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

HAEMOVIGILANCE NEWSLETTER

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A CONTINUING MEDICAL EDUCATION (CME) ON HAEMOVIGILANCE PROGRAMME OF INDIA ORGANISED BY SINDHU HOSPITALS HYDERABAD IN COLLABORATION WITH NATIONAL INSTITUTE OF BIOLOGICALS (NIB), NOIDA ON 07th MARCH, 2025

"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 & 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 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 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.

COLLABORATIVE CME BY NATIONAL INSTITUTE OF BIOLOGICALS (NIB) TO CREATE AWARENESS ABOUT HAEMOVIGILANCE PROGRAMME OF INDIA

Continuing Medical Education (CME) on Haemovigilance Programme of India at Sindhu Hospitals, HITEC city Hyderabad on 07th March 2025

- A Continuing Medical Education (CME) on Haemovigilance Programme of India organised by Sindhu Hospitals Hyderabad in collaboration with National Institute of Biologicals (NIB), NOIDA on 07th March 2025 at Sindhu Hospitals, HITEC city Hyderabad.
- The event featured a keynote address by the Head of HvPI, who delivered an insightful talk on "Haemovigilance Programme of India – An Overview & Update. Dr. A. Ram Kishan Drug Control Administration, Hyderabad gave an insight about Regulation of Blood Centre in India. Dr. Gopal Kumar Patidar (AIIMS, New Delhi) shared insights on donor vigilance and led a case discussion on donor reactions. Other key sessions included rational blood use by Dr. Anil Aribandi, Administration and Safe bedside transfusion practices by Dr. Tejasree, acute and delayed transfusion reactions by Dr. Irfana Nikhat and Dr. B. Shanthi respectively, followed by a case-based discussion on transfusion reactions. The CME concluded with a panel discussion featuring the Head HvPI and Dr. Rajesh Sharma, Scientist-III from NIB, encouraging interactive learning and collaboration among participants.
- The primary objective of the CME was to educate healthcare professionals about the importance of haemovigilance and to promote wider participation in the programme..
- The event witnessed an enthusiastic turnout of around 350 participants, including blood centre officials, clinicians, senior nursing officers, nursing officers, and laboratory technicians. The session facilitated knowledge sharing and strengthened the commitment to haemovigilance in clinical practice.

INSTITUTIONAL REPRESENTATION UNDER HAEMOVIGILANCE PROGRAMME OF INDIA (HvPI)

1. National Workshop on Voluntary Blood Donation – Ahmedabad, Gujarat

- The Head of HvPI was invited as a Guest Speaker at the National Workshop on Voluntary Blood Donation, jointly organized by the Federation of Blood Donor Organizations of India, Indian Red Cross Society – Gujarat State Branch, and the Ahmedabad Red Cross Blood Centre.

  The workshop was held on 12th & 13th January 2025 at the Ahmedabad Red Cross Shatabdi Bhavan, Ahmedabad, Gujarat.

- On 12th January 2025, the Head of HvPI delivered a presentation on the topic:

  "Role of NIB in Haemovigilance and Donorvigilance Programme in India," highlighting the ongoing efforts and achievements in enhancing donor safety and post-donation surveillance across the country.

2. 24th Residential Training Programme on Good Clinical Practices and Pharmacovigilance – New Delhi

- On 21st February 2025, the Head of HvPI presented a session titled "**Overview of the Haemovigilance**" during the 24th Residential Training Programme on Good Clinical Practices and Pharmacovigilance. The training was organized for officials from CDSCO, IPC, and various State Drug Control Departments at the National Institute of Health and Family Welfare (NIHFW), Baba Gang Nath Marg, Munirka, New Delhi.

- The session underscored the vital role of haemovigilance in enhancing transfusion safety.

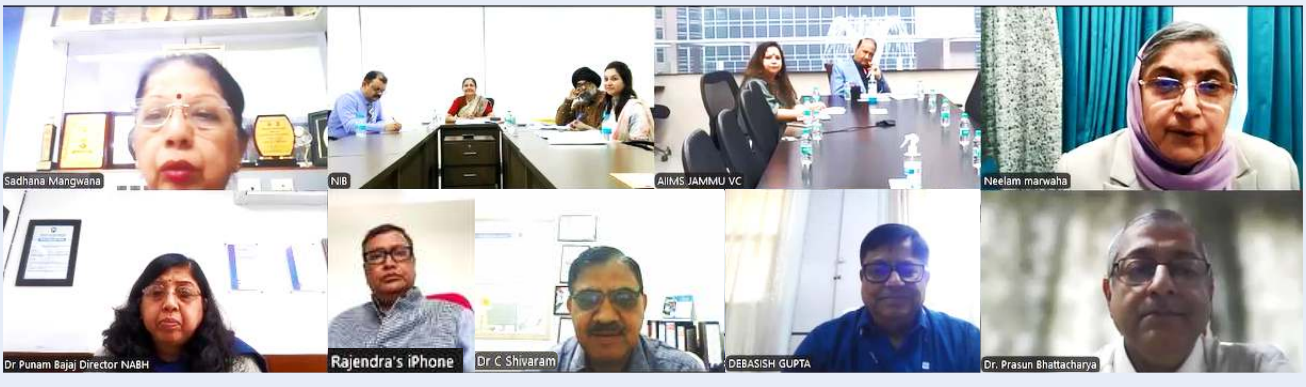
3. Talk on Haemovigilance at Post Graduate Institute of Child Health, Noida

- On 27th February 2025, the Head of the Haemovigilance Programme of India (HvPI) delivered a talk titled "**Haemovigilance Programme of India: Journey So Far**" at the Post Graduate Institute of Child Health, Sector-30, Noida.
- The session provided an overview of the evolution, milestones, and ongoing impact of the HvPI, highlighting its role in improving blood transfusion safety across the country.

MEETING ORGANIZED BY NIB

- A Meeting of Core Group of Haemovigilance Programme of India (Hybrid Mode) was held under the chairpersonship of Director NIB on 24th February, 2025 at NIB, NOIDA.

- A Meeting of National Executive Committee of Haemovigilance Programme of India (Hybrid Mode) was held under the chairpersonship of Dr. Neelam Marwaha, Former Professor & Head, Department of Transfusion Medicine, PGIMER, Chandigarh on 25th February, 2025 at NIB, NOIDA.



- A Meeting of experts was held on 06th May, 2025 at NIB, NOIDA.

NATIONAL SKILL DEVELOPMENT & HANDS-ON TRAINING PROGRAMME ON QUALITY CONTROL OF BIOLOGICALS FOR M.Sc. STUDENTS OF VARIOUS UNIVERSITIES OF THE COUNTRY

- Students from two different universities across the country were introduced to the Haemovigilance Programme of India (HvPI) through dedicated training sessions. These sessions included hands-on training on the Haemovigilance Software, equipping participants with practical skills to support haemovigilance activities.
- A dedicated one-day session on HvPI was incorporated into the National Skill Development & Hands-on Training Programme on Quality Control of Biologicals, which took place from 06th January, 2025 to 17th January, 2025 This initiative aimed to enhance awareness related to haemovigilance among emerging professionals.

Mizoram University, Mizoram & Nagaland University, Nagaland, on 16th January, 2025

ARTICLE PUBLISHED UNDER HAEMOVIGILANCE PROGRAMME OF INDIA

An article on "Evaluation of the progress of a Decade-Long Haemovigilance Programme in India has been published in Vox Sanguinis, The Journal of International Society of Blood Transfusion, Volume 119, Issue 12, December 2024; DOI:10.1111/vox.13741 & can be accessed from: **https://pubmed.ncbi.nlm.nih.gov/39370247/**

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DOI: 10.1111/vox.13741

ORIGINAL ARTICLE

Vox Sanguinis ISBT International Society of Blood Transfusion

Evaluation of the progress of a decade-long haemovigilance programme in India

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Abstract

Background and Objectives: Implementation of national haemovigilance programmes has significantly improved donor and recipient safety. Recently, India completed a decade of successful implementation of its national haemovigilance programmes. The national programme is still enrolling more blood centres. This study aimed to highlight the strengths and weaknesses of Haemovigilance Programme of India (HvPI), thereby providing valuable insights for future initiatives.

Materials and Methods: The National Coordinating Centre (NCC) conducted a multicentre, cross-sectional questionnaire-based survey among the reporting blood centres (January to April 2022). The survey consisted of three sections with a total of 27 questions focusing on the demographics of the participant blood centre as well as the impact on the recipient and donor haemovigilance. The survey was sent to 733 blood centres regularly reporting to the donor and recipient HvPI through Donor and Hemovigil Software.

Results: Total 296 responses were received (response rate of 40.4%) with maximum participation of private non-teaching hospital-based blood centres (33.8%). After their involvement in recipient HvPI, 85.7% of the respondents reported changes in their blood centre's work procedures, with the maximum improvement seen in the documentation of transfusion reactions (92.7%). Out of the 278 respondents who participated in donor HvPI, 89.9% (250) found that their blood centre's policies or work process changed as a result of their involvement in the programme.

Conclusion: In conclusion, our haemovigilance programme facilitates national collaboration for learning and sharing experiences, leading to improved policies and practices in reducing adverse reactions for both recipients and donors.

Keywords
effectiveness, feedback, haemovigilance, improvement

Highlights

- The implementation of national haemovigilance programmes has notably enhanced donor and recipient safety, reflecting a decade of successful execution in India.
- A cross-sectional questionnaire-based survey conducted among reporting blood centres revealed substantial changes in work procedures, particularly in documentation of transfusion reactions, following involvement in the recipient haemovigilance programme.
- The study demonstrates a high percentage of respondents reporting changes in their blood centre's policies or work processes due to participation in the haemovigilance programme, highlighting its effectiveness in driving tangible improvements for both recipients and donors.

NEW MEMBERS ENROLLED UNDER HAEMOVIGILANCE PROGRAMME OF INDIA (64)

ANDHRA PRADESH
1. Apollo Hospitals, Ramaraopet, Kakinada
2. Government General Hospital, Ongole, Prakasam district
3. Amara Blood Center (A Unit of Amara Foundation), Renigunta Mandali, Tirupati (D)

ASSAM
1 GNRC Hospital Blood Centre, Dispur

GUJARAT
1. SIMS Blood Centre, Kalol, Dist. Gandhinagar
2. GMERS Medical College, Vadnagar, Dist. Mehsana
3. Shrimad Rajchandra Hospital and Research Centre-Blood Centre, Dharampur, Dist. Valsad
4. Mayur Blood Centre (Voluntary) Mandvi, Kutch
5. Galbabhai Nanjibhai Patel Charitable Trust Sanchalit Blood Centre, Banas Medical College and Research Institute, General Hospital, Palanpur
6. Red Cross Blood Centre-Choryasi Branch, Surat
7. S.B. P.P. Co-Op. Bank Foundation Blood Centre, Killa Pardi of Manav Arogya Seva Kendra, Dist. Valsad
8. Indian Red Cross Society Blood Centre, Lunawada, Mahisagar

HARYANA
1. Rotary Blood Centre, Faridabad
2. M/s Red Drop Hyderabadi Blood Centre (A unit of Hyderabadi General Hospital & Nursing Home), Panipat
3. J.J Blood Centre, Bahadurgarh

JAMMU & KASHMIR
1. Amandeep BR Medicity Hospital Blood Centre, Srinagar

KARNATAKA
1. Aster Hospital Whitefield Blood Centre, Whitefield, Bangalore

KERALA
1. Dr. K M Cherian Institute of Medical Sciences, Alapuzha (Dist)
2. Blood Center Palaana Institute of Medical Sciences, Kannadi PO, Palakkad
3. CIMAR The Women's Hospital, Blood Centre, Thrissur (Dist.)
4. KIMSAT Hospital (Kadakkal Institute of Medical Science and Technology) Co-operative Hospital, Kadakkal P.O., Kollam Dist.)

MADHYA PRADESH
1. Ram Krishna Medical College Hospital and Research Centre, Bhopal
2. Noble Blood of Component Centre, Misrod Dist. (Bhopal)
3. Blood Centre Atal Bihari Vajpayee Government Medical College, Vidisha
4. ITM Hospital and Research Center, Gwalior
5. SN Krishna Blood Centre, Ujjain

MAHARASHTRA
1. Borivali Blood Centre, Dahisar, Mumbai
2. Lions Blood Centre, Auranagabad
3. M/s Atul Medical and Rehabilitation Society's Arpan Blood Centre, Sangamner, Dist. Aahamadnagar
4. M/s Arpan Blood Centre, Blood Component Lab and Aphersis Centre, Thane
5. Mahatma Gandhi Mission's Medical College and Hospital Blood Centre, Aurangabad
6. ASPL's CSMSS Medical College & Hospital Blood Centre, Dist Chhatrapati Sambhajinagar

NEW DELHI
1. Blood Centre, Sant Parmanand Hospital, Civil Lines, Delhi
2. Rajiv Gandhi Super Speciality Hospital, Tahirpur, Delhi

ODISHA
1. M/s Bagchi Sri Sankara Cancer Centre & Research Institute Blood Centre, Dist. Khorda
2. Ashwini Blood Centre, Cuttack

PUDUCHERRY
1. A.G. Padmavati's Hospital Ltd. Blood Centre, Arumparthapuram

PUNJAB
1. Kidney Hospital & Lifeline Medical Institutions, Jalandhar
2. Homi Bhabha Cancer Hospital & Research Centre, New Chandigarh
3. Ghai Hospital Blood Centre, Jalandhar
4. Pragma Medical Institute Blood Centre, Bathinda
5. Blood Centre Bathinda, Mansa Road, Bathinda

RAJASTHAN
1. Geetanjali Institute of Medical Sciences, Jaipur
2. M/s Blood Centre, Barala Hospital and Research Centre, Jaipur
3. Shri Ambe Hospital and Blood Centre, Jhotwara, Jaipur

TAMIL NADU
1. Arunai Medical College and Hospital, Tiruvannamalai
2. Right Trust Blood Centre, Kilpauk, Chennai
3. Srinivasan Medical College and Hospital, Samayapuram, Tiruchirappalli

TELANGANA
1. Premier Voluntary Blood Centre, Mehdipatnam, Hyderabad
2. Janani Voluntary Blood Center, Kompally, Hyderabad
3. Virchow Foundation Blood Centre, Secundrabad,

UTTAR PRADESH
1. Blood Centre Max Superspeciality Hospital, Gomti Nagar, Lucknow
2. Hind Institute of Medical Sciences-Blood Centre, District-Barabanki
3. ESIC Model Hospital, Blood Centre, Sector-24, Gautam Buddha Nagar
4. Shubham Hospital Blood Centre, Varanasi
5. Janta Blood Centre, Gandhi Nagar, Moradabad
6. Yashoda Superspeciality Hospital & Cancer Institutes, Sanjay Nagar, Ghaziabad
7. Chandan Hospital, Gomati Nagar, Lucknow
8. Amritasha Blood Center (Run by Amritasha Hospital and Trauma Center), Shivpur, Varanasi
9. Tender Palm Hospita Blood Centre, Shaheed Path, Lucknow
10. V Care Hospital, Rajendra Nagar, Sahibabad, Ghaziabad

WEST BENGAL
1. Indian Institute of Liver and Digestive Sciences, Blood Centre, 24 Parganas (S)
2. Nehru Memorial Techno Global Hospital Blood Centre (A unit of Techno India Technologies Limited, Dist. 24, Parganas (North), Kolkata
3. CAMRI Blood Centre, Burdwan

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

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

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 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 FROM (TRRF Version-2)

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										
☐	Leucofiltered PRBC										
☐	Random Donor platelets/ pooled										☐ Repeat 1 to 10
☐	Apheresis Platelets										
☐	Fresh Frozen Plasma										
☐	Cryoprecipitate										☐ Repeat > 10
☐	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

(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)			☐ 3. Recovered with Sequelae
☐	Transfusion Transmitted Bacterial Infection			
☐	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 ENROL YOUR CENTRE UNDER HvPI

Who can Enrol?

Head/ In-charge of Transfusion Medicine Department / Blood Centre

How to Enrol?

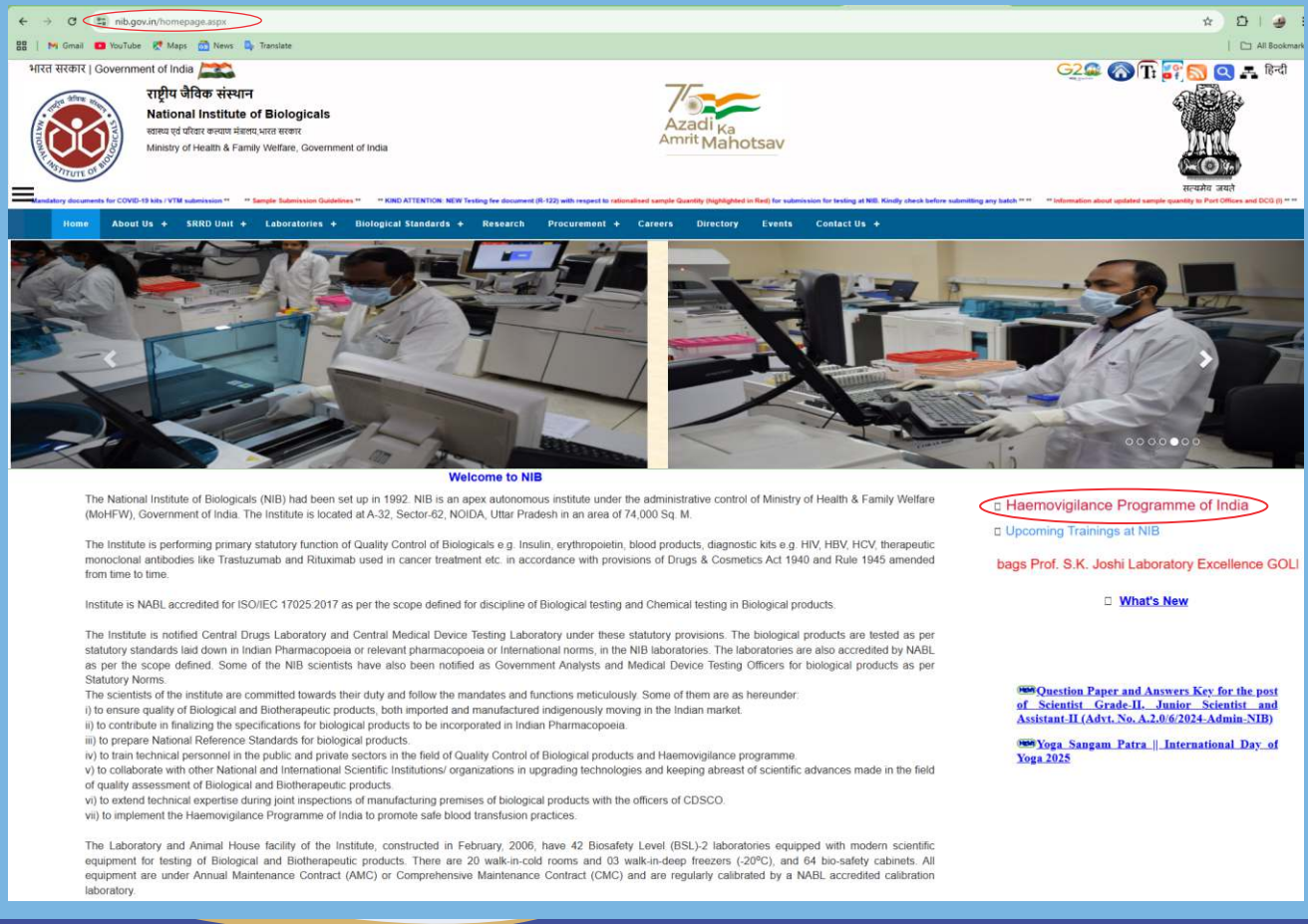
1) Head / Incharge of Transfusion Medicine Department / Blood Centre provides the necessary details to the National Coordinating Centre (NCC) - Haemovigilance Programme of India (HvPI) by sending the duly filled **Enrolment Form** either to NCC at National Institute of Biologicals, Ministry of Health & 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 enroled 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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For any other Information/ Suggestions/ Query related to Haemovigilance Programme of India kindly contact: Dr. Akanksha Bisht, Scientist Grade-I & Head-Haemovigilance Programme of India, NIB, NOIDA at: haemovigilance@nib.gov.in