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

Release of First Guidance Document for Reporting Blood Donor Adverse Reactions by Dr. Bharti Pravin Pawar, Hon'ble Minister of State, Ministry of Health & Family Welfare, Govt. of India

Haemovigilance Newsletter Vol. No. 10 Issue 20, July-December, 2022

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

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Haemovigilance Programme of India - Milestones

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

Haemovigilance is defined as 'a set of surveillance procedures covering the whole transfusion chain from the collection of blood and its components to the follow-up of its recipients i.e. from the vein of the donor to the vein of the recipient. It is intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products and to prevent their occurrence and recurrence'. Haemovigilance is a tool to improve the quality of the blood transfusion chain, primarily focusing on safety.

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

Implementation and coordination of activities of Haemovigilance Programme of India became one of the 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 under Haemovigilance Programme of India (HvPI)

❖ A webinar for 50 blood centres w.r.t. Severity Grading Tool (SGT) study under National Blood Donor Vigilance Programme (NBDVP) was organized by Haemovigilance Division of NIB on 06th April, 2022 to discuss the SGT study cases with explanation. Apart from participating centres, experts from transfusion medicine department also attended the said webinar.

Institutional representation under Haemovigilance Programme of India (HvPI)

❖ Talk on "Journey of Haemovigilance Programme of India (HvPI)" delivered by Head HvPI via online mode on 20th May, 2022 during 2nd North East Workshop on Haemovigilance, Blood Donor Vigilance & on Voluntary Blood Donation organised by Barak Valley Voluntary Blood Donor's Forum central committee & supported by Federation of Blood Donor Organizations of India (FBDOI) held on 20th -21st May, 2022 at Silchar, Assam.

❖ Head-HvPI delivered an online presentation on the topic "NIB- What is Haemovigilance & What Role can FIBDO play for blood safety" on 28th May, 2022 in the Federation of Indian Blood Donors Organisations (FIBDO) West Bengal State Conference- 2022 organized by FIBDO, West Bengal held on 28th-29th May 2022 at Barasat Rabindra Bhawan in North 24 Parganas.

Topic: TRANSFUSION MEDICINE CLINIC

Author Name: Dr. Prasun Bhattacharya,
Designation: Professor and Head
Organization: Dept. of Immunohematology and Blood Transfusion, Medical College Kolkata, 700073



Transfusion of blood and its components are an essential part of any health care facility. In the last two decades our country has progressed immensely in terms of blood component preparation and its applications. Incorporation of new technologies, creating transfusion medicine departments and introducing the capacity building approach adhered to the objectives of National Blood Policy have immensely improved the scenario of blood transfusion services. It has reduced both the short- and long-term complications of blood transfusion. To monitor and generate evidence-based recommendations to minimize the adverse events of blood transfusion the National Haemovigilance program was established on December 10, 2012.[1] The nomenclature of blood banks is now replaced to blood centre by the Central Drugs Standard Control organization (CDSCO), the national regulatory authority, for drug under the Ministry of Health and Family Welfare. Presently there are more than 22 blood components/facilities which are licensed in India and in future the blood centres have the potential to generate many newer generations of blood components.[2]

However, the knowledge, attitude and practice related to the use of blood components across our medical fraternity should not remain static as this specialized medical discipline is not included in the undergraduate curriculum, nor it is still linked to the direct patient care. The centres having transfusion medicine departments should become more pro-active and forward their expertise for better patient care. Patient hemovigilance reporting is incomplete in most of the time unless it is assessed by a transfusion medicine physician. There is a huge scope of improvement in quality of patient care as blood component transfusion is one of the commonest in-patient interventions and allogenic transfusion is no less than a tissue transplant.

The department of Immunohaematology and Blood transfusion (IHBT) was established on July 26, 2010, at Calcutta Medical College Hospital blood bank (now blood centre), in West Bengal with introduction of post-graduate MD in IHBT in 2011. Till now it is the only academic centre in the densely populated state which is consistently providing the services and consultation to the different medical specialties related to the rational application of blood components and their potential hazards. Moreover, our approach to the rational application of convalescent plasma in severe Covid19 patients with ARDS has been recognized by many premier scientific body/institutions across the world. [3,4,5]

Considering our credentials and the faculties' background of direct patient care we were approached by the State Blood cell, National Health Mission (NHM) and State blood transfusion council (SBTC) to provide a day care and indoor patient services on June 9, 2021. The services were initially targeted to the haemoglobinopathy, congenital bleeding/coagulation disorders and better patient care to those who require specialised components like leuko-reduction and extended phenotype matched red cells.

Cont...

To a practical approach to the patient care delivery the Dept. IHBT, Medical College Kolkata started its first OPD services as Transfusion Medicine Clinic on 06.04.2022 and on every Wednesday 9.00 am - 2.00 pm. Our scope of services presently involves:

1. Post-transfusion follow-up clinic to determine both long- and short-term effects of blood transfusion especially in transfusion dependent patients and cancer chemotherapy
2. Pre-operative anaemia and patient blood management
3. Antenatal mothers screening
4. Patients who have poor tolerance to blood component therapy (viz. alloimmunization, recurrent transfusion reactions, platelet refractoriness etc.)
5. Blood donor related services (deferred blood donors, donor adverse events and post donation counselling)
6. Specialised blood component support in critical patients and regenerative medicine clinic

In the long term we expect that the importance of the transfusion services shall be more significant in the tertiary health care facility having solid organ and bone marrow transplant facilities.

Similar initiatives are essential across the country in every teaching institution for the betterment of the transfusion services and exploring the newer horizons of quality and patient safety.

References

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3. Biswas D, Maiti C, Talukder B, Azharuddin M, Saha S, Pandey S et al. A prospective study on COVID-19 convalescent plasma donor (CCP) recruitment strategies in a resource constrained blood centre. ISBT Sci Ser. 2021 Jun 1:10.1111/voxs.12639. doi: 10.1111/voxs.12639. Epub ahead of print. PMID: 34226835; PMCID: PMC8242402.
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5. Ray Y, Paul SR, Bandopadhyay P, D'Rozario R, Sarif J, Raychaudhuri D, Bhowmik D et al. A phase 2 single center open label randomised control trial for convalescent plasma therapy in patients with severe COVID-19. Nat Commun. 2022 Jan 19;13(1):383. doi: 10.1038/s41467-022-28064-7. PMID: 35046397; PMCID: PMC8770561.

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International Conference/Seminar

- Head- HvPI being the Secretary of International Haemovigilance Network (IHN) attended the GAPP (facilitatinG the Authorisation of Preparation Process for blood, tissues and cells), final Dissemination Conference online with the host location Thessaloniki, Greece on 20th & 21st January 2022.
- Head- HvPI being the Secretary of IHN board attended 2022 virtual mini-seminar of the International Hemovigilance Network on plasma vigilance organized by IHN held on 29th March 2022.

Published Article

An article on "First Decade of implementation of Haemovigilance Programme in India" has been published in Transfusion Today, Number 131, April 2022 Issue of International Society of Blood Transfusion (ISBT).

Regional

Akanksha Bisht
National Institute of Biologicals, NOIDA, Ministry of Health & Family Welfare, India

First decade of implementation of Haemovigilance Programme in India

The National Institute of Biologicals (NIB), NOIDA is an APEX autonomous institute under the administrative control of Ministry of Health & Family Welfare, Government of India engaged in Quality Control Evaluation of various biological products like vaccines, blood products, blood reagents, sera, Immuno-diagnostic kits etc. produced and imported into India.

Haemovigilance is a tool to improve the quality of the blood transfusion chain, primarily focusing on safety. The Haemovigilance Programme of India is being implemented since year 2012, with National Institute of Biologicals, NOIDA, Ministry of Health & Family Welfare, Government of India as the National Coordinating Centre. The programme tracks the Adverse Reactions associated with Blood Transfusion and Blood Donation. This system includes monitoring, reporting investigation, identification and analysis of adverse reactions related to transfusion & blood donation. The programme aims to improve the safety & quality of blood being received by the patients and promotes voluntary blood donations with the view to improve safe blood transfusions practices in our country.

The NIB is also actively involved with World health organization (WHO) for organizing workshops for strengthening of blood services and haemovigilance in SEAR countries. Further India is a member of International Haemovigilance Network (IHN) since 2014.

Awareness about the programme, its objectives and its non- punitive implications is being generated through publications in reputed journals/ magazines & Haemovigilance Newsletters and also by organizing CMEs/ Trainings/ Workshops/ Conferences on HvPI in different regions of the country. Till date total 76 CMEs/ Trainings/ Workshops/ Conferences on HvPI have been organized by NIB and about 15,023 blood centre officials, clinicians, nurses, blood centre technical staff, blood donors, motivators etc. all across the country have been trained.

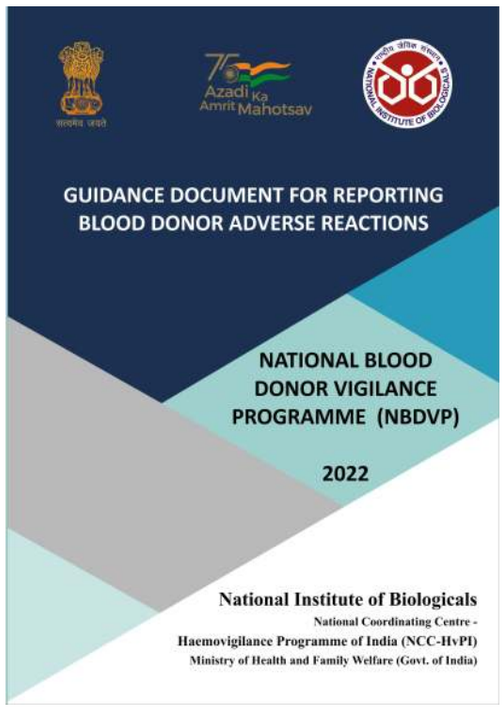
The program is analyzing the reactions being submitted online by Blood Centres through indigenously developed haemovigilance software by NIB (Reporting of Adverse Transfusion Reactions is done online via Haemo-Vigil software & reporting of Adverse Blood Donor Reactions is done via Donor-Vigil software available on NIB website i.e. www.nib.gov.in). There are about 3000 plus licensed blood centers in India. Though reporting for the program is voluntary, 1210 centres are enrolled and reported about 55,000 Adverse Reaction Reports accordingly data analysis reports with recommendations for stakeholders are being published from time to time. Such information is a key to introduce required changes in the applicable policies, improve standards, system, processes and assist in the formulation of guidelines.

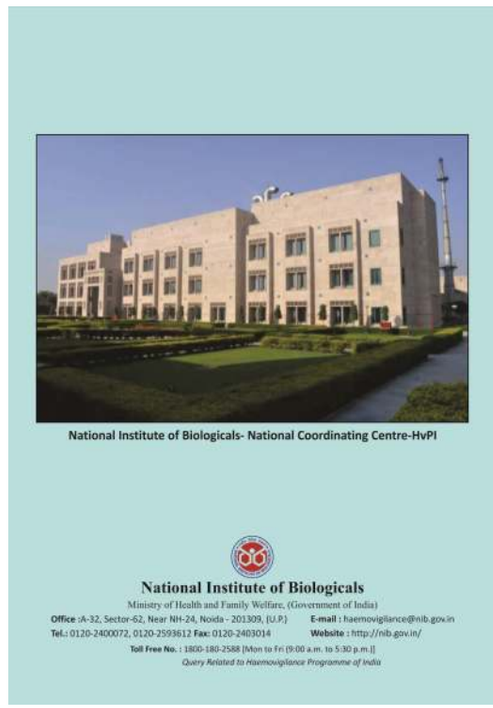
Haemovigilance as a whole has grown over the last decade across the world, there have been many new developments, definitions, classifications and development of preventive strategies for both recipient and donor vigilance. Haemovigilance is one of the potential quality checks in blood transfusion services and could play an essential role to prevent any breach in safety of blood transfusion practices. So, ultimately to promote and improve safe blood transfusion services in India, Haemovigilance Programme of India is utmost important and there is need to sensitize the fraternity about the Blood Safety thorough Haemovigilance.

National Skill Development & Hands-on Training Programme on Quality Control of Biologicals for M.Sc. Biotechnology Students from 06th June to 17th June, 2022 at NIB, NOIDA.

The Students from Sant Gahira Guru Vishwavidyalaya, Sarguja Ambikapur (Chhattisgarh) & Bodoland University, Kokrajhar (Assam) participated in the said training programme. One session during this training programme was kept for Haemovigilance Programme of India on 16th June, 2022. During this session students were apprised about Haemovigilance Programme of India followed by hand on training.

Release of First Guidance Document for Reporting Blood Donor Adverse Reactions





- National Institute of Biologicals (NIB) celebrated Azadi Ka Amrit Mahotsav: 30 Years of NIB in service to the nation on 30th June, 2022.
- Dr. Bharti Pravin Pawar, Hon'ble Minister of State, Ministry of Health & Family Welfare, Govt. of India was the chief guest, Shri Rajesh Bhushan, IAS, Secretary, Health & Family Welfare & Prof. Balram Bhargava, Secretary DHR & Director General, ICMR were the guest of honour.
- On this occasion "Guidance Document for Reporting Blood Donor Adverse Reactions" under National Blood Donor Vigilance Programme (NBDVP) was released by the Hon'ble Minister of State, Ministry of Health & Family Welfare, Government of India.

Meetings organized by NIB

- A Virtual meeting of experts for Severity Grading Tool (SGT) study under National Blood Donor Vigilance Programme (NBDVP) held on 16th February, 2022 to apprise and deliberate on the trends of analysis.

- A virtual meeting to discusse draft concept note for inclusion of adverse events related to therapeutic apheresis in Haemovigilance Programme of India (HvPI) held on 25th February, 2022.

- A Meeting of the Experts held on 24th May, 2022 at National Institute of Biologicals, NOIDA.

New Members Enrolled under Haemovigilance Programme of India (75)

Andhra Pradesh
1. KIMS Hospital Blood Centre, Prakasam Dist.
2. New Life Blood Centre, Visakhapatnam
3. New Life Blood Centre, Vizianagaram
4. New Life Blood Centre, Nellore
5. Konaseema Institute of Medical Sciences & Research Foundation, East Godavari

Assam
1. Blood Centre Nemcare Hospitals Pvt Ltd, Guwahati, Kamrup (M)
2. Down Town Hospital Blood Centre, Guwahati, Kamrup (M)

Bihar
1. Rotary Anup Blood Bank, Patna
2. Blood Centre of M/s Ruban Memorial Hospital, Ratan Stone Clinic (Unit of Ruban Patliputra Hospital Pvt. Ltd.), Patna

Chhattisgarh
1. Raipur Institute of Medical Sciences Blood Bank, Raipur

Gujarat
1. Lions Blood Centre, Ahmedabad
2. Indian Red Cross Society, Ckheda-District, Nadiad
3. Ayush Blood Centre, Vadodara
4. Jeevandeep Blood Center Managed by: The Student Cultual group of Amreli, Rajkot

Haryana
1. M/s Kainos Blood Centre, Rohtak
2. Lions Blood Centre, Sonipat
3. SMS Blood Centre, Hisar
4. M/s Park Hospital (A Unit of Park Medicenters & Institution Pvt. Ltd.), Gurugram
5. Park Healing Touch Hospital Blood Centre, Ambala City
6. Supreme Blood Centre, Faridabad
7. Adesh Medical College & Hospital, Kurukshetra
8. Nidaan Hospital, Sonipat
9. PK Healthcare Pvt Ltd, Sanar International Hospital, Gurgaon
10. SFG Blood Bank, Rohtak

Jammu & Kashmir
1. Bee Enn General Hospital Blood Centre, Jammu

Karnataka
1. Narayana Hrudayalaya Surgical Hospital Private Ltd., Mysore
2. Cytecare Hospitals Pvt. Ltd. Blood Bank, Bengaluru
3. Hemocare Blood Centre, Bangalore
4. K. C. General Hospital, Bengaluru

Kerala
1. Sree Narayana Institute of Medical Sciences, Ernakulam District
2. District Hospital, Mavelikkara, Alappuzha Dist.
3. NS Memorial Institute of Medical Science, Kollam
4. Malabar Institute of Medical Sciences Ltd. Kannur Dist.
5. Magj Hospital, Mookkannoor, Eranakulam Dist.
6. Travancore Medical College Hospital, Kollam Dist.
7. Lisie Hospital, Ernakulam
8. Mar Baselios Medical Mission Hospital Blood Bank, Ernakulam

Meghalaya
1. William Nagar Civil Hospital Blood Centre, East Garo Hills

Maharashtra
1. Apollo Hospital Blood Centre, Navi Mumbai
2. M/s Jupiter Hospital Blood Centre, Thane (W)
3. Sai Healthcare Foundation Charitable Trusts Sanjivani Blood Centre, Ahmednagar
4. Navi Mumbai Blood Centre, Kharghar
5. Ma Saheb Meenatai Thakre Blood Centre, Navi Mumbai Municipal Corporation Blood Centre, Navi Mumbai
6. Seven Hills Healthcare Private Limited Blood Centre, Andheri (E), Mumbai
7. Holy Spirit Hospital Blood Centre, Andheri (E), Mumbai
8. Smt. Kapoorben Vasanji Lathia Blood Centre, Mumbai
9. Rajarshi Shahu Blood Centre, Kolhapur

New Delhi
1. Blood Centre, Maharaja Agrasen Hospital, Dwarka
2. Tarak Hospital Pvt. Ltd. Blood Bank, Dwarka More
3. Kalra Hospital SRCNC Pvt. Ltd., Kirti Nagar
4. Guru Nanak Dev Charitable Blood Centre, Janak Puri

Punjab
1. Blood Center, IVY Hospital, Amritsar
2. Deepak Hospital, Ludhiana

Rajasthan
1. Shriji Blood Bank, Kota
2. Blood Centre Rajkiya Mahila Chikitsalaya, Ajmer
3. Triveni Blood Bank, Ajmer
4. Kshetrapal Multispiciality & Research Centre, Blood Centre, Ajmer

Tamil Nadu
1. Apollo Speciality Hospitals, Trichy
2. Blood Bank, Govt. Dharmapuri Medical College and Hospital, Dharmapuri
3. Sree Balaji Medical College and Hospital, Chennai
4. Government Thiruvannamalai Medical College Hospital, Thiruvannamalai

Telangana
1. Sunshine Blood Centre (A unit of Sarvejana Healthcare Pvt. Ltd.), Secunderabad
2. RVM Institute of Medical Sciences, Siddipet
3. Government Medical College and General Hospital, Suryapet
4. St. Theresa's Hospital Blood Centre, Hyderabad
5. Sunshine Hospitals Blood Centre (A Unit of Raja Lakshmi Healthcare Pvt. Ltd), Ranga Reddy District
6. Life Voluntary Blood Centre (A unit of Life Voluntary Organization), Hyderabad
7. Omni Hospitals Blood Centre, Hyderabad
8. Indian Red Cross Society, Blood Centre, Hanumakonda
9. New Life Blood Centre, Wanaparthy

Uttar Pradesh
1. Awadh Charitable Blood Bank, Lucknow
2. OM Charitable Blood Centre, Gautam Budh Nagar
3. Allahabad Medical Association Blood Bank, Prayagraj

West Bengal
1. Peerless Hospitex Hospital & Research Center Limited, Kolkata
2. Life Care Medical Foundation Blood Centre, Kolkata

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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 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 FORM (TRRF VERSION-2)

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National Institute of Biologicals

Ministry of Health & Family Welfare, Govt. of India

(National Coordinating Center)

HAEMOVIGILANCE PROGRAMME OF INDIA

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

* Mandatory Field

(A) Patient Information

Hospital Code No.:

Patient Initials*: | Gender*: | Blood Group*:

Hospital Admission No.*: | Age/Date of Birth*: | .....Yrs | .....Month | .....Days | .....Hrs | .....Mins

Primary Diagnosis*:

Medical History:

(B) Transfusion Reaction Details*

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

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

Please tick mark the relevant signs and symptoms listed below

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

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?

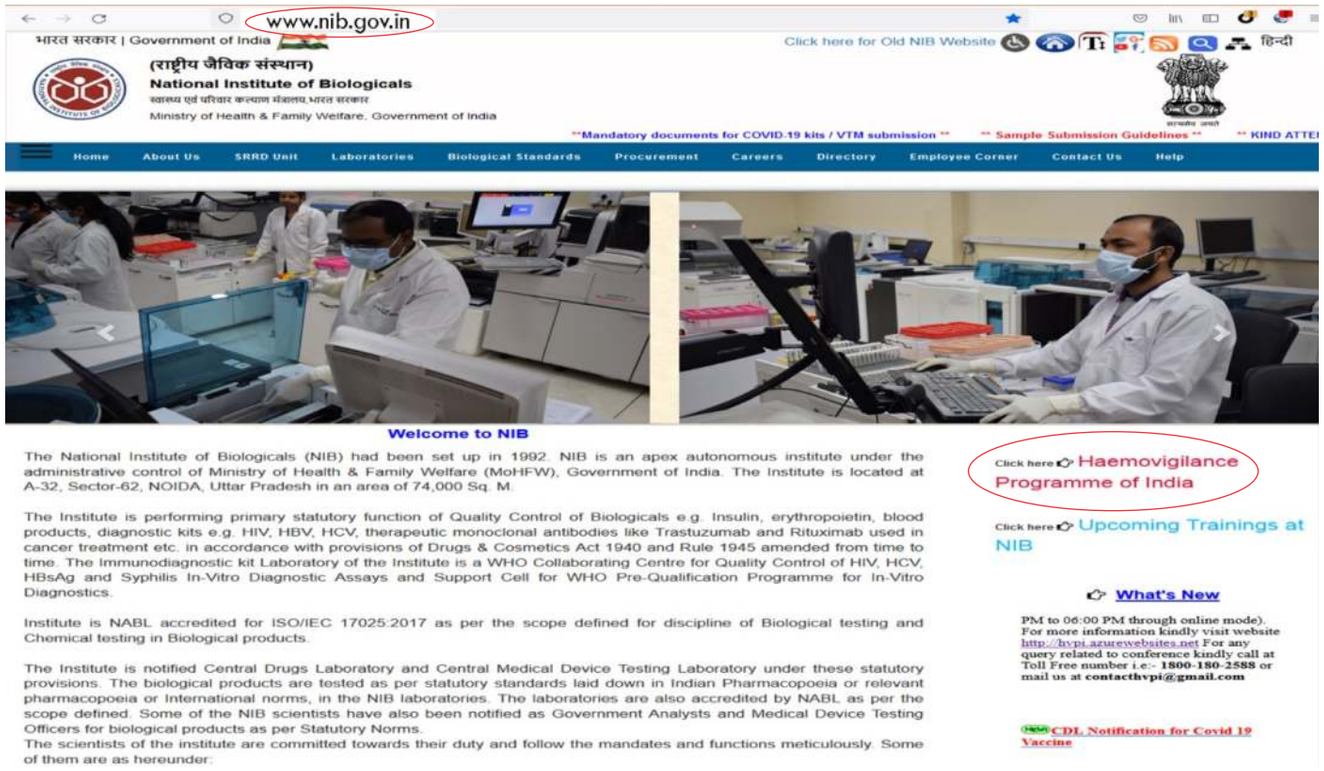
1) Head / Incharge of Transfusion Medicine Department / Blood Centre provides the necessary details to the National Coordinating Centre (NCC) - Haemovigilance Programme of India (HvPI) by sending the duly filled **Enrolment Form** either to NCC at National Institute of Biologicals, Ministry of Health & 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

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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**

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