article Published under National Blood Donor Vigilance Programme (NBDVP)

National Blood Donor Vigilance Programme of India: Analysis of donor adverse reactions reported during the initial 2 years of implementation (2016 and 2017)

The Haemovigilance Programme of India (HvPI) at National level was launched on 10th December 2012 by National Institute of Biologicals (NIB), NOIDA under Ministry of Health and Family Welfare, Government of India as the National Coordinating Centre (NCC). The task of the NCC was to collect and analyze the reports of adverse reactions due to blood transfusions. In 2015, the National Blood Donor Vigilance Programme of India was also launched as the part of the HvPI to collect and analyze the reports of adverse reactions due to blood donations. In this report, we discuss the analysis of the blood donor adverse reactions (DARs) reported during the first 2 years of implementation to the national programme.

DAR reporting form prepared and approved by the National Executive Committee of the Haemovigilance Programme of India was used to capture the data by the blood centers and submitted to Donor-Vigil software prepared and hosted by the official website of NCC. Data reported for the years 2016 and 2017 were reviewed, analyzed, and validated by independent transfusion medicine experts.

During this period, a total of 19,98,101 donations (denominator data) were reported, in which 1,622,600 (80.9%) were valid. A total of 6091 DARs were reported, out of which 3980 (65.35%) were found valid (numerator data). Only validated numerator and denominator data were included in the analysis. The terms and definitions for reporting used were adopted from the Standard for Surveillance of Complications related to blood donation prepared by the International Society of Blood Transfusion (ISBT) in collaboration with the International Haemovigilance Network (IHN) and American Association of Blood Banks (AABB).

Generalized DARs were the most common type of DARs reported (83.7%), followed by “others” type (7.7%), localized (7.6%), allergic (0.4%), and complications related to apheresis (0.4%). The overall DAR rate was 2.45/1000 blood donations, which was higher in apheresis donations (3.07/1000) as compared to whole blood donations (2.39/1000). The DARs rates were higher in females (3.5/1000) compared to male donors (2.3/1000) and in the first time (2.5/1000) compared to repeat donors (2.15/1000).

In this report, we concluded that younger age, first time, and female donors are more prone to DARs as compared to older age, repeat, and male donors. During the analysis of the data, we found some limitations, which can be improved by upgrading the reporting form and conducting regular continuing medical education (CMEs) of participant blood centers.


Original Article

National blood donor vigilance programme of India: Analysis of donor adverse reactions reported during initial 2 years of implementation (2016 and 2017)

An article was published in Asian Journal of Transfusion Science Volume 15, Issue 1, January-June 2021 titled Haemovigilance Programme of India: National Blood Donor Vigilance Programme of India: Analysis of donor adverse reactions reported during the initial 2 years of implementation (2016 and 2017) and can be accessed from **http//www.ajts.org** & also from **https://nib.gov.in**

New Members Enrolled under Haemovigilance Programme of India (51)

Andhra Pradesh
1. Icon Krishi Blood Bank, Visakhapatnam
2. Manipal Hospitals Blood Bank, Vijaywada

Haryana
1. CMC, Blood Bank (Central Medical Centre Blood Bank), Hisar
2. Aashirwad Blood Bank, (C/o M/s R. J. Super Speciality Hospital), Bahadurgarh
3. Noble Blood Centre, Kaithal
4. Rotary Blood Centre, Gurugram

Jammu & Kashmir
1. Govt Gandhi Nagar Hospital, Jammu

Karnataka
1. Dr. Chandramma Dayananda Sagar Institute of Medical Education and Research, Ramanagara Dt.
2. Columbia Asia Hospital Blood Centre, Bangalore
3. Sparsh Hospital Blood Center, Bengaluru
4. M/s Sagar Hospital (Unit of Sagar Health Care and Diagnostic Service Pvt Ltd), Bengaluru

Kerala
1. EMS Memorial Co-Operative Hospital & Research Centre, Kozhikode
2. Apollo Adlux Hospital, Kochi, Ernaculam District
3. Christian Mission Hospital, Pandalam
4. Korambayil Hospital & Diagnostic Centre (P) Ltd., Malappuram
5. Karuna Medical College Hospital Blood Bank, Palakkad
6. KIMS Al-Shifa Healthcare Private Limited, Malapurram Dist.

Madhya Pradesh
1. Jupiter Hospital Projects Pvt. Ltd., Indore

Maharashtra
1. Nowrosjee Wadia Maternity Hospital, Mumbai
2. P.S.M. Prakash Institute of Medical Science, Prakash Hospital and Research Centre, Prakash Blood Centre, Dist-Sangli
3. Akshay Blood Centre, Solapur
4. HCG Manavata Cancer Centre, UNIT II, Nasik

Meghalaya
1. Dr H Gordon Roberts Hospital Blood Centre, Shillong

New Delhi
1. Lok Nayak Hospital, Delhi

Punjab
1. Prolife Blood Bank Inside Prolife Hospitals, Ludhiana
2. Sri Guru Ram Das Charitable Hospital, Amritsar
3. Amandeep Hospital Blood Bank, Amritsar
4. Amandeep Hospital, Pathankot
5. Red-Aid Blood Centre, Ludhiana
6. Amandeep Medicity Blood Bank, Amritsar

Rajasthan
1. NIMS Medical College & Hospital, Jaipur

Tamil Nadu
1. Blood Bank, Government Sivagangai Medical College Hospital, Sivaganga
2. Naruvi Hospitals Blood Bank, Vellore
3. Athma Blood Centre, Chennai
4. Blood Bank, GRH, Madurai, Department of Immunohaematology and Blood Transfusion, Madurai
5. Karpaga Vinayaga Institute of Medical Science and Research Centre, Palayanoor, Madhuranthagam
6. Sri Muthukumaran Medical College Hospital And Research Institute, Chennai
7. Red Cross Blood Centre Tamilnadu Branch, Chennai

Telangana
1. Apollo Hospitals Blood Centre, Hyderabad
2. Apollo Reach Hospitals, Apollo Blood Bank, Karim Nagar
3. Apollo DRDO Hospital Blood Centre, Hyderabad
4. Apollo Hospital Blood Bank, Secunderabad
5. Aware Gleneagles Global Hospitals Blood Centre, Saroornagar, R.R.(Dist)

Uttar Pradesh
1. Dev Nandini Blood Centre, Hapur
2. Chandra Laxmi Hospital Blood Bank, Vaishali, Ghazibad
3. SBD Distt. Hospital, Saharanpur
4. M/s Kailash Hospital & Heart Institute, NOIDA
5. Mahamana Pandit Madan Mohan Malviya Cancer Centre, Varanasi
6. Clear Medi Hospital and Cancer Centre, Vasundhara, Ghaziabad
7. G. S. Medical College and Hospital, Hapur
8. Heritage Institute of Medical Sciences, Varanasi

Introduction of Bilingual Centre Enrolment Form for the Blood Centre

भारतीय रक्तसतर्कता कार्यक्रम

Haemovigilance Programme of India

केंद्र नामांकन प्रपत्र

Centre Enrolment Form

मेडिकल कॉलेज/संस्थान/हस्पताल/रक्तकेंद्र का नाम Name of the Medical College/Institute/Hospital/Blood Centre	
मेडिकल कॉलेज/संस्थान/ हस्पताल/रक्तकेंद्र का पता Address of the Medical College/Institute/Hospital/Blood Centre	
केंद्र की मान्यता/ पहचान जैसे:- Centre recognized as:- क) हस्पताल आधारित (सरकारी) रक्तकेंद्र a) Hospital Based (Government) Blood Centre ख) हस्पताल आधारित (प्राइवेट/ धर्मार्थ/ न्यास) रक्तकेंद्र b) Hospital Based (Private/Charitable/Trust) Blood Centre ग) एकल आधार पर रक्तकेंद्र c) Standalone Blood Centre	
अनुज्ञापत्र संख्या (रक्तकेंद्र) License Number (Blood Centre)	
सम्बंधित नर्सिंग होम/ हस्पताल का नाम एवं पता जिनको आपका रक्त केंद्र रक्त इकाइयों को जारी करता है। (यदि कोई हो) Name and address of the nursing homes/hospital/to which your blood Centre issues blood units (if any)	
नाम (प्रमुख/ प्रभारी-आधान विभाग/ रक्तकेंद्र) Name (Head/Incharge of Transfusion Medicine Department/Blood Centre)	
संपर्क नं. Contact Number	
ईमेल पता Email Address	

हस्ताक्षर एवं मोहर

(प्रमुख/ प्रभारी-आधान विभाग/ रक्तकेंद्र)

Signature & Stamp

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

कृपया ध्यान दें: विधिवत भरा नामांकन फॉर्म राष्ट्रीय समन्वय केंद्र - एचवीपीआई, एनआईबी, नोएडा पर ई-मेल haemovigilance@nib.gov.in के माध्यम से भेजा जा सकता है या डाक द्वारा नीचे बताए पते पर भेजा जा सकता है : नेशनल इंस्टीट्यूट ऑफ बायोलॉजिकलस, ए -32, सेक्टर -62, नोएडा, उत्तर प्रदेश -201309

* 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 -201309

दस्तावेज़ का नाम: एचवीपीआई नामांकन फॉर्म Document Name: HvPI Enrolment Form	
वर्ष से प्रभावी: 2021 Effective from Year: 2021	वैधता: अगले संशोधन तक Validity: Till further addition

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 DonationHr_____ 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

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

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: _____

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

राष्ट्रीय जैविक संस्थान NATIONAL INSTITUTE OF BIOLOGICALS

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_____
☐ 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)										☐ Repeat 1 to 10
☐	Buffy coat depleted PRBC										
☐	Leucofiltered PRBC										
☐	Random Donor platelets/ pooled										☐ Repeat > 10
☐	Apheresis Platelets										
☐	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 & Mr. Rayaz Ahmad Bhat (Bench Biologists),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