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An Overview on Haemovigilance Programme of India

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Abstract

Blood transfusion plays a vital role in the improvement of health and saves many lives. Haemovigilance system is the programme which ensures the transfusion safety by monitoring every step of transfusion process from donor to recipient. The ultimate object of haemovigilance system is improving the quality and safety of transfusion therapy. This article briefly describes about objective and reporting of the haemovigilance programme of India.

Keywords: Transfusion Safety; Haemovigilance; Haemovigilance in India

Haemovigilance

Haemovigilance is a continuous process of data collection and analysis of transfusion-related adverse reactions in order to investigate their causes and outcomes, and prevent their occurrence or recurrence. It includes the identification, reporting, investigation and analysis of adverse reactions and events in recipients and blood donors as well as incidents in manufacturing processes and, eventually errors and "near-misses". A Haemovigilance system is also an integral part of quality management in a blood system, triggering corrective and preventive actions, and for the continual improvement of the quality and safety of blood products and the transfusion process.

Haemovigilance is from the vein of the donor to the vein of the recipient and covers adverse reactions both due to blood transfusion and blood donation. It has two arms:

i. The recipientís 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 India.

ii. The donorís 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's Blood Donor Day at Science City Kolkata under the ambit of HvPI.

Objective of Haemovigilance Programme of India

Recipient Haemovigilance

i) Monitor transfusion reactions,
ii) Create awareness amongst health care professionals,
iii) Generate evidence based recommendations,
iv) Advise Central Drugs Standard Control Organization (CDSCO) for safety related regulatory decisions,
v) Communicate findings to all key stakeholders and
vi) Create national & international Linkages.

Donor Haemovigilance

i) Improve donor safety and satisfaction through monitoring, analyzing and researching adverse events,

ii) Analyze risk factors , implement and evaluate preventive measures,

iii) Provide evidence based support for Blood Donation Process improvement,

iv) Reduce the frequency of adverse events

v) Increase donation frequency.

Reporting Under the National Programmes

Under these programmes, the data pertaining to adverse reactions occurring in the patients & donors is collected, collated and analyzed by expert committees under HvPI at National Coordinating Centre of HvPI, NIB. NIB has a web based reporting system for adverse transfusion reactions and donor reactions via indigenously developed software(s) Haemo-Vigil and Donor-Vigil. The reporting of reactions is done via Software(s) in a uniform format i.e. Transfusion Reaction Reporting Form (TRRF) and (DARRF) respectively Figure 1 & 2 by enrolled centres using unique user id and password being provided by HvPI. NIB also launched the Toll Free No. (1800-180-2588) for the queries related to HvPI.

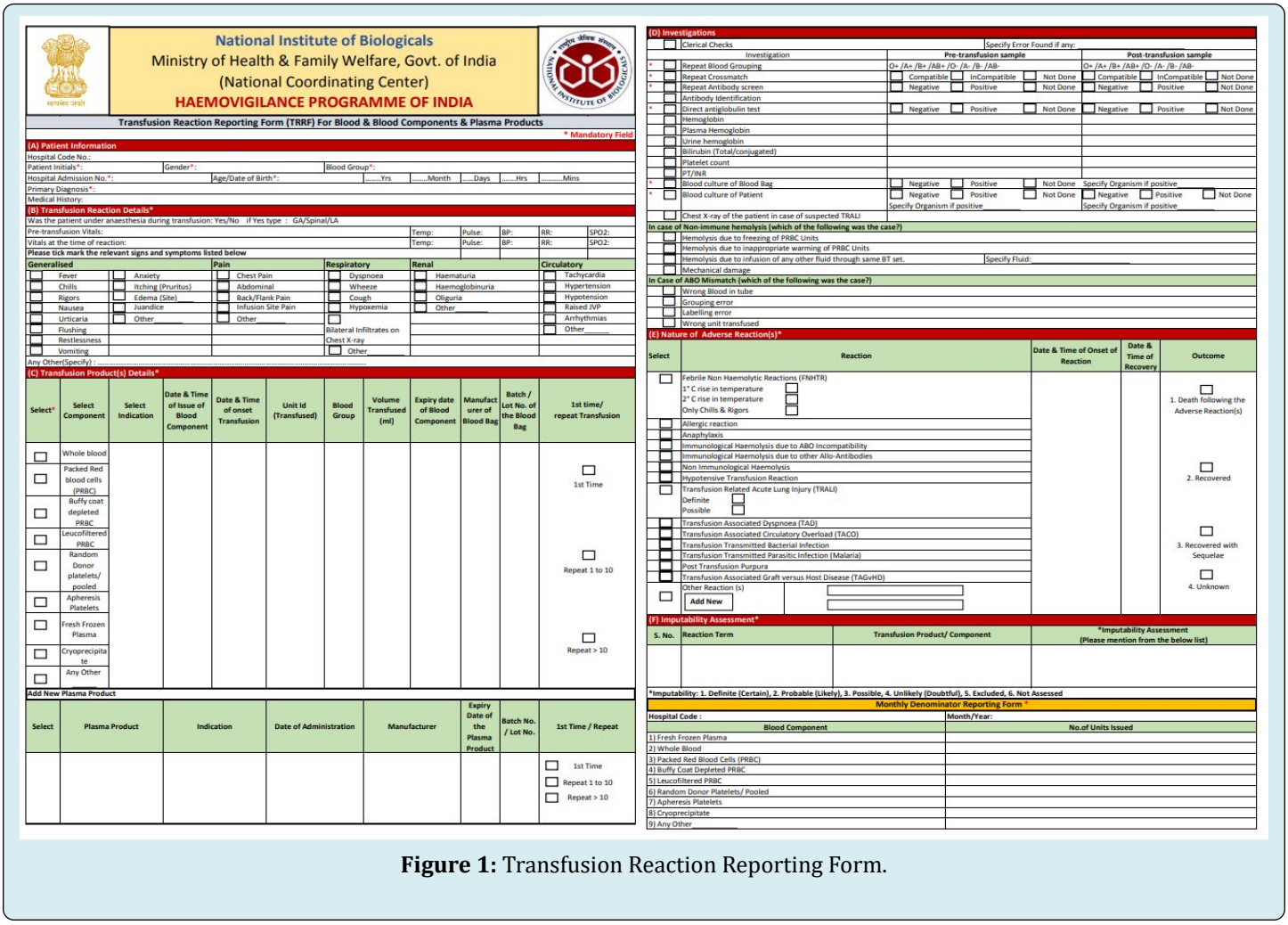
National Institute of Biologicals
Ministry of Health & Family Welfare, Govt. of India
(National Coordinating Center)
HAEMOVIGILANCE PROGRAMME OF INDIA
Transfusion Reaction Reporting Form (TRRF) For Blood & Blood Components & Plasma Products
* Mandatory Field
(A) Patient Information
Hospital Code No.:
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: Fever, Chills, Rigors, Nausea, Urticaria, Flushing, Restlessness, Vomiting, Anxiety, Itching (Pruritus), Edema (Site)___, Juandice, Other___
Pain: Chest Pain, Abdominal, Back/Flank Pain, Infusion Site Pain, Other___
Respiratory: Dyspnoea, Wheeze, Cough, Hypoxemia, Bilateral Infiltrates on Chest X-ray, Other___
Renal: Haematuria, Haemoglobinuria, Oliguria, Other___
Circulatory: Tachycardia, Hypertension, Hypotension, Raised JVP, Arrhythmias, 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
Whole blood
Packed Red blood cells (PRBC)
Buffy coat depleted PRBC
Leucofiltered PRBC
Random Donor platelets/ pooled
Apheresis Platelets
Fresh Frozen Plasma
Cryoprecipitate
Any Other
1st Time
Repeat 1 to 10
Repeat > 10
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
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
Allergic reaction
Anaphylaxis
Immunological Haemolysis due to ABO Incompatibility
Immunological Haemolysis due to other Allo-Antibodies
Non Immunological Haemolysis
Hypotensive Transfusion Reaction
Transfusion Related Acute Lung Injury (TRALI) Definite Possible
Transfusion Associated Dyspnoea (TAD)
Transfusion Associated Circulatory Overload (TACO)
Transfusion Transmitted Bacterial Infection
Transfusion Transmitted Parasitic Infection (Malaria)
Post Transfusion Purpura
Transfusion Associated Graft versus Host Disease (TAGvHD)
Other Reaction (s) Add New
1. Death following the Adverse Reaction(s)
2. Recovered
3. Recovered with Sequelae
4. Unknown
(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) Fresh Frozen Plasma
2) Whole Blood
3) Packed Red Blood Cells (PRBC)
4) Buffy Coat Depleted PRBC
5) Leucofiltered PRBC
6) Random Donor Platelets/ Pooled
7) Apheresis Platelets
8) Cryoprecipitate
9) Any Other

Figure 1: Transfusion Reaction Reporting Form.

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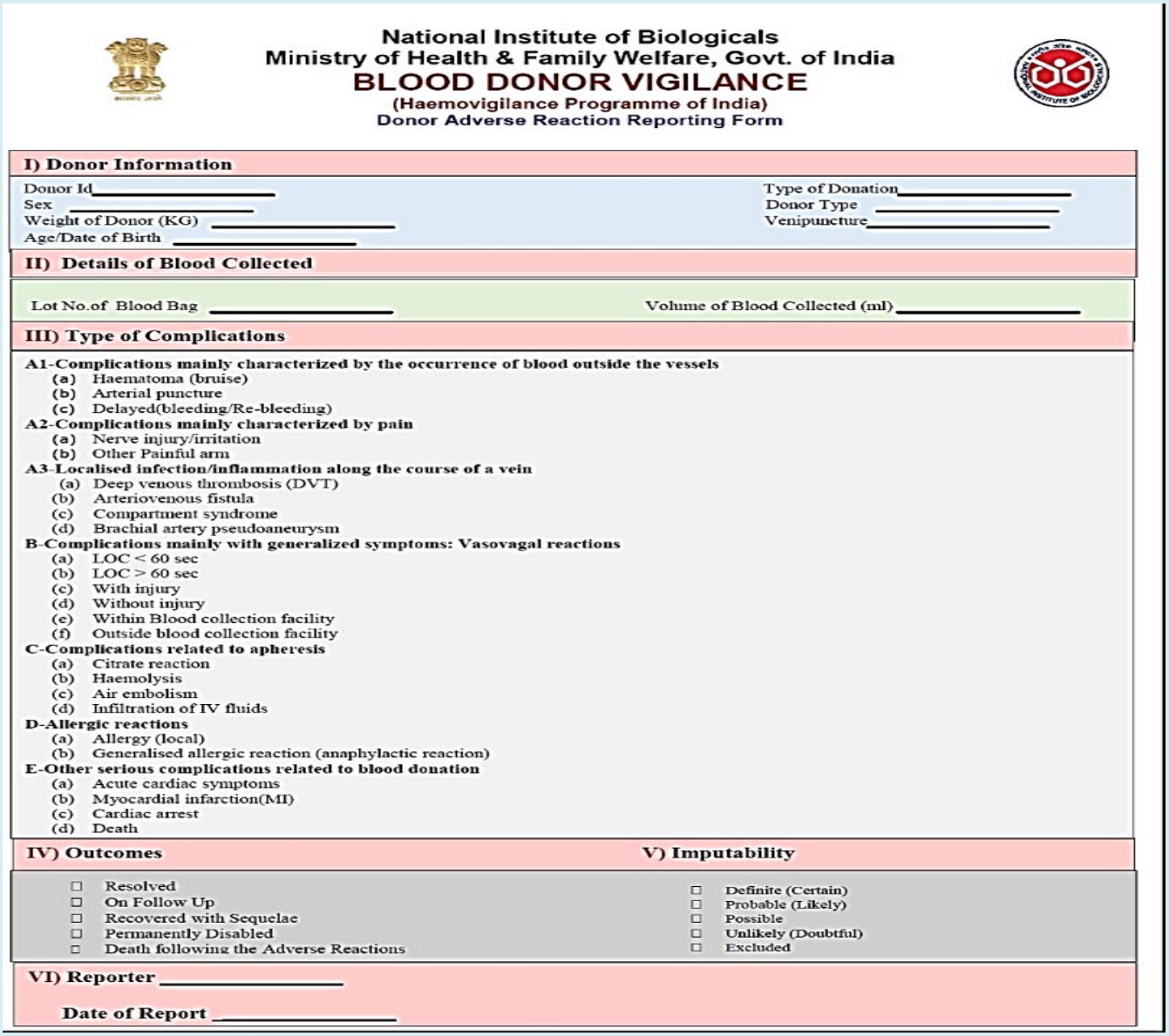

National Institute of Biologicals
Ministry of Health & Family Welfare, Govt. of India
BLOOD DONOR VIGILANCE
(Haemovigilance Programme of India)
Donor Adverse Reaction Reporting Form

I) Donor Information

Donor Id _____ Type of Donation _____
Sex _____ Donor Type _____
Weight of Donor (KG) _____ Venipuncture _____
Age/Date of Birth _____

II) Details of Blood Collected

Lot No.of Blood Bag _____ Volume of Blood Collected (ml) _____

III) Type of Complications

A1-Complications mainly characterized by the occurrence of blood outside the vessels
(a) Haematoma (bruise)
(b) Arterial puncture
(c) Delayed(bleeding/Re-bleeding)
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) Deep venous thrombosis (DVT)
(b) Arteriovenous fistula
(c) Compartment syndrome
(d) Brachial artery pseudoaneurysm
B-Complications mainly with generalized symptoms: Vasovagal reactions
(a) LOC < 60 sec
(b) LOC > 60 sec
(c) With injury
(d) Without injury
(e) Within Blood collection facility
(f) Outside blood collection facility
C-Complications related to apheresis
(a) Citrate reaction
(b) Haemolysis
(c) Air embolism
(d) Infiltration of IV fluids
D-Allergic reactions
(a) Allergy (local)
(b) Generalised allergic reaction (anaphylactic reaction)
E-Other serious complications related to blood donation
(a) Acute cardiac symptoms
(b) Myocardial infarction(MI)
(c) Cardiac arrest
(d) Death

IV) Outcomes

☐ Resolved
☐ On Follow Up
☐ Recovered with Sequelae
☐ Permanently Disabled
☐ Death following the Adverse Reactions

V) Imputability

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

VI) Reporter _____

Date of Report _____

Figure 2: Blood Donor Adverse Reaction Reporting Form.

Procedure to Enrolment Under HvPI

Who Can Enrol?

Head/ Incharge of Transfusion Medicine Department/Blood Banks of India

How to Enrol?

1) Head / Incharge of Transfusion Medicine Department / Blood Bank provides the necessary details to the National Coordinating Centre (NCC) - Haemovigilance Programme of India (HvPI) by sending the duly filled Enrolment Form Figure 3 either to NCC at National Institute of Biologicals, Ministry of Health & Family Welfare, Plot No. A-32, Sector-62, Institutional Area, NOIDA -201309 (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 Bank to access the Haemo-Vigil Software and Doner-vigil Software for onward Submission of Transfusion Reactions Reports and Adverse Blood Donor Reaction Reports to NCC.

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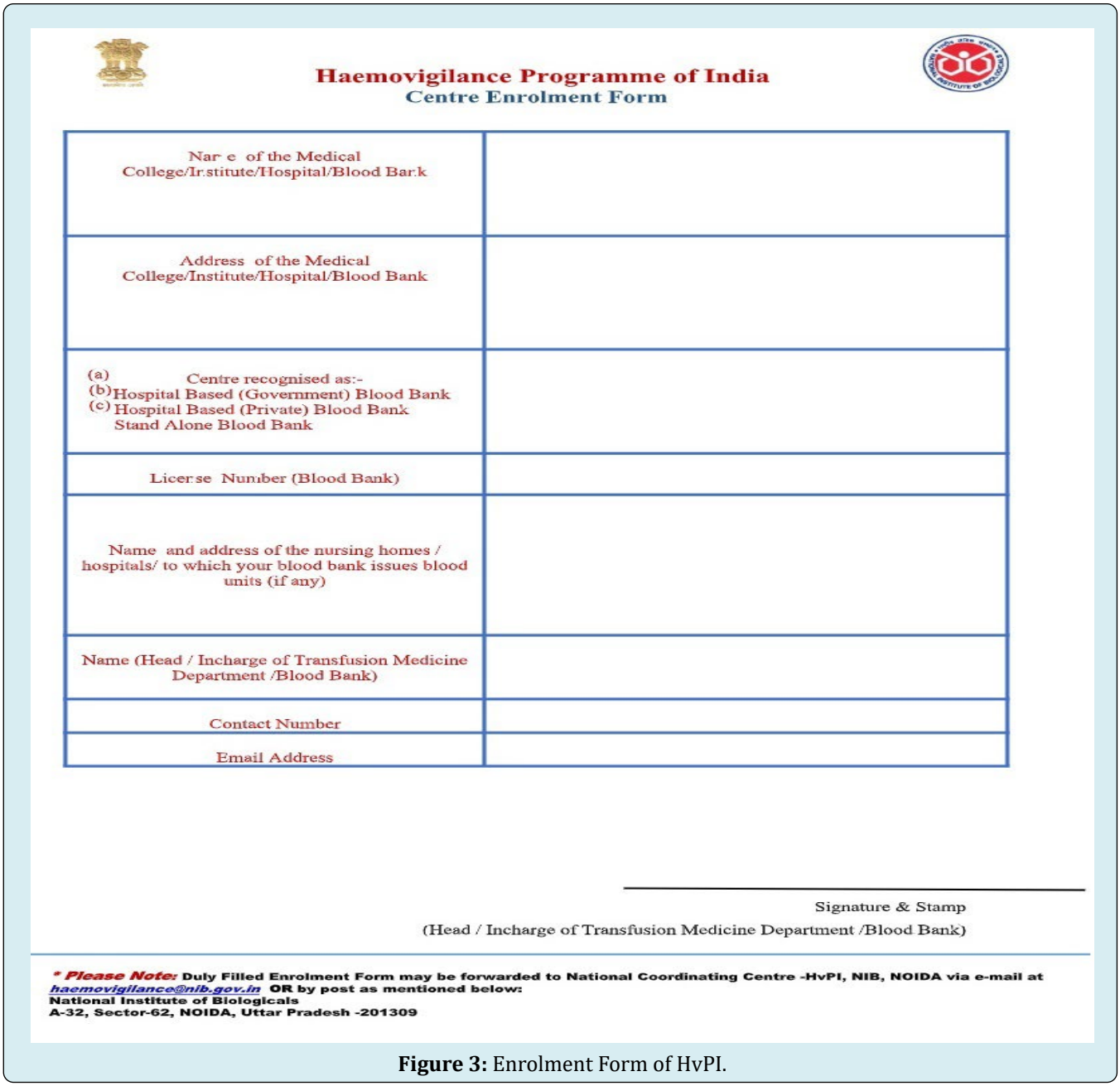

Haemovigilance Programme of India
Centre Enrolment Form

Name of the Medical College/Institute/Hospital/Blood Bank	
Address of the Medical College/Institute/Hospital/Blood Bank	
(a) Centre recognised as:- (b) Hospital Based (Government) Blood Bank (c) Hospital Based (Private) Blood Bank Stand Alone Blood Bank	
License Number (Blood Bank)	
Name and address of the nursing homes / hospitals/ to which your blood bank issues blood units (if any)	
Name (Head / Incharge of Transfusion Medicine Department /Blood Bank)	
Contact Number	
Email Address	

Signature & Stamp
(Head / Incharge of Transfusion Medicine Department /Blood Bank)

* **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

Figure 3: Enrolment Form of HvPI.

International Linkages

India is a member of International Haemovigilance Network (IHN) since 2014. NIB has also provided its services to the Royal Government of Bhutan for establishment of Haemovigilance System in their country [1-5].

Conclusion

Haemovigilance is a continuous process of data collection and analysis of transfusion-related adverse reactions in order to investigate their causes and outcomes, and prevent their further incidence. Haemovigilance is thus a tool to advance the quality of the blood transfusion chain, primarily focusing on safety. Haemovigilance is the quality indicator of a transfusion services. The HvPI envisages protecting & promoting public health by ensuring safe blood transfusion practices in the nation.

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