सत्यमेव जयते

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

HAEMOVIGILANCE NEWSLETTER

Haemovigilance Programme of India

राष्ट्रीय जैविक संस्थान
NATIONAL INSTITUTE OF BIOLOGICALS

HAEMOVIGILANCE GOING VIRTUAL IN PANDEMIC

Safety is Priority

HAEMOVIGILANCE NEWSLETTER VOL. NO. 9, ISSUE 17, JANUARY-JUNE, 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"

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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.

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

Enrollment and Participation of Centers

Total number of enrolled centres at the end of the years 2016 and 2017 was 475 and 615, respectively. Figure 1 shows year-wise enrolment of blood centres under HvPI with the highest number of enrollment in the year 2016.

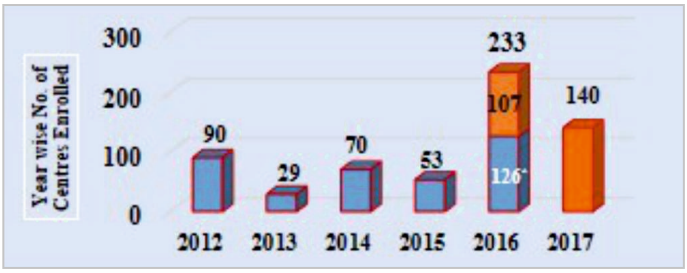


Fig. 1

Analysis of Adverse Transfusion Reactions Based on Various Parameters

After the launch of the first version of reporting software "Haemo-Vigil" in January 2013 and a revised second version in 2016, the number of adverse blood transfusion reaction reports submitted to HvPI is shown in Figure 2, and there is a continuously increasing trend with the highest number of reports submitted to HvPI in 2017.

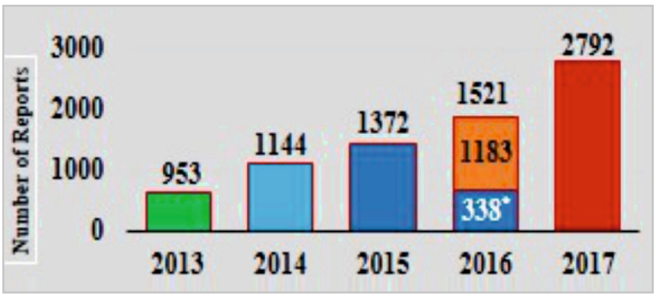


Fig. 2 : *338 reports of 2016 reported via TRRF 1.0 from 1st January, 2016 to 30th April, 2016 were analyzed and published in 2013-2016 report.

A total of 8162 adverse transfusion reactions have been reported to HvPI since inception till Decemer 2017. As depicted in Figure 3, from 2013 to April 30, 2016, a total of 3903 transfusion reactions were reported to HvPI which had occurred in 3807 patients and 96 patients had more than one reaction. A total of 1279 transfusion reactions were reported to HvPI from May 1, 2016, to December 2016, which had occurred in 1169 patients; thus, 108 patients had suffered more than one reaction and 2980 transfusion reactions were reported in 2017 to HvPI which had occurred in 2768 patients; thus, 212 patients had suffered more than one adverse reaction during transfusion.

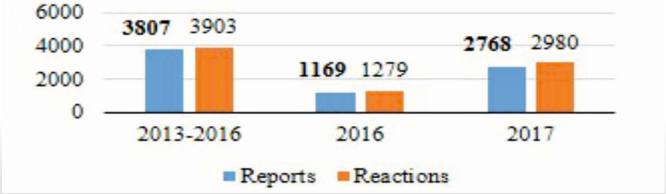


Fig. 3

Observations

Mortalities reported to Haemovigilance Programme of India

A total of 28 death cases has been reported to HvPI since inception, with 17 cases reported from 2013 to April 30, 2016, 3 cases reported from May 1, 2016, to December 30, 2016, and 8 cases in the year 2017.Among 28 death cases, 14 cases were unlikely related to transfusion and only 14 were due to possible/probable immutability.

Rate of Adverse Transfusion Reactions Reported to Haemovigilance Programme of India from May 2016 to December 2017

The overall incidence of adverse reactions reported to HvPI from May 1, 2016, to December 31, 2017 was 8.4 per 10,000 of blood products transfused with a rate of 8.5 in 2016 and 8.3 in 2017.

Age Group Wise Distribution of Males and Females

Total number of males and females with age groups reported to HvPI in 2016-2017 is shown in Table 1.

Table 1:

Age Category	Males 2016 - 2017	Females 2016 - 2017	Total
Pediatric (<=12 Years)	46 - 142	35 - 66	289
Adolescent (12 to <=18)	35 - 69	40 - 65	209
Adult (>18)	463 - 1156	550 - 1270	3439
Total	**544 - 1367**	**625 - 1401**	**3937**

Implicated Blood Products

A total of 1204 blood products were implicated in causing adverse reactions in 1169 patients, 17 patients were transfused more than one blood product from May 1, 2016, to December 31, 2016. A total of 2823 blood products were implicated in causing adverse reactions in 2768 patients, 30 patients were transfused more than one blood product in 2017. Details of blood products transfused are shown in Figure 4. Any other products included washed packed red blood cells (PRBCs), cryosupernatant plasma, and platelet-rich plasma.

Fig. 4

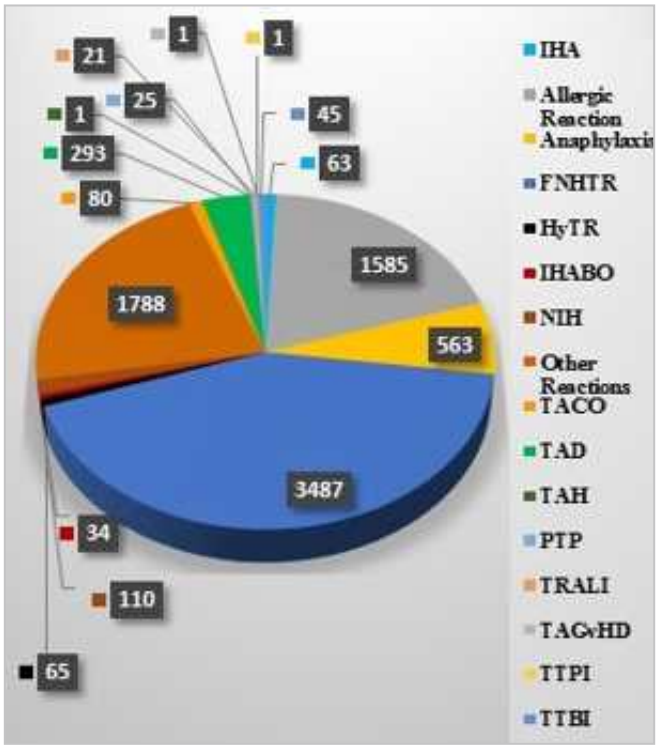


Fig. 5 : Overall distribution of adverse transfusion reactions

Table 2. Distribution of adverse transfusion reactions year wise from 2013to 2016

Adverse Reaction	2013-2016* (%)	2016 (%)	2017 (%)
Immunological Haemolysis due to other Allo-Antibodies	58 (1.49)	4 (0.31)	1 (0.03)
Allergic Reaction	N/A**	456 (35.66)	1129 (37.89)
Anaphylaxis/Hypersensitivity	495 (12.68)	22 (1.72)	46 (1.54)
FNHTR	1594 (40.84)	627 (49)	1266 (42.5)
Hypotensive Transfusion Reaction	0	25 (1.95)	40 (1.34)
Immunological Haemolysis due to ABO Incompatibility	22 (0.56)	5 (0.4)	7 (0.23)
Non Immunological Haemolysis	84 (2.15)	6 (0.47)	20 (0.67)
Other Reactions	1476 (37.82)	57 (4.46)	255 (8.56)
TACO	26 (0.67)	14 (1.1)	40 (1.34)
TAD	93 (2.38)	47 (3.7)	153 (5.13)
Transfusion associated hypertension	0	0	1 (0.03)
PTP	25 (0.64)	0	0
TRALI	10 (0.25)	3 (0.23)	8 (0.27)
TAGvHD	1 (0.03)	0	0
Transfusion Transmitted Parasitical Infection (malaria)	1 (0.03)	0	0
TTBI	18 (0.46)	13 (1.00)	14 (0.47)
Total	3903	1279	2980

*Up to 30th April, 2016 before new Haemo-Vigil Software was launched
**Covered under Anaphylaxis/Hypersensitivity Category till 30th April, 2016 before new Haemo-Vigil Software was launched

Summary and Key Recommendations

The participation of blood centers in HvPI is increasing continuously. A total number of reports submitted to HvPI were 1183 in 2016 (May 1, 2016, to December 31, 2016) plus 338 (January 1, 2016, to April 30, 2016, included in the TRRF version 1 report) and 2792 in 2017. A total of 4259 transfusion reactions of the year 2016 and 2017 were included and reviewed. These were based on the new Haemo-Vigil software incorporating TRRF version 2. Thirty-eight reports were excluded from the analysis, 14 reports from 2016 data, and 24 reports from 2017 data due to three main reasons after review: incomplete data for analysis 17 reports, absence of a transfusion reaction 12 reports, and discrepant data 9 reports.

The overall incidence of adverse reactions reported to HvPI from May 1, 2016, to December 31, 2017, was 8.4 per 10,000 of blood products transfused with a rate of 8.5 in 2016 and 8.3 in 2017. FNHTRS and allergic reactions continue to remain the most frequently reported adverse transfusion reactions. Better discrimination between mild-to-moderate allergic reactions and anaphylaxis was achieved with the TRRF version 2. Transfusion reactions with respiratory complications such as TRALI, TACO, and TAD were better defined. The broad group of "other reactions" narrowed to more specific diagnoses.

About 88%–89% apheresis platelets and almost 70% RDPs were transfused within 1 h of issue. Plasma components were also largely transfused (70%) within 1 h. Two-third of platelets and one-third of FFPs were transfused within 30 min. However, only one-third of red cell components were transfused within 30 min of issue. Awareness of good bedside transfusion practices needs to be increased.

FNHTRs constituted 49% of all transfusion reactions reported in 2016 (May 1 to December 31) and 42.5% in 2017. These were defined into three categories, and it was noted that milder reactions were more common, characterized by either chills and rigors alone or 1°C rise in temperature. The most frequently implicated blood component was PRBC. This reflects the fact that the most commonly transfused blood component in clinical settings are red cells. Leukofiltered PRBCs had less FNHTR rate as compared to buffy coat-reduced PRBC and nonleukoreduced PRBCs. Whole blood and plasma/platelet products had less reaction rate than PRBCs. It may be related to the age of storage of PRBCs and/or underreporting of febrile transfusion reactions with plasma/platelet products and needs further elucidation.

Allergic reactions constituted the second most commonly encountered acute transfusion reactions. Allergic reactions comprised 456 (35.66%) reactions of 1279 reported reactions in 2016 and 1129 (37.89%) reactions of 2980 reported reactions. Apheresis platelets were seen to have the highest reaction rate. Anaphylactic reactions constituted only a small proportion of all acute reactions, with 1.72% in 2016 and 1.6% in 2017. The implication rate was maximum with apheresis platelets both in 2016 and 2017. One death due to the reaction was reported in 2016, the imputability was possible. Two death cases associatedwith anaphylaxis were reported in 2017 with a possible imputability.

The TRRF version 2 has captured the anaphylactic reactions with better clarity and accuracy. It is a reaction with a potential fatal outcome, and close monitoring and immediate management of the recipient is essential.

Hemolysis due to other alloantibodies was reported in 1.49% of patients in 2013–2016 reports via TRRF version 1. It was 0.31% in 2016 and 0.03% in 2017 through TRRF version 2. From the new software reports, it seems underreported since more investigations are necessary to diagnose this reaction. Alloantibody screening and identification technologies need to be upgraded in blood centers, as this might not reflect the true incidence in view of significant multi-transfused thalassemia major patients in the country.

Hemolysis due to ABO incompatibility was seen with a frequency of 0.56% in the 2013–2016 reports, 0.4% in 2016 new software, and 0.23% in 2017. All reactions were due to red cell products except in one O blood group apheresis platelets were transfused out of group. WBIT, blood grouping error, labeling, and bedside administration error were some of the causative factors recorded. These errors are preventable and can be minimized by adhering to standard operating procedures in blood centers and implementation of good bedside clinical practices. Need for education and training in both these areas is required.

Nonimmunological hemolysis was observed with a frequency of 2.15% in 2013–2016 reports, 0.47% in 2016 new software, and 0.67% in 2017. The causative factors were as follows: hemolysis due to inappropriate warming of PRBC units, hemolysis due to infusion of any other fluid through the same BT set, and hemolysis due to freezing of PRBC units and mechanical damage. One patient death was reported in 2017 and imputability was possible.

Education and training for bedside handling, storage, and administration of blood are recommended.

TACO constituted 0.67% of adverse transfusion reactions from 2013 to 2016*, 1.1% in 2016, and 1.34% in 2017. The incidence of reported TACO is increasing with comparatively lower incidence from 2013 to 2016 and higher in 2017. This indicates better awareness and more accuracy of data in the current format. Almost two-third of patients had received repeat transfusions. A total of 3 deaths have been reported to HvPI having a temporal relationship with TACO, imputabilty was unlikely in one case and probable in two cases.

TAD constituted 2.4% of adverse transfusion reactions from 2013 to 2016*, 3.7% in 2016, and 5.13% of adverse transfusion reactions in 2017. Increasing frequency of TAD could reflect better awareness of knowledge and diagnosis of transfusion reactions with a progressive increase in the reach of HvPI.

TRALI constituted 0.26% of adverse transfusion reactions from 2013 to 2016*, 0.23% in 2016, and 0.27% of adverse transfusion reactions in 2017. The incidence of TRALI has remained largely unchanged, more awareness and better reporting is required. All blood products have been implicated It was also causally related to mortality in view of a possible imputability.

TTBI constituted 0.46% of adverse transfusion reactions from 2013 to 2016*, 1.02% in 2016, and 0.47% of adverse transfusion reactions in 2017. TTBI was reported with all types of blood products. Both Gram-negative and Gram-positive bacteria have been implicated. However, posttransfusion patient samples were scant; diagnosis was suspected on the basis of symptoms and culture of the blood bag. Mortality has been observed in one neonatal patient only. It needs to be emphasized to the reporting centers for taking posttransfusion samples of patients for confirmation of the diagnosis of TTBI

An article 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" was published as a special report in Asian Journal of Transfusion Science Issue Volume 14, Issue 2, July-December 2020 and can be accessed from http//www.ajts.org.

First report was published in Asian Journal of Transfusion Science Volume 12, Issue 1, January-June 2018 titled "Haemovigilance Programme of India: Analysis of transfusion reactions reported from January 2013 to April 2016 and key recommendations for blood safety". and can be accessed from http//www.ajts.org

VIRTUAL TRAINING WORKSHOPS

WHO SEAR Countries: Pilot Online Training Program for Haemovigilance (23-Nov-2020 to 27-Nov-2020)

A glance from the training program showing various resource persons and speakers

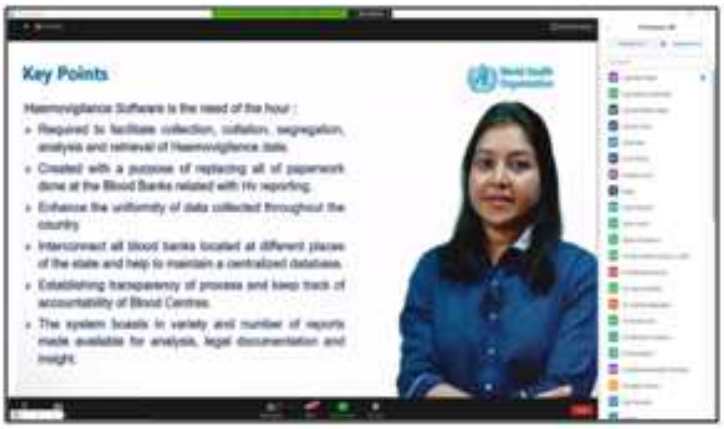
Background : This initiative of WHO in collaboration with JSS Academy of Higher Education and Research, in the present COVID-19 scenario, was directed towards nurturing capacity building of safe blood transfusion practices through a unique mode of online training imparted through prerecorded videos, which in a short duration of time and with a wider regional and national reach to the healthcare providers, will help them in optimum utilization of their limited resources, capitalization of their inherent potential and capabilities.

Aim : The aim of this program was to conduct online training through pre-recorded videos on the concept and implementation of Haemovigilance for the healthcare providers engaged in blood transfusion services in the countries of the SEAR for establishing / upgradation of National systems for haemovigilance throughout the transfusion chain to promote blood safety.

SALIENT FEATURES OF THE TRAINING PROGRAM

- A well-structured five-day pilot online training program was conducted from 23-Nov-2020 to 27-Nov-2020 in which 05 member countries of SEARO participated.
- A total of 26 expert speakers which included 8 international speakers from 7 countries were involved in this training program.
- A total of 27 sessions and eight panel discussion & live interactions.
- Training program was conducted virtually through display of pre-recorded video presentations via zoom conferencing.
- About 139 participants from 05 member countries of SEARO i.e. Nepal, Bangladesh, Indonesia, Maldives and Timor-Leste participated

Head-Haemovigilance Programme of India served as a resource person and was moderator as well as one of the speakers in WHO SEAR countries: Pilot Online Training Program for Haemovigilance conducted from 23-Nov-2020 to 27-Nov-2020. Head-HvPI presented on "Role of Software in capturing adverse transfusion/donor reaction/event and data analysis.



OUTCOME OF TRAINING

The representatives from countries where the hemovigilance system is yet to be developed were motivated to initiate and implement concepts learnt during the program for enhancing the safe transfusion practices. The participating countries felt that conduct of such online programs in future should be continued.

New Blood Centres enrolled under Haemovigilance Programme of India (31) from July, 2020 to December, 2020

CHHATTISGARH
1. Narayana Hrudyalaya MMI Blood Bank, Raipur

HARYANA
1. Umkal Healthcare Pvt Ltd C/o Metro Hospital and Heart Institute, Gurugram
2. JIMS Blood Bank, Jindal Institute of Medical Sciences, Hisar

KARNATAKA
1. Sparsh Super Speciality Hospital Blood Bank, Bengaluru

KERALA
1. Sanjivani Multispecialty Hospital, Alappuzha Dist.
2. Blood Bank, Taluk Head Quarters Hospital, Mannarkkad, Palakkad (Dist)
3. Valluvanad Hospital Blood Bank, Palakkad
4. The Palakkad District Co-operative Hospital and Research Centre, Palakkad

MADHYA PRADESH
1. CHL- Charitable Trust Blood Bank, Indore
2. Jabalpur Hospital and Research Centre, Jabalpur

MAHARASHTRA
1. Dr. D. Y. Patil Hospital and Research Centre Blood Bank, Navi Mumbai
2. P.D. Hinduja National Hospital and Medical Research Centre, Mumbai
3. Reliance Hospital Blood Center/Bank, Navi Mumbai
4. Rainbow Blood and Component Bank (A unit of Rainbow Medical Services and Research Trust), Nagpur
5. Jehangir Hospital Blood Centre, Pune

NEW DELHI
1. Divine Charitable Blood Bank, MayurVihar-I
2. Venkateshwar Hospital, Dwarka
3. Madhukar Rainbow Children's Hospital, Malviya Nagar

PUNJAB
1. GianSagar Medical College and Hospital, Patiala

RAJASTHAN
1. Eternal Heart Care Centre & Research Institute (EHCC), Jaipur

TAMIL NADU
1. Meenakshi Medical College Hospital and Research Institute, Kanchipuram
2. Blood Bank, Government Thiruvarur Medical College, Thiruvarur
3. Fortis Healthcare Limited Blood Bank, Chennai
4. Rotary Central TTK VHS Blood Bank, Chennai

TELANGANA
1. Apollo Institue of Medical Sciences and Research, Hyderabad
2. Continental Hospital Blood Bank, Hyderabad
3. M/s Osmania General Hospital Blood Bank, Hyderabad

UTTAR PRADESH
1. Shanti Gopal Hospital, Ghaziabad
2. Nutema Blood Bank, A Unit of Nutema Health Care Pvt. Ltd, Meerut

WEST BENGAL
1. Blood Bank Command Hospital (Eastern Command), Kolkata
2. OM Blood Centre, Kolkata

NIB-FBDOI National Level CME & workshop on Haemovigilance, Donor Vigilance & Voluntary Blood Donation in COVID-19 Pandemic-Online Webinar

The National Level CME on Haemovigilance, Donor Vigilance and Voluntary Blood Donation in COVID-19 Pandemic was organized by Federation of Blood Donor Organizations of India in association with National Institute of Biologicals (NIB), NOIDA, Ministry of Health and Family Welfare, Government of India on 18th and 19th October, 2020. The two-day webinar was supported by Mani Trust, Kalimpong and Animesh Gosh, Cancer Awareness Center, West Bengal. About 48 participants participated from 16 states all across the country in the said online webinar. This webinar focused on importance of blood donations during the present pandemic situation and on ways and means to continue blood donations post COVID-19 period.

The webinar was inaugurated by Dr. Reba Chhabra, Director i/c, NIB, NOIDA, Dr. Naresh Kumar Bhatia President FBDOI, New Delhi and Shri Apurba Ghosh, Secretary General FBDOI, Kolkata

From Left to Right Dr. Reba Chhabra Director i/c, NIB, Dr. Naresh Kumar Bhatia President FBDOI, New Delhi & Shri Apurba Ghosh, Secretary General FBDOI, Kolkata

First Day (18.10.2020)

SPEAKERS

1. Mr. Apurba Ghosh, Secretary General, FBDOI from Kolkata
2. Subash Mani Singh, Chairman, FBDOI West Bengal
3. Dr. Debasish Gupta, Founder President, FBDOI from Thiruvantapuram,Kerela
4. Dr. SaiprasadBhavsar, Kalimpong
5. Mr. Laxman Rao Santaram, Vice President, FBDOI from Chennai
6. Dr. Akanksha Bist, Scientist, Scientisht II & Head Haemovigilance, NIB, Noida
7. Dr. Chinta Mani Sharma Director, SBTC, Sikkim

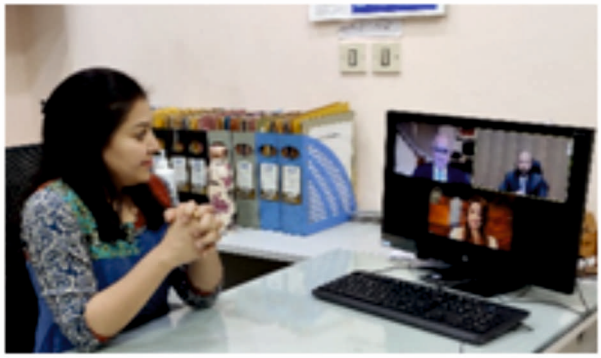
SPEAKERS

1. Mr. SK Singh FBDOI Member from Jamsedpur, Jharakhand
2. Dr. Naresh Chandra Sahu FBDOI Member from Koraput, Odisha
3. Mr. Vikash Mittal FBDOI Member from Haryana
4. Mr. ET Rao from AVBD, Odisha
5. Mr. Rahul Solarpurkar, Secretary, FBDOI Delhi Chapter
6. Mr. DhanajiRane, Chairman FBDOI Maharastra Chapter
7. Mr. Kabi Ghosh, Secretary, FBDOI,West Bengal

Second Day (19.10.2020)

VIRTUAL MEETINGS

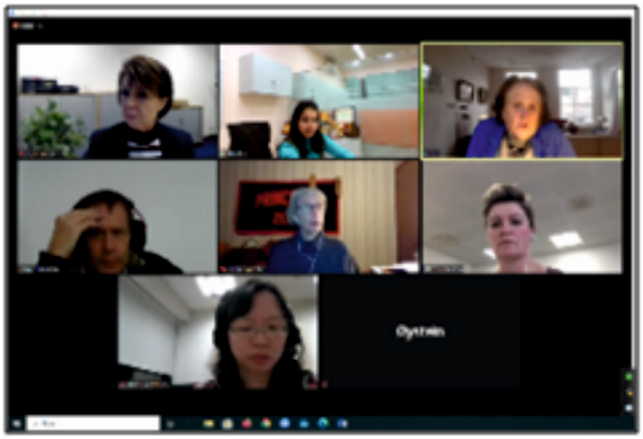
WHO online training : Head HvPI attended the online meeting on 24th August, 2020 at 4.30 via Zoom/Google app to discuss forthcoming WHO online training programme on the concept and implementation of Haemovigilance for the healthcare providers engaged in blood transfusion services in the SEAR countries organized by WHO in collaboration with JSS Academy of Higher Education & Research, Mysuru.



e-Conference on blood donation in time of COVID-19: Head-HvPI invited as a guest speaker in national e-conference on blood donation in time of COVID-19 via webinar organized by Federation of Indian Blood Donors Organizations (FIBDO) member organisation, Hindustan Welfare Blood Donors Club, Phagwara in association with LPU on 1st October, 2020.

IHN Teleconference : Head - HvPI & Secretary of International Haemovigilance Network (IHN) attended teleconference of IHN Board on 07th October, 2020 & 30th November, 2020 at 06:30 pm of Indian Standard Time.

IHN General Assembly : Head - HvPI being the Secretary of IHN attended the virtual annual General Assembly (GA) of the IHN on the 4th of December, 2020 & delivered the presentation on IHN main events of 2019 during the said GA



Meeting of experts of National Blood Donor Vigilance Programme

An online meeting of the Experts to discuss Donor reports submitted via Donor- Vigil Software for year 2018-2019 organized by HvPI Division of National Institute of Biologicals (NIB), NOIDA on 10th December, 2020.

CONVALESCENT PLASMA UNDER SURVEILLANCE

Looking to the Convalescent plasma therapy uses in case of COVID-19 in India, HvPI being the blood safety surveillance programme of the country has started monitoring the safety of Convalescent plasma and a tab of Convalescent plasma has been added in haemovigilance software for reporting adverse reactions associated with Convalescent plasma during or post Blood Donation & Blood Transfusions.

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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 Date of Donation * _____

BP (Diastolic):____ mmHg 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

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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)

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										☐ Repeat 1 to 10
☐	Leucofiltered PRBC										
☐	Random Donor platelets/ pooled										
☐	Apheresis Platelets										
☐	Fresh Frozen Plasma										☐ Repeat > 10
☐	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)			☐ 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 Enroll your Centre under HvPI

Who can enrol?

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

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/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 HAEMOVIGILANCE PROGRAMME OF INDIA

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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/

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