HAEMOVIGILANCE PROGRAMME OF BHUTAN
GUIDANCE DOCUMENT

2017

Blood Safety Program
Health Care and Diagnostic Division
Department of Medical Services
Ministry of Health

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FOREWORD

Hemovigilance has been recognized as one of the most important activities in the field of blood transfusion because of its contribution to increased transfusion safety and improved quality. Despite this, establishing a National Hemovigilance System (HVS) remains a challenge to many countries including Bhutan.

I am happy that the decision to launch the Hemovigilance Program of Bhutan was taken on 11th November 2016 and that the Blood Safety Program, Department of Medical Services has taken the lead and has engaged all relevant stakeholders for developing this Program.

The ultimate goal will be to identify and prevent occurrences and recurrences of transfusion related reactions and adverse events thereby increasing the safety and quality of blood and blood products administration. The information collected through the submission of reaction reports by the hemovigilance centers will facilitate corrective and preventive actions to minimize the potential risks associated with blood collection, processing and transfusion to patients.

Such information will also be helpful to introduce required changes in polices, improve standards, systems and processes and assist in the formulation of national guidelines. In future, the Hemovigilance Program of Bhutan can also contribute to international efforts by linking and sharing data to Regional and International networks.

Such a Program shall therefore bring under its umbrella all relevant stakeholders namely blood centers, hospitals, Committees, Drug Regulatory Authority, Ministry and its development partners. Hence all responsible parties have an important role to play in achieving this goal.

This Guidance document prepared with valuable inputs from experts from National Institute of Biologicals, Transfusion specialists from India and national counterparts, Blood Technical Advisory Committee members, Drug Regulatory Authority, laboratory technicians and nursing personnel shall act as a valuable tool for better implementation of Hemovigilance Program of Bhutan.

I sincerely believe that this document will be a useful guide for all clinicians, technicians, nurses and other health care professionals involved in blood transfusion practice and in public health.

(Dr. Pandup Tshering)
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Department of Medical Services
Ministry of Health

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PREFACE

The contents of this document are designed on the basis of various functional Hemovigilance System in other countries and are modified as per the Bhutanese context as suggested by the participants and resource persons during the First Continued Medical Education on 'Establishing Hemovigilance System in Bhutan' held from 8-11 November 2016 in Thimphu.

This document is a set of information and guidelines helpful in the practice of Haemovigilance. The main aim of its development is to ensure that all personnel involved in Hemovigilance Program of Bhutan (HvPB) get easy access to information on the processes and activities involved in HvPB.

It includes standard case definitions, forms for reporting transfusion related adverse reactions and guidance on the online submission of data through the Hemovigil software.

It can be used as a tool for training all personnel involved in HvPB. The document will be amended from time to time as per the requirements after obtaining necessary approval from competent authority.

Contents

INTRODUCTION

Blood transfusion is a lifesaving medical intervention. However, transfusion of blood and blood products is not without risks and it can lead to complications which could be life threatening in few cases. Transfusion of blood and blood products may be associated with adverse events or/and reactions or events such as transmission of blood borne pathogens including viruses, bacteria and parasites. Non-infectious hazards of transfusion can also harm the patients.

Systematic and proactive surveillance of events during and after administration of blood products helps to detect and identify adverse effects of blood transfusion and can be very effective in improving both patient safety and quality and safety of blood.

Haemovigilance is a continuous process of data collection and analysis of blood transfusion related Adverse Events and Reactions (AE/AR), investigation of their causes and outcomes, and prevention of their occurrence or recurrence.

It includes the identification, reporting, investigation and analysis of AE/AR in blood recipients and blood donors as well as incidents in manufacturing processes, human errors and "near-misses".

A Haemovigilance system is an integral part of quality management in a blood transfusion service, triggering corrective and preventive actions for the continual improvement of the quality and safety of blood products and of the transfusion process.

The establishment of a haemovigilance system involves all relevant stakeholders and should be coordinated between the national blood safety programme under the ministry of health, blood transfusion services, hospital clinical units, hospital transfusion committees, professional bodies, public health institutions, and regulatory agencies

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), 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"

International Hemovigilance Network(IHN)

Importance of reporting adverse reactions associated with blood transfusion

- Reporting is a tool for obtaining information which can be used to improve the product safety.
- A national reporting system therefore can usefully be regarded as a tool to make policy recommendations concerning patient safety.
- Reporting can help identify hazards, risks and provide information as to where the system is breaking down.
- This can help target improvement efforts and system changes to reduce the likelihood of injury to future patients.
- Reporting of Suspected Adverse Reactions in a timely manner facilitates effective risk management.

Importance of hemovigilance program

- Provides objective data on transfusion risks
- Increases awareness of transfusion and its complications among hospital staff
- Annual Haemovigilance reports - opportunities for education on transfusion risks
- Hospital Transfusion Committees (HTxC) can use data to review and improve processes involved in handling and administration of blood and components
- Identify potential hazards which may be present but unrecognized

Establishment of haemovigilance programme of Bhutan (HvPB)

To assure patient safety & promote Public Health, a centralized Haemovigilance Programme that will monitor Adverse Reactions (AR) associated with blood transfusion is being established for the very first time in the country. It will initially start as a pilot project including 4 blood centers namely national, two regional and district blood center at Phuntsholing hospital for duration of 6 months. The implementation of the program will be reviewed after 6 months of the launch and then extended to rest of the blood centers.

The Blood Safety Program (BSP) will be coordinating the Haemovigilance Programme. The identified blood centers will be submitting the data in relation to AR via software program called 'Haemo-Vigil' developed by National Institute of Biologicals (NIB), India which is the National Co-ordination center for Hemovigilance Program of India(HvPI).

The decision to launch the HvPB was taken during the CME on Hemovigilance on 11th November 2016. The CME was conducted by NIB officials and participated by thirty two participants from the nursing profession and medical laboratory technicians, Drug Regulatory Authority, Royal Center for Disease Control and Blood Technical Advisory Committee (BTAC) members. It was financially supported by WHO/OFID Project on 'Prevention of Transfusion Transmissible HIV/AIDS and hepatitis-Phase II.

OBJECTIVES

- Monitor Transfusion Reactions in blood recipients
- Create awareness amongst health care professionals
- Generate evidence based recommendations
- Advise Drug Regulatory Authority (DRA) for safety related regulatory decisions
- Communicate findings to all key stakeholders
- Create national, regional & international linkages
- Be system oriented, focusing on changes in systems & process rather than at individual performance
- It shall be non-punitive but mandatory wherein all blood centers will enroll in a phase wise manner.

RECOMMENDATIONS

For successful implementation of the program, the following are the recommendations identified at different levels**:**

A. **Ministry of Health**

For implementation of haemovigilance at national level, Ministry of Health should:

1. Enshrine surveillance of the entire blood cold chain in the National Blood Policy;
2. Provide effective leadership, direction and governance for the development of a national haemovigilance program;

3. Recognize that haemovigilance is essential for quality and safety of blood donation and transfusion;
4. Develop strategic plans to set up and maintain HvPB which evolves in a stepwise manner from basic to complex;
5. Set up an organizational structure for HvPB;
6. Put in place protocols and tools for data collection, analysis, and use data for learning and process improvement in transfusion chain;
7. Establish mechanisms for coordination and collaboration of all stakeholders involved in blood transfusion chain;
8. Ensure that haemovigilance links efficiently into policy changes;
9. Provide necessary resources both financial and human for effective implementation of HvPB.

B. **Hospitals/health facilities**

For implementation of haemovigilance at hospital and other health care facilities, hospital administrators and clinical staff should:

1. Implement National Guidelines on Clinical Use of Blood for Doctors and Nurses based on National Standards for Blood Transfusion Services including;
    - Positive identification of patients prior to transfusion using unique patient identifier
    - Transfusion triggers;
    - Standard blood ordering schedules;
    - Appropriate documentation of the transfusion process;
    - Audit clinical transfusion practice by constituting Hospital Transfusion Committee (HTxC)
2. Develop mechanisms of reporting of adverse transfusion events (near misses, reactions and incidents) including use of:
    - Standard adverse transfusion reaction forms, incident reporting form;
    - Protocol for investigations of transfusion reactions;
    - Standard laboratory transfusion reaction investigation form;
    - Clear roles and responsibilities for reporting and follow up;
    - Regular review of adverse reactions and incidents by the HTxC.
3. Allocate sufficient human and financial resources to establish an effective Haemovigilance Program at hospital level.
4. Provide periodic training and education on haemovigilance and transfusion safety to all staff involved in the transfusion chain.
5. Form hospital transfusion committees (HTxC).
6. Designate the In-charge of the blood center as the nodal point for all Haemovigilance related activities.

C. **Blood centres**

1. Define roles and responsibilities of blood centres in relation to haemovigilance.
2. Develop systems for reporting of adverse donor reactions and errors including data collection, notification and reporting, monitoring and analysis and evaluation.
3. Establish mechanism for liaison with hospitals, Blood Storage Centers, and HTxC.

4. Secure traceability (bidirectional tracking from donor to transfused patient and vice versa using appropriate IT and Communication tools).
5. Integrate haemovigilance into the quality management system

HvPB–ORGANOGRAM

STAKEHOLDERS-BLOOD CENTERS AND HEALTH CARE PROFESSIONALS, BLOOD SAFETY PROGRAM AND PATIENTS

⇧

NATIONAL BLOOD REGULATORY AUTHORITY (DRA)

⇧

NATIONAL HEMOVIGILANCE COMMITTEE (BTAC)

⇧

NATIONAL HEMOVIGILANCE CENTER (DRA)

⇧

NATIONAL CO-ORDINATING CENTRE FOR HvPB (BSP)

⇧

HEMOVIGILANCE CENTER (ENROLLED BLOOD CENTER)

⇧

CLINICAL AREA OF THE HEALTH FACILITY

RESPONSIBILITIES OF STAKEHOLDERS

1. **Medical and nursing staff of the health facility /hospital**

Physicians and nurses attending the patient having suspected transfusion complications should perform the following functions:

- ✓ Attending nursing staff should report suspected transfusion reaction (STR)immediately to the attending physician;
- ✓ Document the details of the patient's signs and symptoms and the implicated unit in the patient's file;
- ✓ Document the details in 'Blood Transfusion Reaction Form' (Annexure I**)** and follow the protocol for investigation of an acute transfusion reaction (Annexure II);
- ✓ Maintain records of the complications in the patient's medical record, including the report of the investigation completed by the Blood center (Annexure III).

2. **Blood centre**

The Blood center is responsible:

- ✓ To receive the patient's samples and the implicated blood unit;
- ✓ To perform and document the results in the Transfusion Reaction Investigation Form. (Annexure III);

- ✓ To send a copy of the Transfusion Reaction Investigation Form (Annexure III) to the concerned ward;
- ✓ To submit all TRRFs in the Haemo-Vigil Software for onward transmission of data to BSP;
- ✓ At the end of each month, to submit the Monthly Denominator Reporting Form (Annexure VII) in the Haemo-Vigil Software for onward transmission of data to BSP;
- ✓ All transfusion reactions reports must be submitted to Hospital Transfusion Committee or any equivalent Committee;
- ✓ To review the reported transfusion reactions for improving hospital transfusion practices.

3. **National co-ordinating centre (NCC)**

The NCC is responsible for:

- ✓ Oversight and management of Hemovigilance Program;
- ✓ Administrative tasks namely Bhutan NCC role and administrative role;
- ✓ Collection and collation of Haemovigilance data from the TRRFs;
- ✓ Submission of collated data to NHC at DRA for deliberation by the Haemovigilance sub-committee of BTAC;
- ✓ Monitoring the functioning of the centers & quality of the data
- ✓ Investigating underlying causes and providing expert guidance to address the root causes;
- ✓ Preparation of SOPs, guidance documents and training manuals;
- ✓ Providing training to the staff involved in Hemovigilnace;
- ✓ Publication of Haemovigilance data;

4. **National Hemovigilance Center (NHC)**

National Hemovigilance Center at the DRA shall have the following responsibilities:

- ✓ To receive reports of all adverse reactions and events and maintain records of all the serious adverse reactions and events (Annexure IV);
- ✓ To coordinate and organize the National Hemovigilance Committee meetings;
- ✓ To provide feedback to the hemovigilance centers;
- ✓ To take regulatory measures and issue public notifications based on the severity of reactions and events and such other matters related to it;
- ✓ To liaise or collaborate with other international or regional hemovigilance agencies.

5. **Committees**

I. Blood Technical Advisory Committee (BTAC**)**

- ✓ Functions as the National Hemovigilance Committee;
- ✓ Reviews all TRRF and reports to study and ensure quality of reporting
- ✓ Identifies trends and investigates underlying causes;
- ✓ Reviews and finalises the imputability and
- ✓ Make recommendations for regulatory actions
- ✓ Conduct periodic review, monitoring and evaluation of the HvPB

II. Hospital Transfusion Committee (HTxC)

- ✓ Monitoring and reviewing serious adverse effects of transfusion;
- ✓ Taking corrective and preventive measures for improving hospital transfusion practices

HAEMO-VIGIL SOFTWARE

Process of enrolment of the centres under HvPB

All the blood centres will be enrolled under HvPB.

- ✓ The head / in-charge of individual blood center will be the focal point for HvPB.
- ✓ First of all, he/she submits the duly filled Enrolment Form (Annexure V) to the BSP officer.
- ✓ The BSP officer verifies the details in the form.
- ✓ On verification, BSP officer issues the User Id and Password to the focal person of the center.
- ✓ This will allow him/her to access the Bhutan Haemo-Vigil Software for onward transmission of Transfusion Reactions Reports.
- ✓ The focal person will be the only authorised user in his/her center and will not share the password to any other staff. He or she can authorise another staff to submit data in absence or leave.

The home page of Bhutan Haemo- Vigil software has five sections:

1. Transfusion Reaction Reporting Form- to report the adverse transfusion reaction(s).
2. Nil Reaction Reporting- to report in case no adverse reaction has occurred in the particular month.
3. Monthly Denominator Reporting Form- To mandatorily report the denominator details of the blood components/ products on monthly basis.
4. Inbox-to check the status of all information saved & submitted by the centre
5. Edit Request-to send the edit request & edit the TRRF in case the wrong information has been submitted.

Please refer to the Instruction manual for entry of data in HEMO-VIGIL software. (Annexure IX)

STANDARD CASE DEFINITIONS

{Reference: These have been adopted from the document published by International Society of Blood Transfusion (ISBT) working party on Haemovigilance as on June 2013 endorsed by Internal Hemovigilance Network(IHN)}

a. Adverse Event

An adverse event is an undesirable and unintended occurrence before, during or after transfusion of blood or blood component which may be related to the administration of the blood or component. It may be the result of an error or an incident and it may or not result in a reaction in a recipient.

b. Incident

An incident is a case where the patient is transfused with a blood component which did not meet all the requirements for a suitable transfusion for that patient, or that was intended for another patient. It thus comprises transfusion errors and deviations from standard operating procedures or hospital policies that have led to mis-transfusions. It may or may not lead to an adverse reaction.

c. **Near Miss**

A near miss is an error or deviation from standard procedures or policies that is discovered before the start of the transfusion and that could have led to a wrongful transfusion or to a reaction in a recipient.

d. **Adverse Transfusion Reaction (ATRs)**

An adverse reaction is an undesirable response or effect in a patient temporally associated with the administration of blood or blood component. It may, but need not, be the result of an incident

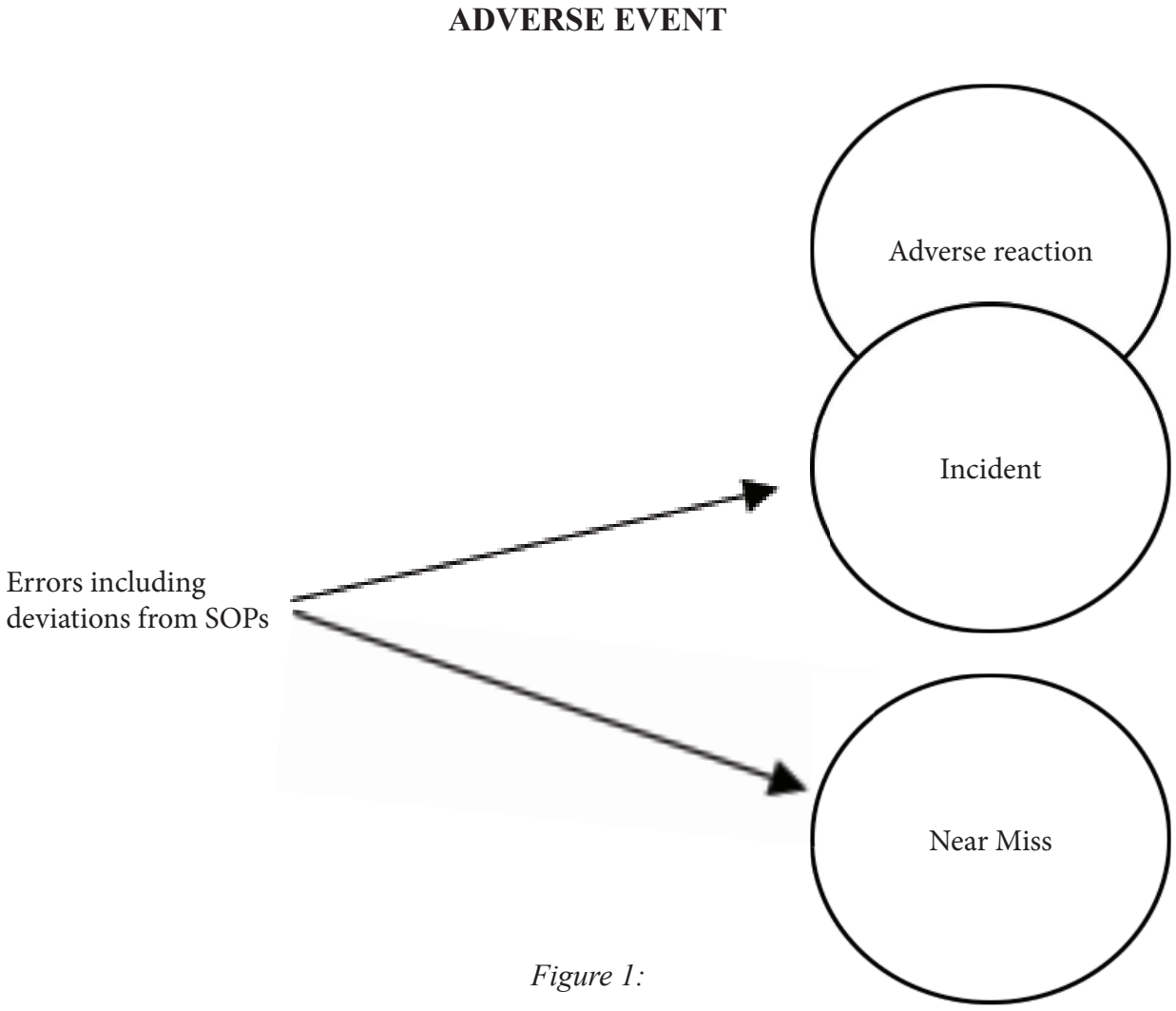
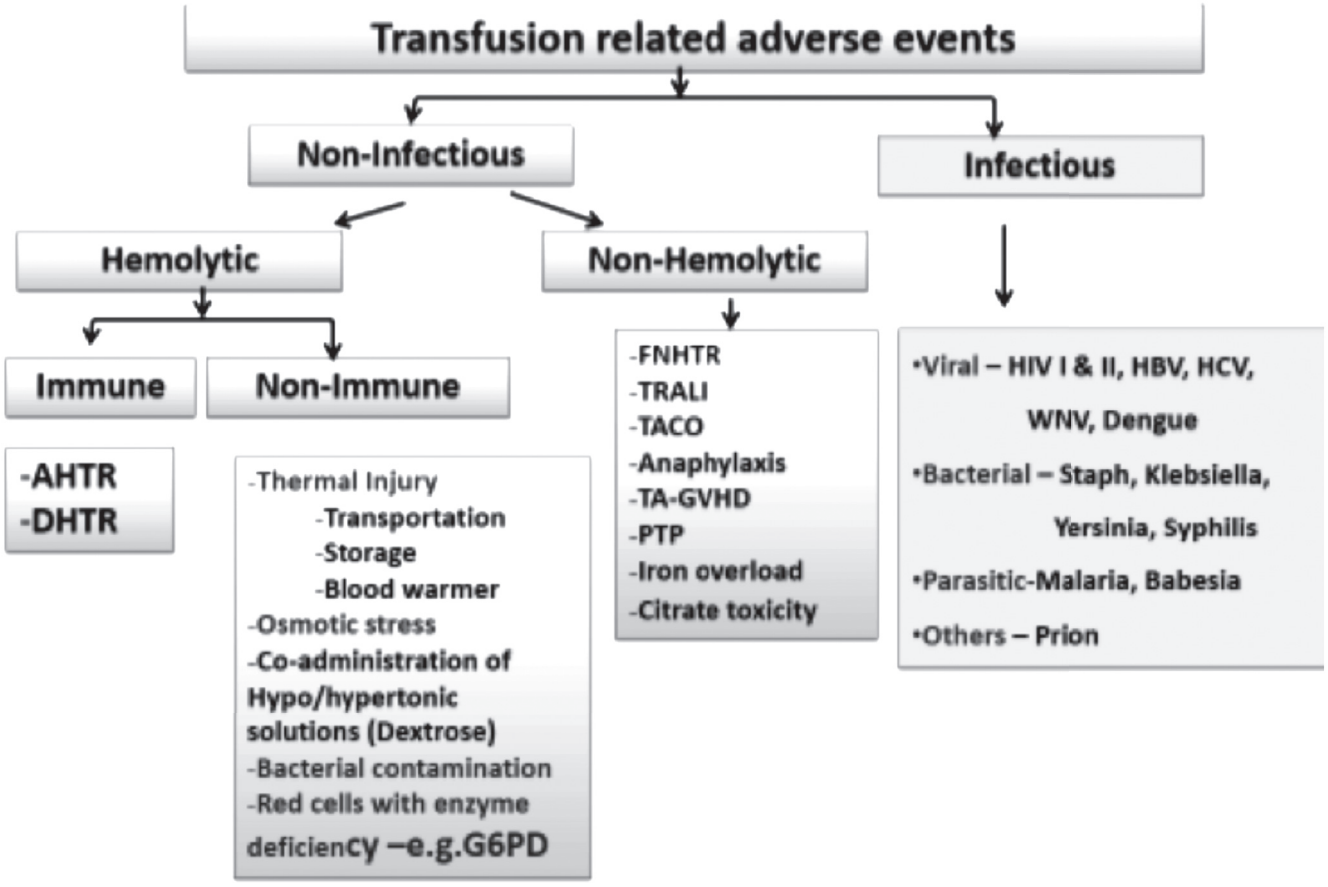


Figure 1:

Figure 2:



NATURE OF TRANSFSUION REACTIONS

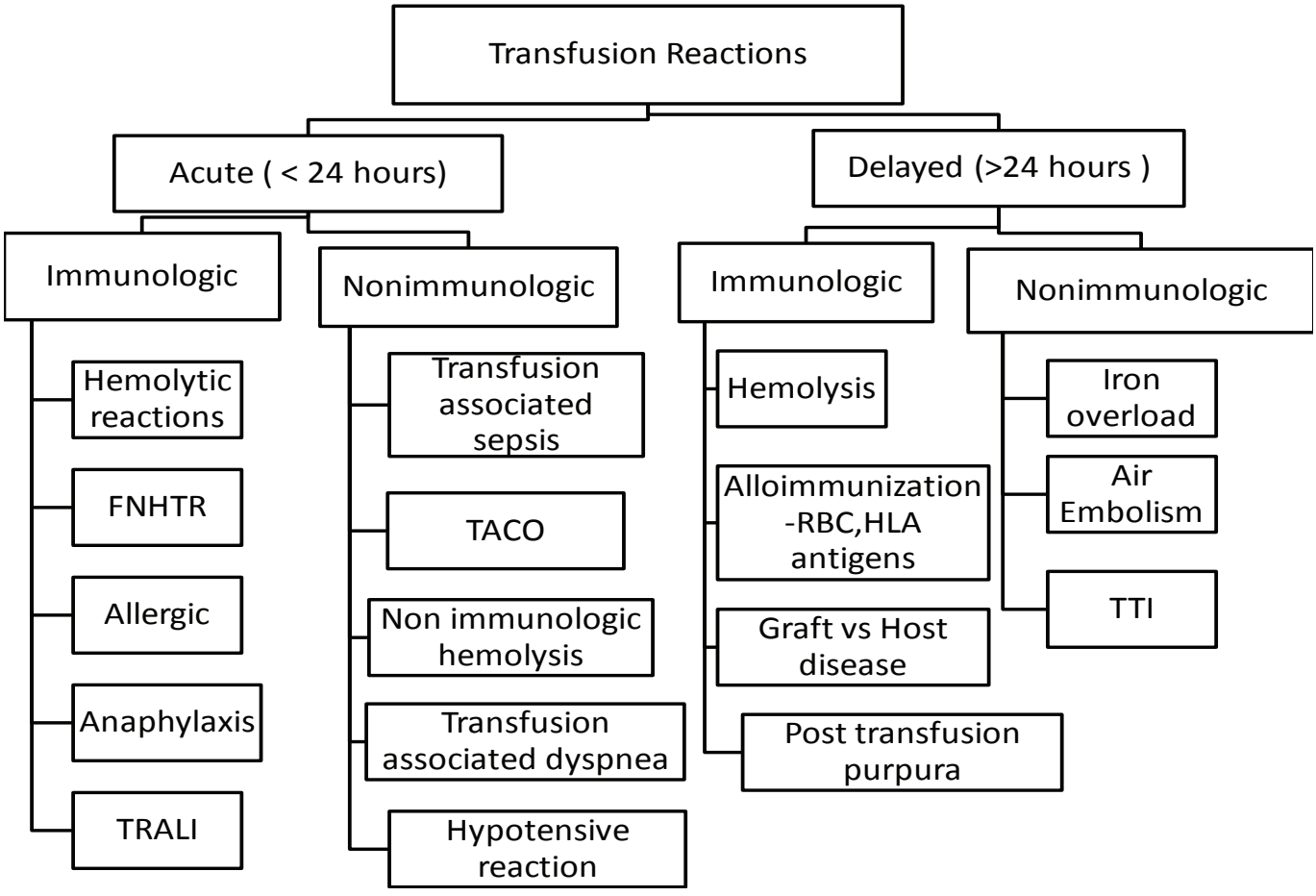
A. Acute Transfusion Reactions (Onset within 24 hours of transfusion)

1. Acute Haemolytic Transfusion Reaction (AHTR)
2. Febrile Non-Hemolytic Transfusion Reaction (FNHTR)
3. Bacterial Contamination
4. Allergic Reaction
5. Anaphylaxis and Anaphylactoid Reaction
6. Transfusion Related Acute Lung Injury (TRALI)
7. Transfusion Associated Circulatory Overload (TACO)
8. Transfusion Associated Dyspnea (TAD)
9. Hypotensive Transfusion Reaction

B. Delayed Transfusion Reactions (Onset after 24 hours of transfusion)

1. Delayed Hemolytic Transfusion Reaction (DHTR)
2. Post Transfusion Purpura (PTP)
3. Transfusion Associated Graft versus Host Disease (TAGvHD)
4. Transfusion Transmitted Viral Infections
5. Transfusion Transmitted Parasitic Infection

Figure 3:



Diagnostic features

Haemolytic transfusion reaction is one in which symptoms and clinical or laboratory signs of increased red cell destruction are produced by transfusion. Haemolysis can occur intravascularly or extravascularly and can be immediate (acute) or delayed.

Acute haemolytic transfusion reaction (AHTR)

An AHTR has its onset within 24 hours of a transfusion. Clinical or laboratory features of haemolysis are present.

Common signs of AHTR are:

- Fever
- Chills/rigors
- Facial flushing
- Chest pain
- Abdominal pain
- Back/flank pain
- Nausea/vomiting
- Diarrhoea
- Hypotension
- Pallor

- Jaundice
- Oligo or anuria
- Diffuse bleeding
- Dark urine

Common laboratory features are:

- Positive DAT
- Hemolysis seen in plasma or serum of the patient
- Haemoglobinemia
- Haemoglobinuria
- Unconjugated hyperbilirubinemia
- Decreased haemoglobin levels
- Increased LDH and AST levels
- Decreased serum haptoglobin

Not all clinical or laboratory features are present in cases of AHTR.
Blood group serology usually shows abnormal results but absence of immunological findings does not exclude AHTR. AHTR may also be due to erythrocyte auto-antibodies in the recipient or to non-immunological factors like mechanical factors inducing haemolysis (malfunction of a pump, of a blood warmer, use of hypotonic solutions, etc.).

Delayed Haemolytic Transfusion Reaction (DHTR)
A DHTR usually manifests between 24 hours and 28 days after a transfusion and clinical or laboratory features of haemolysis are present.

Signs and symptoms are similar to AHTR but are usually less severe. DHTR may sometimes manifests as an inadequate rise of post-transfusion haemoglobin level or unexplained fall in haemoglobin after a transfusion..

Laboratory findings:

- Blood group serology usually shows abnormal results.
- Demonstration of clinically significant antibodies against red blood cells which were previously absent (as far as is known) and when there are no clinical or laboratory features of haemolysis. This term is synonymous with allo-immunization.

Delayed Serologic Transfusion Reaction(DSTR)
There is a DSTR when, after a transfusion, clinically significant antibodies against red blood cells are now detected which were previously absent. There are no clinical and laboratory features of hemolysis. This term is similar to allo-immunization

Non-Haemolytic transfusion reaction
Febrile Non-Haemolytic transfusion reaction (FNHTR).
Characterised by one or more signs and symptoms :

- Fever ($\geq 38\ ^0C$ oral or equivalent and a change of $\geq 1\ ^0C$ from pre-transfusion value),

- chills/rigors
- This may be accompanied by headache and nausea.
- At times fever may be absent, only chills or rigors are manifested.

Note: FNHTR is suspected if occurring during or within four hours following transfusion without any other cause such as haemolytic transfusion reaction, bacterial contamination or underlying condition.

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FOR THE PURPOSE OF INTERNATIONAL COMPARISONS ONLY THE MOST SERIOUS CASES OF FNHTR SHOULD BE ACCOUNTED FOR:

- fever ($\geq$39 ^{0}C oral or equivalent and a change of $\geq$2 ^{0}C from pre-transfusion value) and
- chills/rigors

Allergic reaction

An allergic reaction may present only with mucocutaneous signs and symptoms:

- Morbilliform rash with itching
- Urticaria (hives)
- Localized angioedema
- Edema of lips, tongue and uvula
- Periorbital pruritus, erythema and edema
- Conjunctival edema

Note: Occurring during or within 4 hours of transfusion. In this form it usually presents no immediate risk to the life of patient and responds quickly to symptomatic treatment like anti-histamine or steroid medications. This type of allergic reaction is called 'minor allergic reaction' in many haemovigilance systems.

For the purpose of classification this type of allergic reaction would be non-severe.

***Anaphylactic reaction*:** Such a reaction usually occurs during or very shortly after transfusion.

Signs and symptoms:

- When an allergic reaction involves respiratory and/or cardiovascular systems causing airway compromise or severe hypotension requiring vasopressor treatment (or associated symptoms like hypotonia, syncope).
- Tightness in the throat, dysphagia, dysphonia, hoarseness,
- Dyspnoea, cough, wheezing/bronchospasm, hypoxemia, stridor

For the purpose of classification, this type of allergic reaction would be graded as II(severe), III(life-threatening) or IV(death) depending on the course and outcome of the reaction.

Cause:

An allergic reaction classically results from the interaction of an allergen and preformed antibodies. A rise of mast cell tryptase can support the diagnosis of an allergic reaction. IgA deficiency and/or anti-IgA in the recipient has been associated with severe allergic reactions but is only one infrequent cause out of many others.

Transfusion associated graft-versus-host disease (TA-GvHD)
TA-GvHD is a clinical syndrome characterized by symptoms of fever, rash, liver dysfunction, diarrhoea, pancytopenia and findings of characteristic histological appearances on biopsy occurring 1-6 weeks following transfusion with no other apparent cause.

The diagnosis of TA-GVHD is further supported by the presence of chimerism**.**

Post transfusion purpura (PTP)
PTP is characterized by thrombocytopenia arising 5-12 days following transfusion of cellular blood components with findings of antibodies in the patient directed against the Human Platelet Antigen (HPA) system**.**

Transfusion-related acute lung injury (TRALI)
In patients with no evidence of acute lung injury (ALI) prior to transfusion, TRALI is diagnosed if a new ALI is present: (All five criteria should be met)

- Acute onset
- Hypoxemia
    - $PaO_2 / FiO_2 < 300$ mm Hg or
    - Oxygen saturation is < 90% on room air or
    - Other clinical evidence
- Bilateral infiltrates on frontal chest radiograph
- No evidence of left atrial hypertension (i.e. circulatory overload)
- No temporal relationship to an alternative risk factor for ALI during or within 6 hours of completion of transfusion.

Alternate risk factors for ALI are:

- Direct Lung Injury
    - Aspiration
    - Pneumonia
    - Toxic inhalation
    - Lung contusion
    - Near drowning
- Indirect Lung Injury
    - Severe sepsis
    - Shock
    - Multiple trauma
    - Burn injury
    - Acute pancreatitis
    - Cardiopulmonary bypass
    - Drug overdose

It has been suggested by the Toronto TRALI Consensus Panel to add a category of *Possible TRALI* that would have the same definition as TRALI except for the presence of a temporal relationship to an alternative risk

factor for ALI (as described above). In such a circumstance TRALI should be indicated with a '*Possible'* imputability to transfusion.

TRALI is therefore a clinical syndrome and presence of anti-HLA or anti-HNA antibodies in donor(s) or confirmation of cognate antigens in recipient are required for diagnosis.

***Transfusion associated dyspnea (TAD*)**
TAD is characterized by respiratory distress within 24 hours of transfusion that does not meet the criteria of TRALI, TACO, or allergic reaction. Respiratory distress should be the most prominent clinical feature and should not be explained by the patient's underlying condition or any other known cause.

Transfusion associated circulatory overload (TACO)
TACO is characterized by any 4 of the following:

- Acute respiratory distress
- Tachycardia
- Increased blood pressure
- Acute or worsening pulmonary edema on frontal chest radiograph
- Evidence of positive fluid balance occurring within 6 hours of completion of transfusion.

An elevated B-typnatriuretic peptide(BNP) is supportive of TACO.

Hypotensive transfusion reaction
This reaction is characterized by hypotension defined as a drop in systolic blood pressure of ≥ 30 mm Hg occurring during or within one hour of completing transfusion and a systolic blood pressure ≤ 80 mm Hg.

Most reactions do occur very rapidly after the start of the transfusion (within minutes). This reaction responds rapidly to cessation of transfusion and supportive treatment. This type of reaction appears to occur more frequently in patients on ACE inhibitors.

Hypotension is usually the sole manifestation but facial flushing and gastrointestinal symptoms may occur. All other categories of adverse reactions presenting with hypotension, especially allergic reactions, must have been excluded. The underlying condition of the patient must also have been excluded as a possible explanation for the hypotension.

Other transfusion reactions:
Haemosiderosis
Transfusion-associated haemosiderosis is being defined as a blood ferritin level of >1000 micrograms/l, with or without organ dysfunction in the setting of repeated RBC transfusions.

Hyperkalemia
Any abnormally high potassium level (> 5 mml/l, or >1.5 mml/l net increase) within an hour of transfusion can be classified as a transfusion- associated hyperkaliemia.

Unclassifiable Complication of Transfusion (UCT)
Occurrence of an adverse effect or reaction temporally related to transfusion, which cannot be classified according to an already defined ATE and with no risk factor other than transfusion and no other explaining cause.

Table 1:

Differential Diagnosis of TR

Presenting with fever	
Acute	**Delayed**
• Acute hemolytic • Febrile Non hemolytic • Sepsis • TRALI	• Delayed Hemolytic • TA-GVHD
Presenting without fever	
Acute	**Delayed**
• Allergic • Hypotensive • TACO	• Post transfusion purpura • Iron overload

Table 2:

Differential Diagnosis of Acute TR

Clinical symptoms	AHTR	FNHTR	Allergic	Anaphyl axis	TACO	TRALI	Bacterial sepsis
Fever	+++	+	-	-	-	++	++++
Hypotension	++	-	-	+++	+++	+	+++
Urticarial rash	-	-	+++	+++	-	-	-
Resp. Distress	+	-	-	++++	++++	++++	++
Hburia	+++	-	-	-	-	-	-
Urine output	+++	-	-	-	+	-/+	-/+
Non Specific Symptoms	++++	-	-	-	+	-	-

ISBT Table of Reportable Serious Adverse Reactions (SARs)

Table 3:

Serious Adverse Reactions	Clinical Features	Laboratory Features
Immunological Haemolysis due to ABO incompatibility	Fever, chills/rigors, facial flushing, chest pain, abdominal pain, back/flank pain, nausea/vomiting, diarrhoea, hypotension, pallor, jaundice, oligoanuria, diffuse bleeding, dark urine, decreased haemoglobin levels. Reactions may occur within 24 hours (acute) or may not manifest for up to 28 days (delayed)	Blood group serology shows ABO incompatibility /mismatch between recipient and donor, DAT positive Haemoglobinuria , unconjugated hyperbilirubinaemia, increased LDH and AST levels, decreased serum haptoglobin
Immunological Haemolysis due to other allo-antibody	As above	DAT positive Haemoglobinuria , unconjugated hyperbilirubinaemia, increased LDH and AST levels, decreased serum haptoglobin, Blood group serology shows either allo-antibodies to donor red cells or auto-antibodies in the recipient
Non-immunological haemolysis	As above	Due to non-immunological nature, possibility of mechanical factors such as malfunction of a blood warmer or pump or uncontrolled squeezing of the blood in the unit, freezing or uncontrolled warming of blood or the use of hypotonic solutions (Ringers, dextrose etc)
Transfusion-transmitted bacterial infection. **Note** – MUST be reported	Fever, rigors and joint pain with no evidence of symptoms pre-transfusion or alternative source of infection.	Positive blood cultures from recipient and donor pack (matching organisms) or at least one component received by the infected recipient shown to contain the agent of infection

Serious Adverse Reactions	Clinical Features	Laboratory Features
Anaphylaxis/hypersensitivity	Mucocutaneous signs and symptoms including urticaria, rash, pruritus, localised angioedema, oedema of lips, tongue, uvula and conjuctiva with airway compromise or severe hypotension requiring vasopressor treatment (or associated symptoms like hypotonia, syncope). Respiratory symptoms may be laryngeal (throat tightness, dysphagia, dysphonia, hoarseness, stridor) or pulmonary (dyspnoea, cough, wheezing/bronchospasm, hypoxemia) Usually occurs during or very shortly after transfusion.	Rising mast cell tryptase levels or IgA deficiency and/or anti- IgA in the recipient
Transfusion related acute lung injury(TRALI)	Hypoxaemia ($PaO_2/FiO_2 < 300$ mm Hg or O_2 sats < 90% on room air), bilateral infiltrates on frontal chest X-ray, no evidence of TACO, no temporal relationship to an alternative risk factor for ALI during or within 6 hours of completion of transfusion. Usually acute onset.	
Transfusion-transmitted viral infection (HBV)		Include if the recipient shows evidence of infection post-transfusion and there was no evidence of infection prior to transfusion or any alternative source of the infection, PLUS either at least one component received by the infected recipient was shown to contain the agent of infection or at least one component received was donated by a donor who has evidence of the same transmissible infection.
Transfusion-transmitted viral infection (HCV)		As above
Transfusion-transmitted viral infection HIV 1& 2		As above
Transfusion-transmitted viral infection – other		As above

Serious Adverse Reactions	Clinical Features	Laboratory Features
Post transfusion purpura(PTP)	Bruising, severe haemorrhage, oozing wounds. Usually occurs 5-12 days post transfusion.	Thrombocytopenia (5-12 days post transfusion) and anti-HPA antibodies present
Transfusion associated graft versus host disease(TAGVHD)	Fever, rash, liver dysfunction, diarrhea. Usually occurs 1-6 weeks after transfusion.	Pancytopenia, characteristic histological appearances on bone marrow biopsy, bone marrow hypoplasia, chimerism
Other serious reaction(s) - Specify	E.g. Febrile non haemolytic transfusion reactions (FNHTR) where fever >= 39 ºC oral or equivalent and a change of >= 2 ºC from pretransfusion value, chills, rigors, headache, nausea. Usually occurs within 4 hours of transfusion and without any evidence of hemolysis, bacterial contamination or underlying condition. E.g. Transfusion associated circulatory overload (TACO) – acute respiratory distress, tachycardia, increased blood pressure, acute or worsening pulmonary oedema on frontal chest x-ray, evidence of positive fluid balance. Usually occurs within 6 hours of completion of transfusion. E.g. Transfusion associated dyspnea (TAD) – respiratory distress occurring within 24 hours of transfusion but without the symptoms of TRALI, TACO or allergic reactions and not explained by any underlying condition	

The following points must be included while taking a patient's history while classifying the nature of reactions.

Table 4:

Patient History

Diagnosis	• Gives clue about type of reaction • Eg: transfusion in anemic patient will have the probability of having TACO
H/O transfusion/ pregnancy	• Allo immunization can result in AHTR/ FNHTR
Blood component transfused	• If plasma - whether the reaction is caused by plasma protein
Type of Patient	• Multi transfused prone to have recurrent FNHTR
IgA deficiency	• Anti IgA may cause anaphylaxis
Medicaltions	• Pyrogenic agents known to cause fever such as Amphotericin • ACE inhibitors causes hypotensive reactions • Pruritogenic agents such as vancomycin

IMPUTABILITY

Imputability means the likelihood that an Adverse Reaction in a recipient can be attributed to the Blood or Blood Component transfused.

It is the assessment of the strength of relation to the transfusion of the ATE, once the investigation of the Adverse Transfusion Event (ATE) is completed.

Imputability levels:

Term	**Assessment Scale**
Definite (Certain)	When there is conclusive evidence beyond reasonable doubt that the adverse event can be attributed to the transfusion.
Probable (Likely)	When the evidence is clearly in favour of attributing the adverse event to the transfusion.
Possible	When the evidence is indeterminate for attributing the adverse event to the transfusion or an alternate cause.
Unlikely (Doubtful)	When the evidence is clearly in favour of attributing the adverse event to causes other than the transfusion.
Excluded	When there is conclusive evidence beyond reasonable doubt that the adverse event can be attributed to causes other than the transfusion.

Grading of severity

Severity-degree	*Clinical importance of a reaction*
Grade I (non severe)	Resolves on symptomatic treatment
Grade II (Severe)	Requires medical or surgical intervention &/ prolongs hospital stay
Grade III (life threatening)	Require major intervention like ICU care
Grade IV (Death)	Resulting in to mortality

ANNEXURE I

BLOOD TRANSFUSION REACTION FORM (TO BE FILLED BY THE NURSE)

Patient's name: _____, DoB /Age & Sex: _____/__,

CID No. /Hospital Reg. No.: _____, Diagnosis: _____,
Hospital & Ward:_____

Date / Time transfusion started:_____

Date / Time of onset of reaction:_____

Time of discontinuing the unit:_____

Doctor informed: Yes/No and at what time & date:_____

Blood unit no.:_____, The unit is WB/PRC/ Plasma / Platelet (to circle) and
Volume of blood /component transfused:_____ml

Vitals

Pre-transfusion	Temperature: °C	Pulse: /m	BP: mmHg	RR: /m
At time of reaction	Temperature: °C	Pulse: /m	BP: mmHg	RR: /m

Please tick the relevant signs and symptoms in the box

General S/S		Pain		Circulatory S/S	Respiratory S/S		Renal S/S
fever	restlessness	chest pain	pain at site of blood given	Tachycardia	dyspnoea	CXRay finding	hematuria
chills / rigors	anxiety	abdominal pain	back/flank pain	high BP	cough		Oliguria
flushing	itching			low BP	wheezing		
nausea	jaundice			raised JVP	Hypoxemia		
vomiting	edema at any site			arrythmias			

Any IV fluid or drug given through the same venous line as that of the blood transfusion? Yes/No
If yes, specify:_____

Any heating, freezing done on the blood unit before transfusion: Yes/No
If yes, specify:_____
Was the patient under anesthesia during transfusion? Yes/No
Did the reaction occur during referral of patient from one facility to another: Yes/No
Previous H/o Transfusion: Yes/No H/o previous reaction: Yes/No
In case of females: H/o pregnancy or abortion in the last three months
Name/signature of the staff reporting the reaction: _____,
Date/Time reported:_____

ANNEXURE II

PROTOCOL FOR THE INVESTIGATION OF ACUTE TRANSFUSION REACTION

The attending physician/nurse must send the following for investigation

A. Patient's Samples

Type of sample and vial	Volume	Laboratory investigations required are:	To send to
Plain clotted sample (red)	4ml	Repeat ABO, Rh, antibody screen and crossmatching	Blood Center
Plain clotted sample (red)	4ml	Liver functions, renal functions and electrolytes	Biochemistry
EDTA sample (purple)	2ml	Direct Coombs test	Blood Center
EDTA sample (purple)	2ml	Complete blood count and Peripheral blood film	Hematology
Sodium citrated sample	2ml	Coagulation profile	Hematology

B. The implicated blood unit /bag to the blood center for Repeat ABO, Rh, crossmatching and blood culture for suspected septic reaction.

ANNEXURE III

TRANSFUSION REACTION INVESTIGATION FORM

Patient's name: _____, DoB /Age &sex: _____,

CID No. /Hospital Reg. No.: _____, Diagnosis: _____,

Name of Hospital & Ward:_____ Date: _____

a)Repeat ABO grouping

	Cell grouping			Serum grouping			ABO group	Rh group	Remarks
	-A	-B	-AB	Ac	Bc	Oc			
Pre-transfusion patient's sample no:___									
Post-transfusion patient's sample no: ___									
Blood sample from the bag issued no:___									
Blood sample from the bag returned no:___									

b) Direct Anti-globulin test on the post transfusion patient's sample: Positive/Negativec) Physical examination of the patient's post-transfusion sample: Hemolysed/ Not Hemolysed.

d) Cross-matching with patient's post –transfusion sample and blood sample from the bag

RT	37ºC	IAT	CCC	Compatible or not

e) Cross-matching with patient's pre-transfusion sample and blood sample from the bag

RT	37ºC	IAT	CCC	Compatible or not

f) Antibody screen result with post–transfusion sample of patient: Positive/Negative/Not done
g) Blood culture result of the unit: Positive/Negative/Not done
h) Blood culture result of the patient: Positive/Negative/Not done
i) Patient outcome: Recovered, recovered with sequel, died or unknown
j)Grade: I, II, III or IV (Circle)
k) Imputability: Definite, Probable, Possible, Unlikely or Excluded (Circle)
Comments of the Blood Center IC/staff: _____

ANNEXURE IV

FORM: VI-ATR
REGULATION 82
SERIOUS ADVERSE REACTION/EVENTS IN PATIENT/DONOR REPORTING FORM (CONFIDENTIAL)

(Report identification No._____)

If you are suspicious that adverse reaction/events may be related to blood donation/transfusion of a blood or a blood products, PLEASE COMPLETE THIS FORM

A.PATIENT/DONOR DETAILS

Patient/Donor name: ……
Age/Sex: ……
CID No: …….
Patient's Diagnosis: ……

B. SUSPECTED BLOOD UNIT (for blood transfusion reaction)

Type of the blood product(s)	Unit no. & exp date	Volume transfused (ml)	Reason(s) for Transfusion	Date and Time of start of transfusion	Date and Time of stopping transfusion

C.DETAILS OF SUSPECTED ADERSE REACTION/EVENTS

Description of the reaction/events & any treatment given	Date & time of reaction :_____ **Outcome(tick only one)** □ Patient/donor recovered with no damage to body function □ Serious sequelae/significant disability directly attributable to reaction/event □ Patient/donor died due to reaction/event

ANNEXURE V

ENROLLMENT FORM FOR BLOOD CENTERS

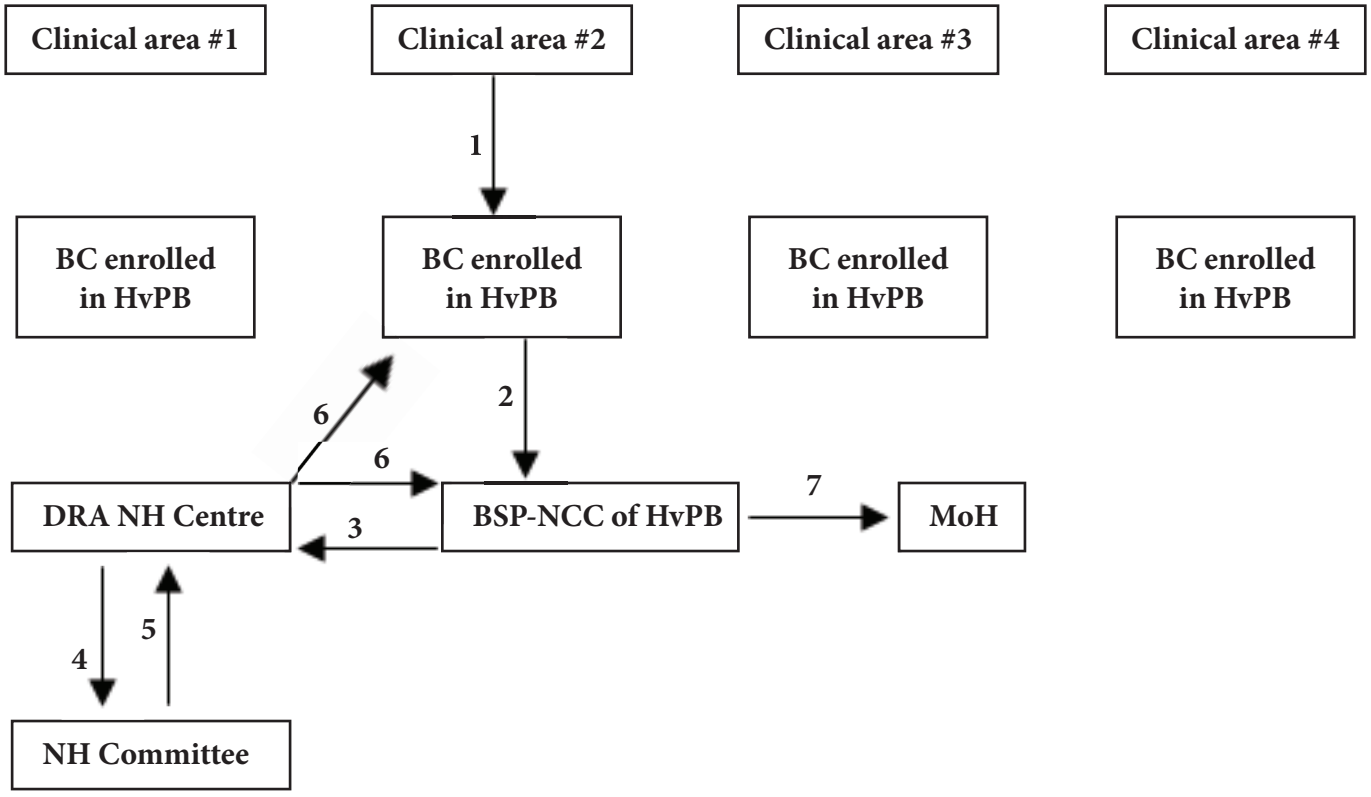
Name of the Blood Center /Hospital	
Address of the Blood Center/hospital including Pin code	
Technical Clearance /Technical Authorization of the Blood Center	
Name -Head / Incharge of Blood Center	
Mobile Contact Number of the I/C	
Email Address of the I/C	

Signature and Stamp
(Head/Incharge of Blood Center)

Please fill this form and email to Blood Safety Program Officer

ANNEXURE VI

PROCESS FLOW IN HVPB



1. Observe , detect and report a Transfusion Reaction(TR)
2. Investigate TR and submit TRRRF to BSP thr HEMOVIGIL software
3. Collect, collate & submit all TRRFs to NH Center
4. NH Centre submits TRRFs to NH Committee
5. NH Committee analyses data, classifies, concludes and recommends to NH Center
6. NH Centre informs the concerned blood center on CAPA or implements enforcement measures
7. NH Center notifies BSP for system improvements, provide technical advice or policy change recommendations

ANNEXURE VII

MONTHLY DENOMINATOR REPORTING FORM

Hospital code no.: ___	Month:____ Year:_____
Product	Number of units issued
Whole Blood	
Packed Red Cell	
Fresh Frozen plasma	
Random donor Platelet concentrates	
Cryprecipitate	
Any other	

ANNEXURE VIII

Transfusion Reaction Reporting Form (TRRF) for Blood & Blood Products
HAEMOVIGILANCE PROGRAMME OF BHUTAN

For reporting of Transfusion Reactions by Healthcare Professionals

* Mandatory Field

(A) PATIENT INFORMATION

Patient Initials*: ..... | DOB/Age in Years*: ..... | Blood Group*: .. | Diagnosis: .....

CID No./Any other identification no.* (Hospital Admission No, passport No. or permit no.): ..... | Sex* F ☐ M ☐

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

Signs /Symptoms(please select the revelant signs and symptoms)*

Please tick mark the relevant signs and symptoms listed below

Generalized		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	☐ Jaundice	☐ Infusion Site Pain	☐ Hypoxemia	☐ Other	☐ Raised JVP
☐ Uticiria	☐ Other	☐ Other	☐ Bilateral Infiltrates on Chest X-ray		☐ Arrhythmias
☐ Flushing			☐ Other		☐ Other .....
☐ Restlessness					
☐ Vomiting					

Any Other (Specify) : .....

Was the reaction occur during referral of patient from one facility to another ☐ Yes ☐ No

(B) TRANSFUSION PRODUCT DETAILS*

Select	Component	Indications for transfusion	Date & Time of issue of of the unit	Date & Time of start of Transfusion	Unit Id (Transfused)	Expiry Date of Blood Product	Manufacturer of Blood Bag	Lot Number	Any heating, freezing done on the unit	Any IV fluid	Any drug given through same IT set. specify
☐	Whole blood								☐ Yes (Specify (Heating/ Freezing)) ☐ No	☐ Yes ☐	☐ Yes (Specify (Kl., NS, D5S, 5% dextrose)) ☐ No
☐	Packed Red blood cells										
☐	Random Donor Platelet Concentrates										
☐	FFP										
☐	Cryoprecipitate										
☐	Any Other										

(C) INVESTIGATIONS

* ☐ Clerical Checks — Specify Error Found if any: .....

	Investigation	Pre-transfusion sample	Post-transfusion sample
* ☐	Blood Group of the Unit	O+ /A+ /B+ /AB+ /O- /A- /B- /AB-	O+ /A+ /B+ /AB+ /O- /A- /B- /AB-
* ☐	Blood Group of the Patient	O+ /A+ /B+ /AB+ /O- /A- /B- /AB-	O+ /A+ /B+ /AB+ /O- /A- /B- /AB-
* ☐	Crossmatching	☐ Compatible ☐ Incompatible ☐ Not Done	☐ Compatible ☐ Incompatible ☐ Not Done
* ☐	Physical Examination		
* ☐	Direct Antiglobulin Test		☐ Negative ☐ Positive ☐ Not Done
☐	Antibody Screening		
☐	Antibody Identification		
☐	Blood culture of Patient	☐ Negative ☐ Positive ☐ Not Done Specify Organism if positive	☐ Negative ☐ Positive ☐ Not Done Specify Organism if positive .....
☐	Blood culture of Blood Bag	☐ Negative ☐ Positive ☐ Not Done	Specify Organism if positive .....
☐	Chest X-ray of the Patient		

(D) NATURE OF ADVERSE REACTIONS *

Select	Reaction	Date & Time of onset of reaction	Outcome
☐	Immunological Haemolysis due to ABO Incompatibility		☐ 1. Death following the Adverse Reaction(s)
☐	Immunological Haemolysis due to other Allo-Antibodies		
☐	Non Immunological Haemolysis(due to freezing, heating, IV fluid, drug or mechanical pressure)		
☐	Transfusion Transmitted Bacterial Infection		
☐	Anaphylaxis / Hypersensitivity		
☐	Transfusion Related Acute Lung Injury (TRALI)		
☐	Transfusion Transmitted Viral Infection (HBV)		
☐	Transfusion Transmitted Viral Infection (HCV)		☐ 2. Recovered
☐	Transfusion Transmitted Viral Infection (HIV-1/2)		
☐	Transfusion Transmitted Viral Infection, other (Specify)		
☐	Transfusion Transmitted Parasitic Infection (Malaria)		☐ 3. Recovered with Sequelae
☐	Transfusion Transmitted Parasitic Infection, other (Specify)		
☐	Post Transfusion Purpura		
☐	Transfusion Associated Graft versus Host Disease (TAGvHD)		
☐	Febrile Non Haemolytic Reactions(FNHTR)		
☐	Transfusion Associated Dyspnea(TAD)		☐ 4. Unknown
☐	Transfusion Associated Circulatory Overload (TACO)		
☐	Allergic Reaction		
☐	Other Reactions		

(E) DETAILS OF THE REPORTING HEMOVIGILANCE CENTER*

Name of the Center Address: .....

Name of the Reporter Email: .....

Date of this report (DD/MM/YYYY): .....

Tel No. (with STD code) .....

(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

ANNEXURE IX

Haemovigilance Programme of Bhutan

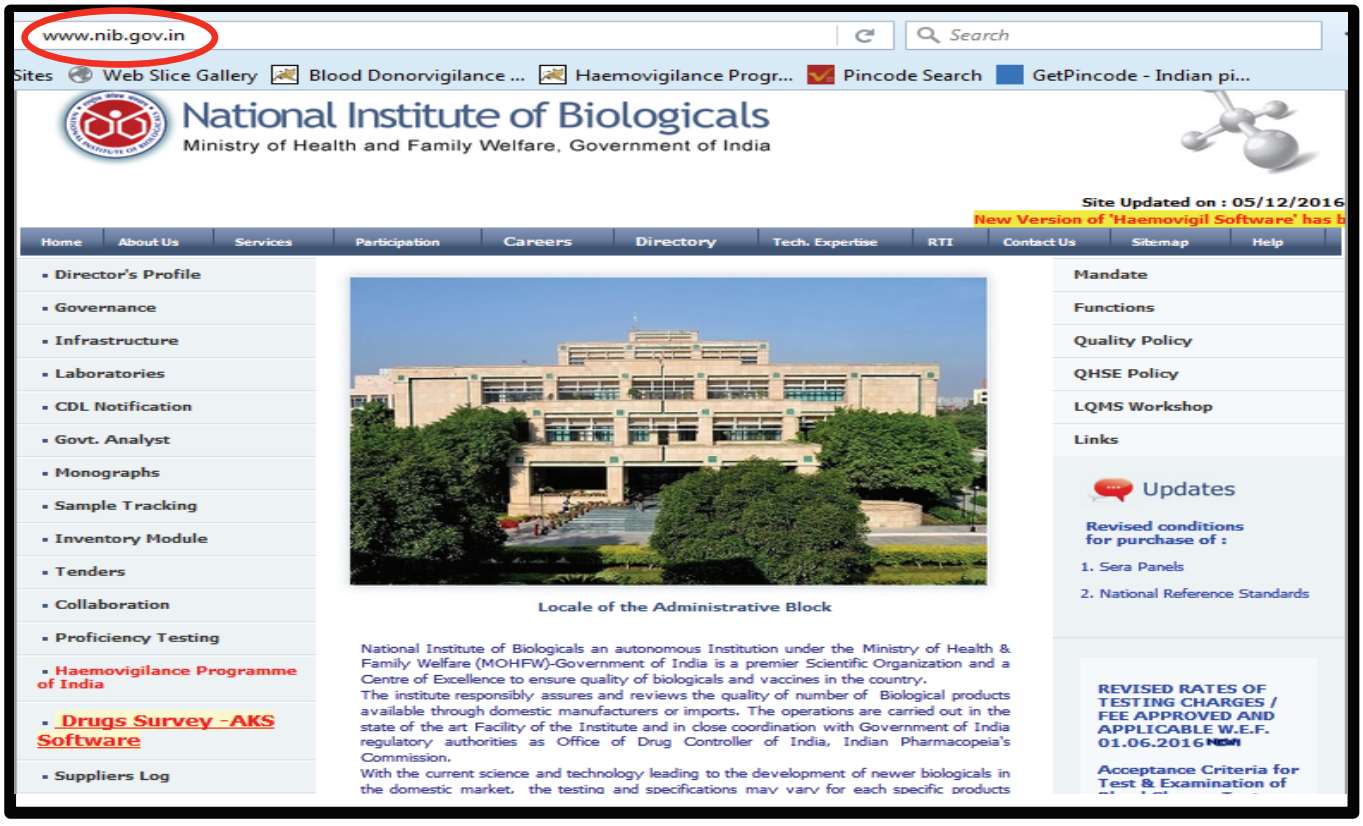
Instruction Manual

HAEMO-VIGIL SOFTWARE

INDEX

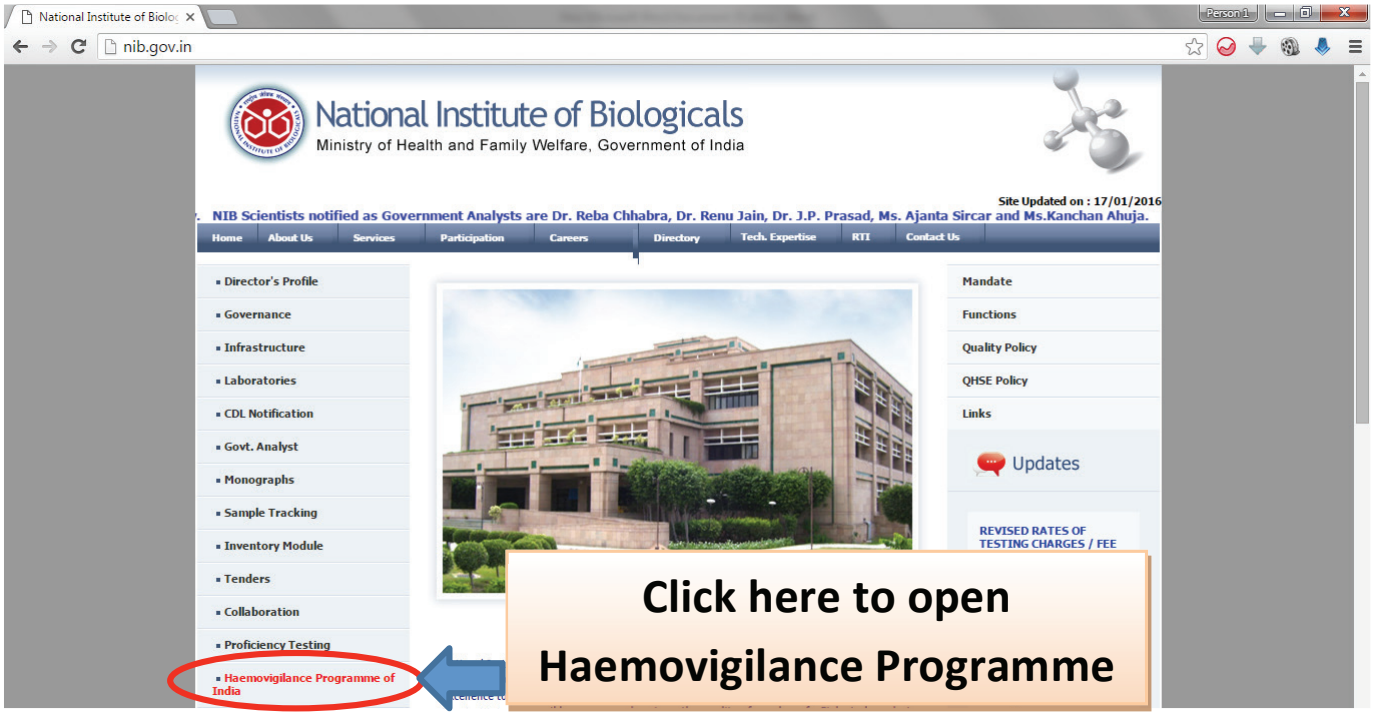
TOPIC

STEP-1

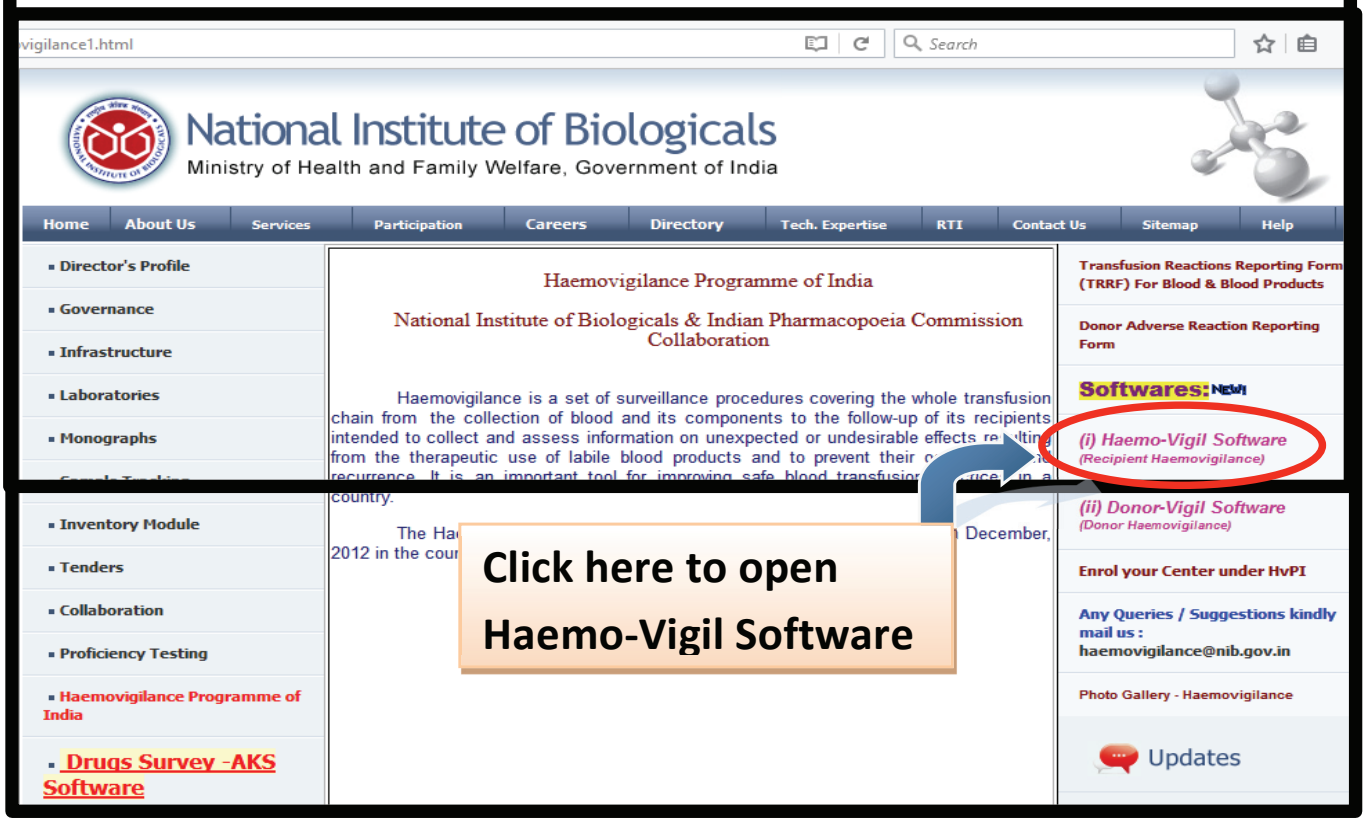


Link to NIB website- http://nib.gov.in/

STEP-1A



STEP-1B

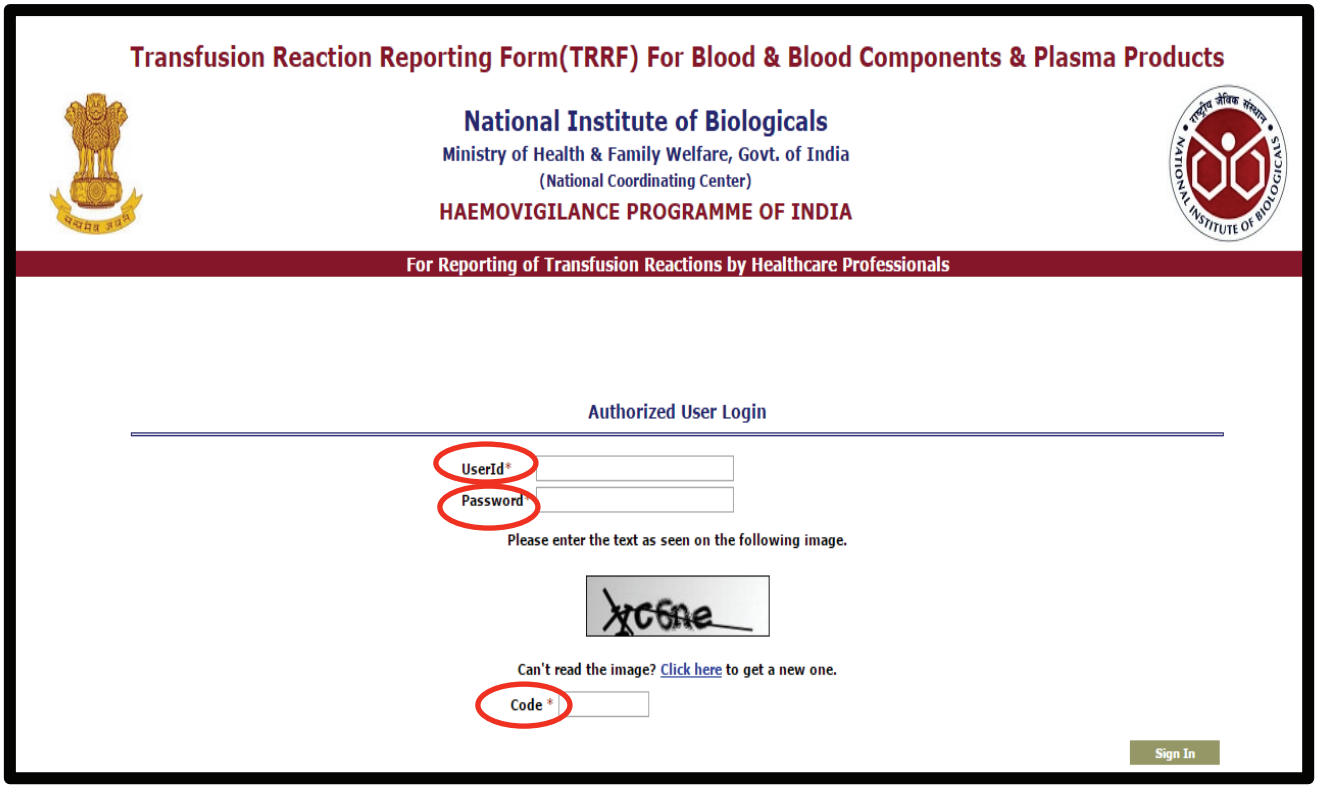


Link to Haemovigilance Software

- Go to**http://nib.gov.in/** - the homepage of **National Institute of Biologicals(NIB)**will be displayed.
- Click on the **"Haemovigilance Programme"** tab.
- On the right hand side of the page click on the "**Haemo-Vigil-Software"** tab for login page of the software.

ON CLICK TO THE "HAEMO-VIGIL SOFTWARE", LOGIN PAGE WILL BE OPEN FOR AUTHORIZED USER LOGIN.

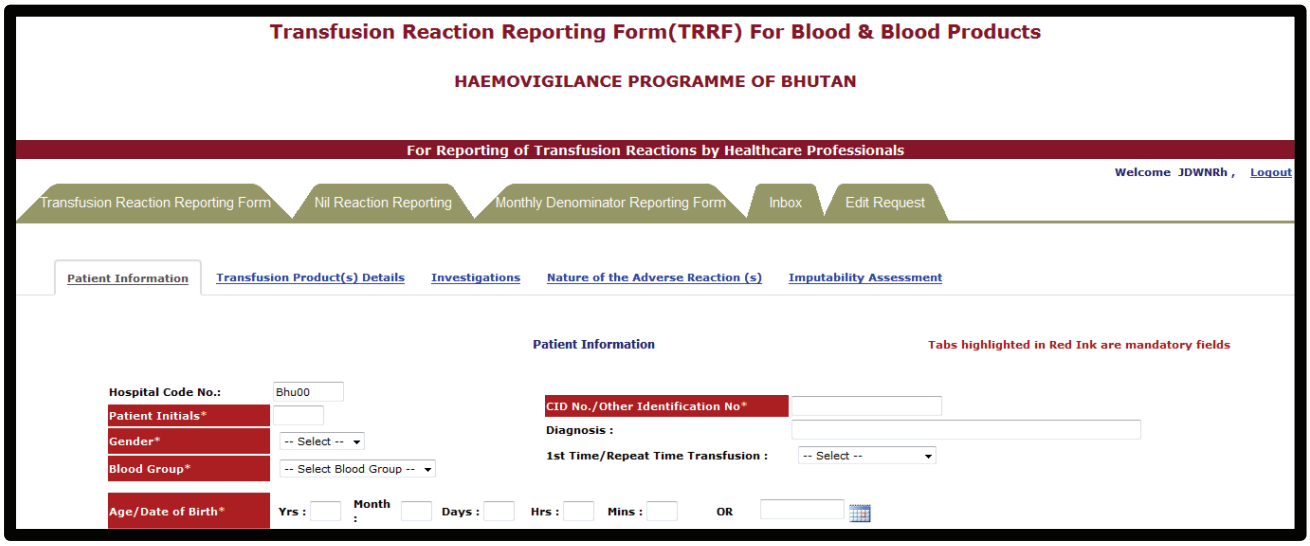
STEP-02



Login Page

- Enter **"Username"** and **"Password"** in the given fields.
- Enter the **''Validation''** Code and click on **Sign In.**

- By clicking on sign in user is redirected to the home page of Bhutan Haemo-Vigil software having five tabs:
  1. Transfusion Reaction Reporting Form
  2. Nil Reaction Reporting
  3. Monthly Denominator Reporting Form
  4. Inbox
  5. Edit Request



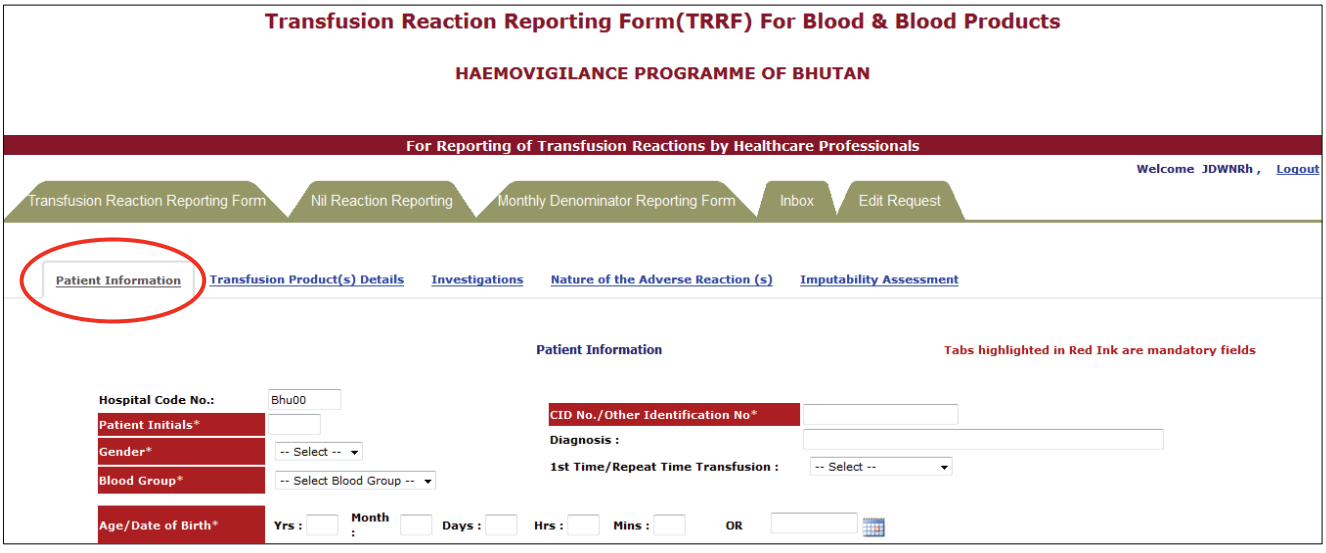
Tab 1. TRANSFUSION REACTION REPORTING FORM (TRRF)

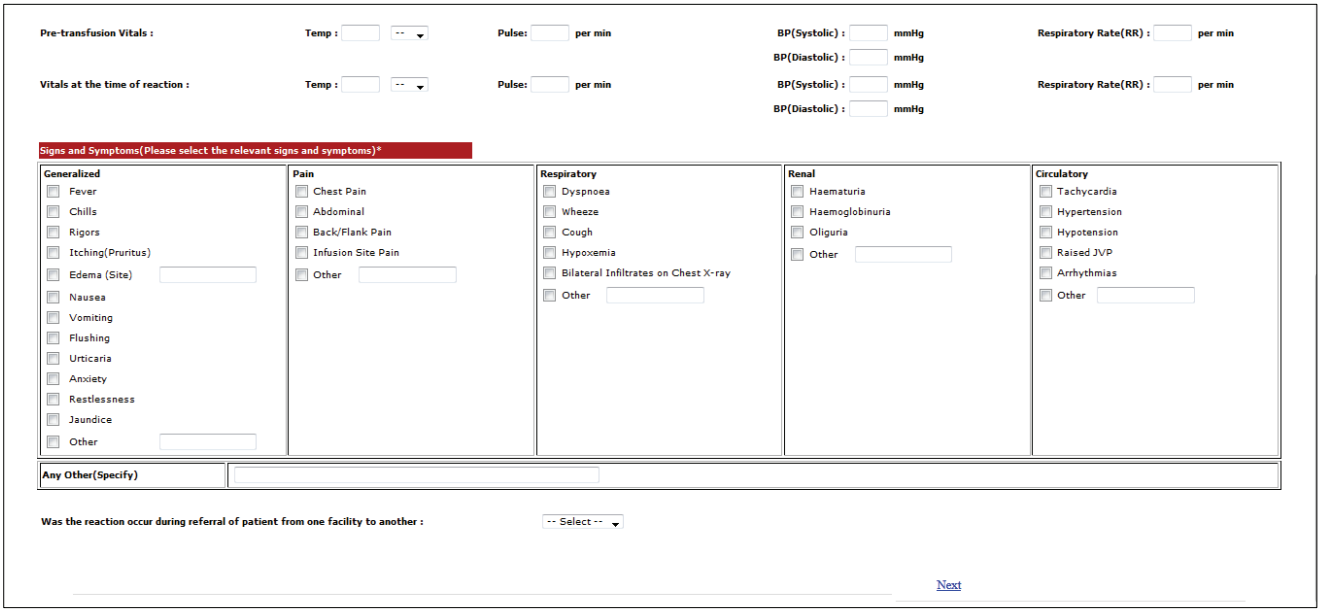
THIS PAGE DISPLAYS BLANK TRRF WHERE ADVERSE REACTION DATA IS TO BE FILLED.

THE TRRF IS DIVIDED INTO **6 SECTIONS**.

- **SECTION- A** (Patient Information)
- **SECTION-B**(Transfusion Reaction Details)
- **SECTION-C** (Transfusion Product(s) Details)
- **SECTION-D**(Investigations)
- **SECTION-E** (Nature of the Adverse Reaction(s)
- **SECTION-F**(Imputability Assessment)

STEP-03 **START FILLING TRRF WITH PATIENT INFORMATION WHICH IS SECTION -A**





Section-A

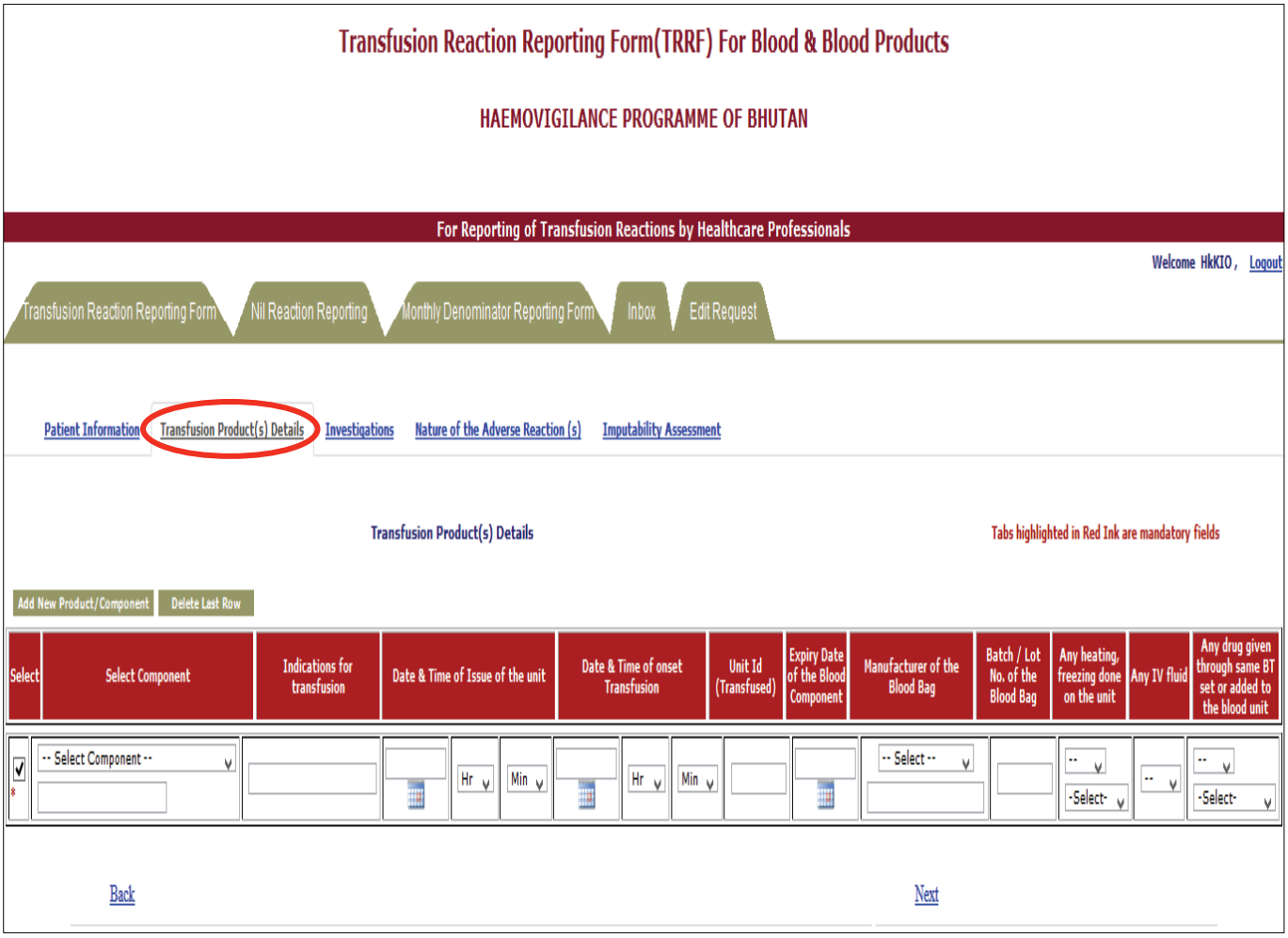
❖ PATIENT INFORMATION

- **"Hospital Code Number"** is auto generated by the system.
- Enter the **"Patient's Initials"** (For e.g. Ravi Kumar Sharma should be entered as RKS). Special characters aren't allowed.
- Select the **"Gender"** from drop down menu.
- Select **"Blood Group"** from drop down menu.
- Enter the "**Age** of the patient in numerical form (Year, Month, & Days/ Hrs. and Mins) or select the **Date of Birth** from the Calendar  by clicking on the Calendar tab. If date of birth is not known, select date and month as 01/01 and year according to age provided.
- Enter the **"CID No./Other Identification No"**
- Enter the **"Diagnosis"**.
- Select **"1st Time/ Repeat Transfusion"** from drop down menu.
- **In "Pre-transfusion Vitals":**

  Enter the **Temperature**, **Pulse**, **Blood pressure**, **Respiratory Rate**, and **SPO2.**
- **In "Vitals at the time of reaction":**

  Enter the **Temperature**, **Pulse**, **Blood Pressure**, **Respiratory Rate**, and **SPO2 (Optional).**
- Select the **Sign** and **Symptoms** at least one from the given column i.e. **Generalized, Pain, Respiratory, Renal and Circulatory**.
- In case of **Generalized** if "**Edema**" is selected mention it site of occurrence.
- If the **Sign** & **Symptoms** in the columns (Generalized, Pain, Respiratory, Renal and Circulatory) is other than listed than click on the "**Other"** tab provided at the bottom of the respective column.
- In case of any other information the same may be mentioned in the tab provided i.e. **"Any Other (Specify)"** available at the bottom of the page.
- Once details in **Section A** was completed click on the **Next** Tab to move on **Section B** i.e. **Transfusion Product(s) Details** of the TRRF.

STEP-04


Transfusion Reaction Reporting Form(TRRF) For Blood & Blood Products
HAEMOVIGILANCE PROGRAMME OF BHUTAN
For Reporting of Transfusion Reactions by Healthcare Professionals
Welcome HkKIO , Logout
Transfusion Reaction Reporting Form
Nil Reaction Reporting
Monthly Denominator Reporting Form
Inbox
Edit Request
Patient Information
Transfusion Product(s) Details
Investigations
Nature of the Adverse Reaction (s)
Imputability Assessment
Transfusion Product(s) Details
Tabs highlighted in Red Ink are mandatory fields
Add New Product/Component
Delete Last Row
Select
Select Component
Indications for transfusion
Date & Time of Issue of the unit
Date & Time of onset Transfusion
Unit Id (Transfused)
Expiry Date of the Blood Component
Manufacturer of the Blood Bag
Batch / Lot No. of the Blood Bag
Any heating, freezing done on the unit
Any IV fluid
Any drug given through same BT set or added to the blood unit
-- Select Component --
Hr
Min
-- Select --
-Select-
Back
Next

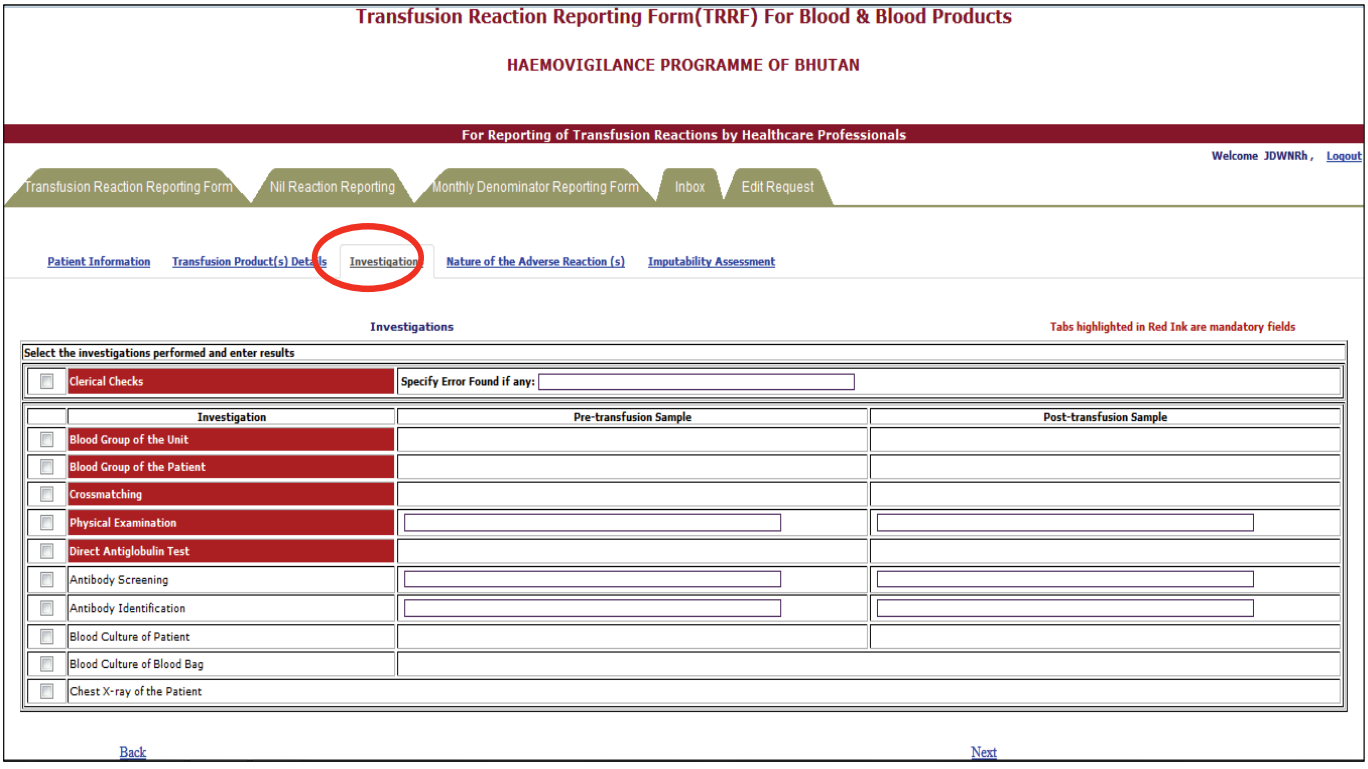
SECTION–B

❖ TRANSFUSION PRODUCT(S) DETAILS

- Select one or more components from the list.
- In case the component transfused is not listed then select **"Any Other"** tab and mention the details in the space provided.
- Select one or more **"Indication for Transfusion"** from the given list in drop down menu, and in case the indication is other than listed then click on the **"Others"** tab and mention the details in the space provided.
- Enter the "**Date of issue of the unit"** by clicking on the calendar tab.
- Select the "**Time issue of the unit"** from drop down menu (Hrs. & Min).
- Enter the **"Date & Time of Transfusion"**in a same manner as mentioned above.
- Enter the **"Unit Id (Transfused)"** in the given box.
- Enter the **"Expiry Date of the Blood Component"** by clicking on the calendar tab.
- Select **"Manufacturerof the Blood Bag"** from drop down menu, in case the name of manufacturer is not listed then select option **"Any Other"** &specify in the given box.
- Enter **"Batch/ Lot No. of the Blood Bag"**.

- Select **Yes**& mentionwhether Heating, Freezingdone on the unit or select **No** if not done.
- Select Yes or NO if any IV fluid given &any Drug giventhrough same BT set or added to the blood unit If "Yes" than select the case applicable from the drop own menuor select **No** if not done.
- After completion of data in **Section B** click on **Next** button to move on to **Section C (Investigations)** of TRRF.

STEP-05



SECTION-C

❖ INVESTIGATIONS

- **"Select the investigations performedand enter results"**from the below rows along with their units.
- Select **"Clerical Checks"** &**"Specify Error Found if any"** in the space provided.
- Select one or more from the **"Investigation"** tab & enter results of **"Pre Transfusion Sample"** and **"Post Transfusion Sample".**
- Once details was completed then move to next **Section-D(Nature of the Adverse Reaction(s)** of TRRF by clicking on **Next** button.

STEP-06

Transfusion Reaction Reporting Form(TRRF) For Blood & Blood Products

HAEMOVIGILANCE PROGRAMME OF BHUTAN

For Reporting of Transfusion Reactions by Healthcare Professionals

Welcome HkKIO , Logout

Transfusion Reaction Reporting Form | Nil Reaction Reporting | Monthly Denominator Reporting Form | Inbox | Edit Request

Patient Information | Transfusion Product(s) Details | Investigations | Nature of the Adverse Reaction (s) | Imputability Assessment

Nature of the Adverse Reaction (s)

Tabs highlighted in Red Ink are mandatory fields

Select	Reaction		Date & Time of Onset of Reaction			Outcome
☐	Immunological Haemolysis due to ABO Incompatibility					
☐	Immunological Haemolysis due to Other Allo-Antibodies					
☐	Non Immunological Haemolysis(due to freezing,heating,IV fluid,drug or Mechanical Pressure)					
☐	Transfusion Transmitted Bacterial Infection					
☐	Anaphylaxis / Hypersensitivity					
☐	Transfusion Related Accute Lung Injury(TRALI)					
☐	Transfusion Transmitted Viral Infection(HBV)					
☐	Transfusion Transmitted Viral Infection(HCV)					
☐	Transfusion Transmitted Viral Infection(HIV-1/2)					
☐	Transfusion Transmitted Viral Infection	specify if Other				
☐	Transfusion Transmitted Parasitic Infection(Malaria)					
☐	Transfusion Transmitted Parasitic Infection	specify if Other				
☐	Post Transfusion Purpura					
☐	Transfusion Associated Graft versus Host Disease(TAGvHD)					
☐	Febrile Non Haemolysis Reactions(FNHTR)					
☐	Transfusion Associated Dyspnea(TAD)					
☐	Transfusion Associated Circulatory Overload(TACO)					
☐	Allergic Reaction					
☐	Other Reactions					

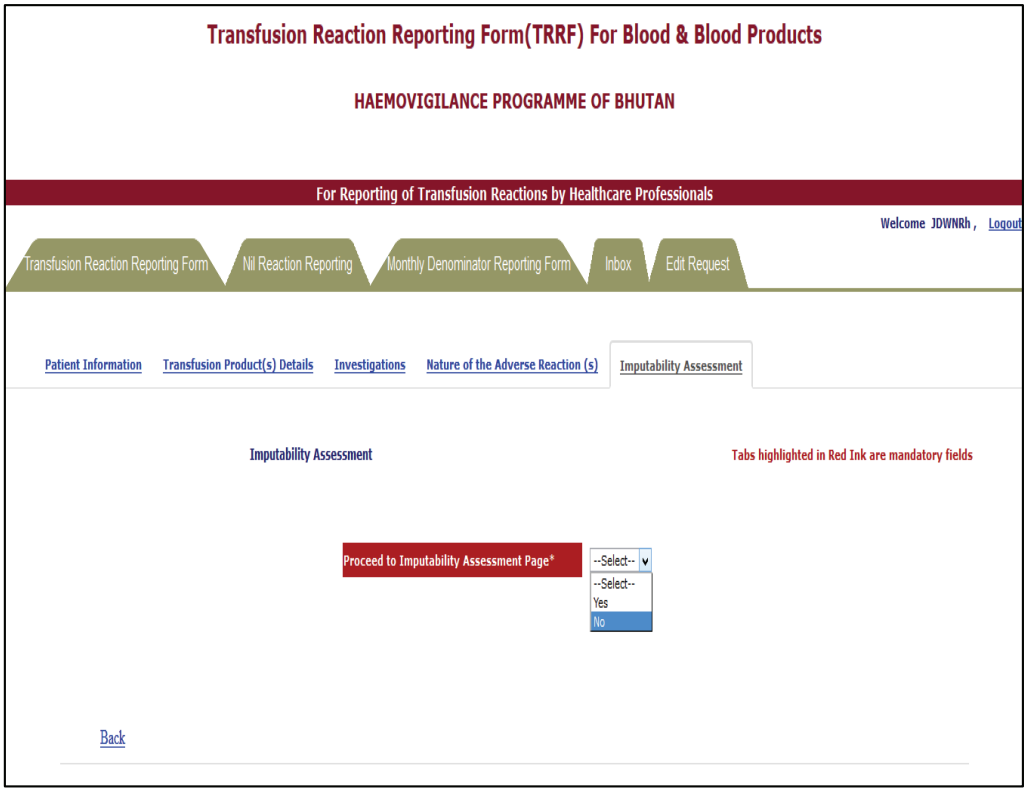
Back | Next

SECTION–D

❖ NATURE OF THE ADVERSE REACTION(S)

- Select one or more **"Reaction"** from the list provided in the **"Nature of Adverse Reaction(s)"** tab.
- Select the **"Date&Time of Onset of Reaction"** and **"Date&Time of Recovery"** by clicking on calendar tab for Date & from drop down menu (Hrs. &Mins)for Time.
- Select the **"Outcome"**of the reaction(s)from drop down menu.
- In case of **"Other Reactions"** click on sameto open new row and fill all required details in the space provided.
- Once details was completed then move to next **Section-E(Imputability Assessment)** of TRRF by clicking on **Next**button.

STEP-07

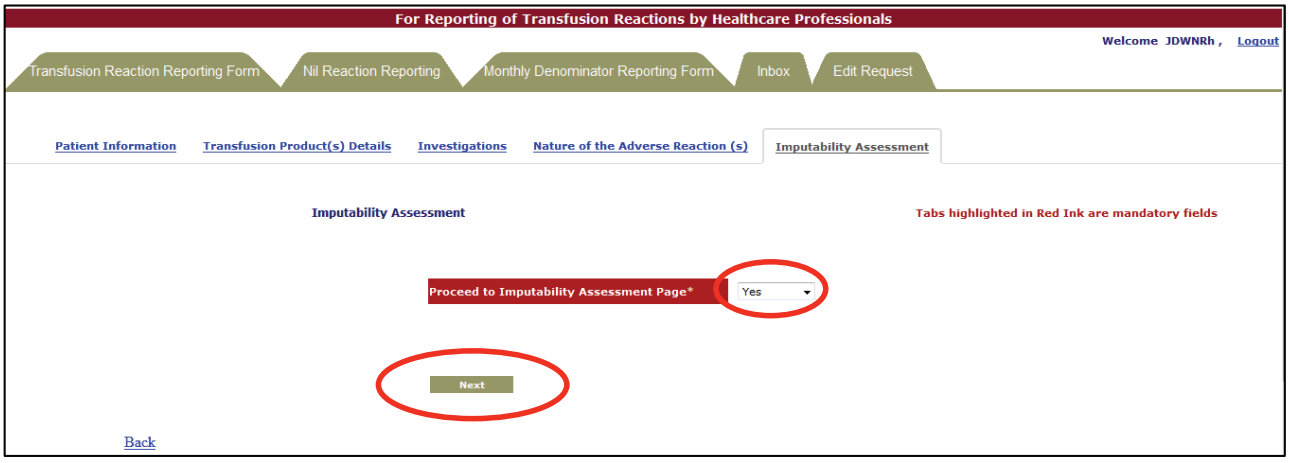


SECTION-F

❖ IMPUTABILITY ASSESSMENT

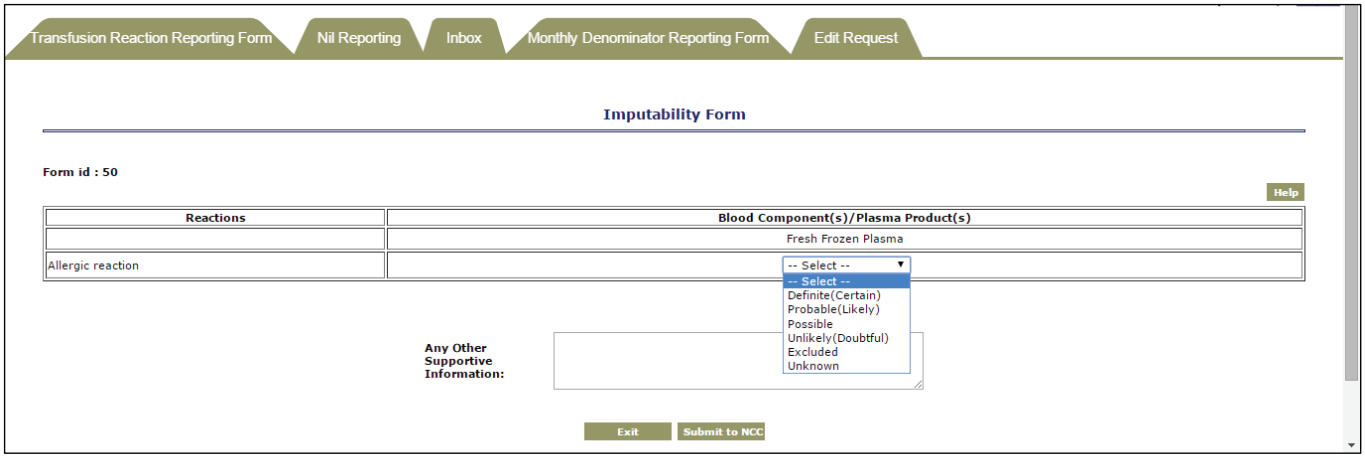
- Kindly proceed to **"Imputability Assessment"** page for Imputability Assessment by selecting "**YES**" or **"NO".**
- By clicking on **"Preview"** button filled TRRF can be previewed.

STEP-07 A



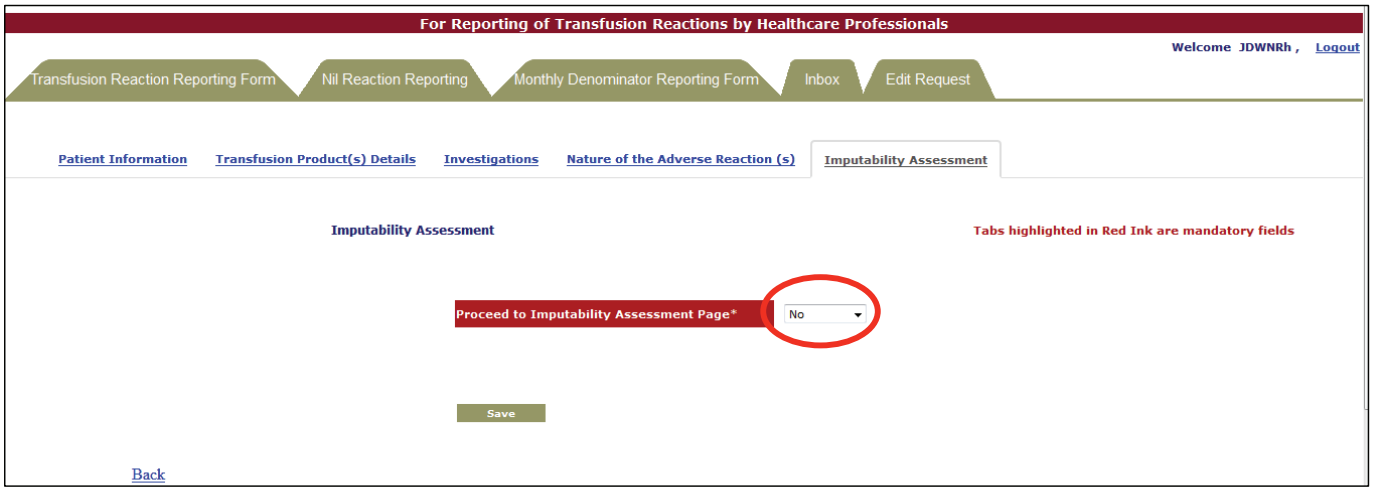
- If select **"YES"** then user will be redirected to the **"Imputability Form"** page by clicking on the **Next**button.

STEP-07 B



❖ IMPUTABILITY FORM

- Select one or more suitable Imputability Assessment criteria from drop down menu for adverse reaction(s).
- Two options are provided at the bottom of the Imputability Form i.e., **"Exit"**and **"Submit to NCC"**.
- Click on the **"Submit to NCC"** button after the Imputability Assessment then TRRF details saved successfully.
- The saved TRRF can be view under **"Inbox"**tab of **"List Completed TRRF Submitted to NCC"**.
- If select **"Exit"** then form will be saved and can we view under **"Inbox"** tab of **"List of the In-completed TRRF pending for Submission to NCC"**.
- Any other supportive information related to transfusion may be provided by the user in the tab **"Any Other Supportive Information".**

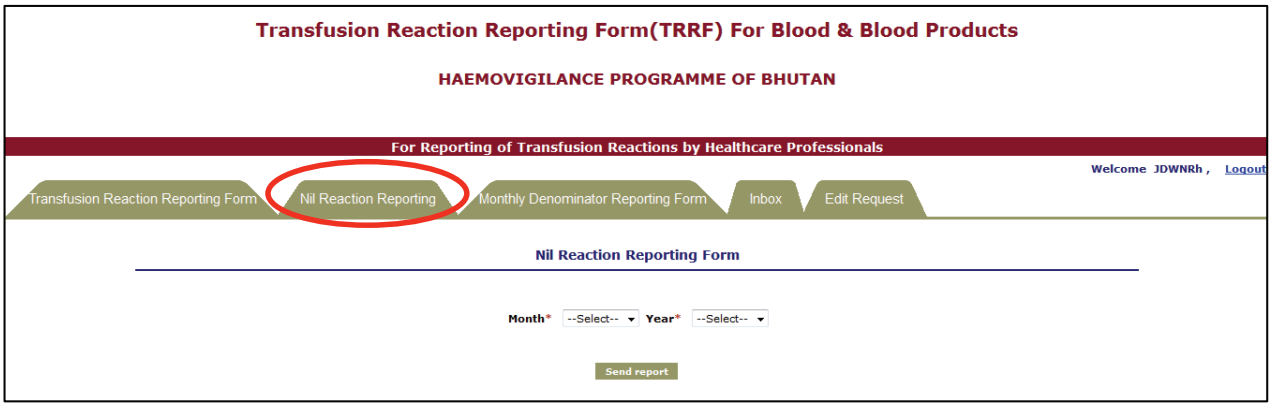


- If select **"NO"**then the user will be provided with **"Save"**option.
- If select **"Save"**the details will be savedunder**Inbox** tab of **"List of the In-completed TRRF pending for Submission to NCC"**.

STEP-08

Tab 2. NIL REACTION REPORTING

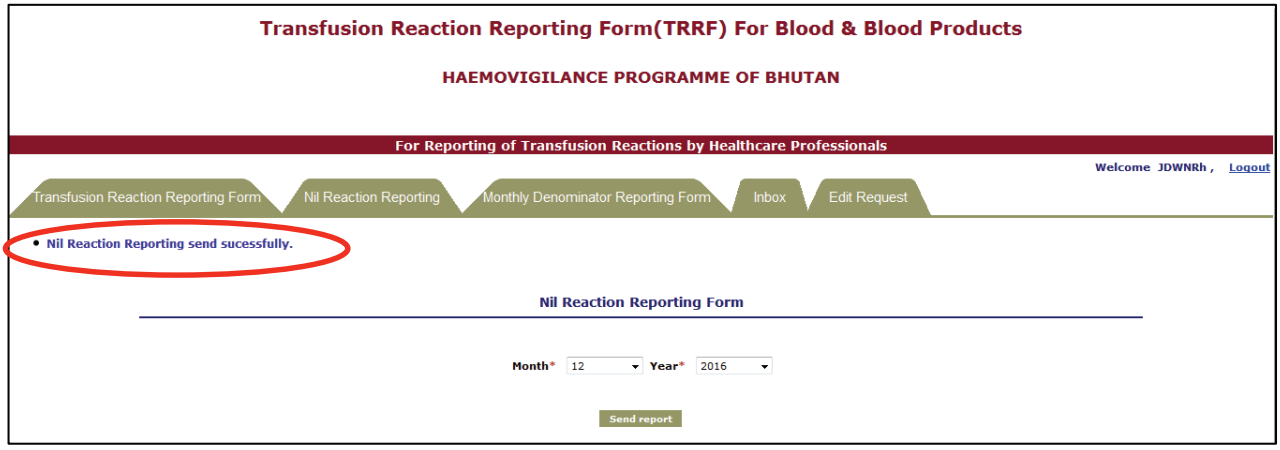
User has to fill the Nil Reporting in case no adverse reaction has occurred in the particular month.



❖ NIL REACTION REPORTING FORM

- Click on the **"Nil Reporting"** tab to open **"Nil Reaction Reporting Form"**.
- Select the Particular **"Month"** and **"Year"**to report in case no transfusion reaction has occurred in your center in a particular monthfrom the drop down menu.
- After selecting Month and Year click on **"Send Request"** tab.

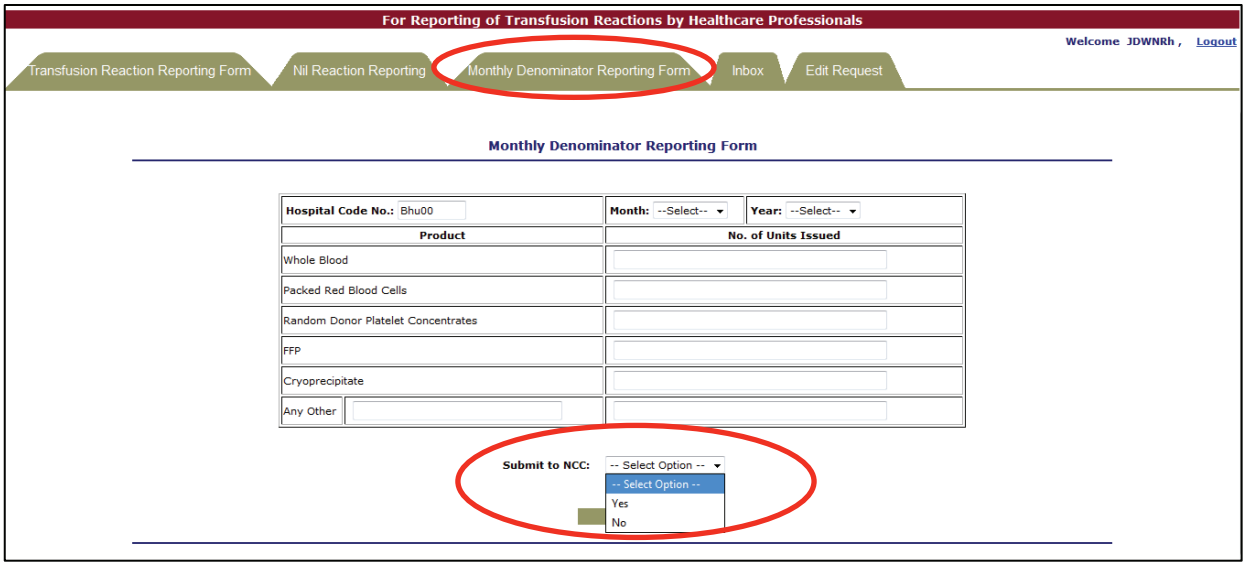
STEP-08 A



- Highlighted/ circled area shows that **Nil Reaction Reporting**has been sent successfully.

Tab 3. MONTHLY DENOMINATOR REPORTING FORM

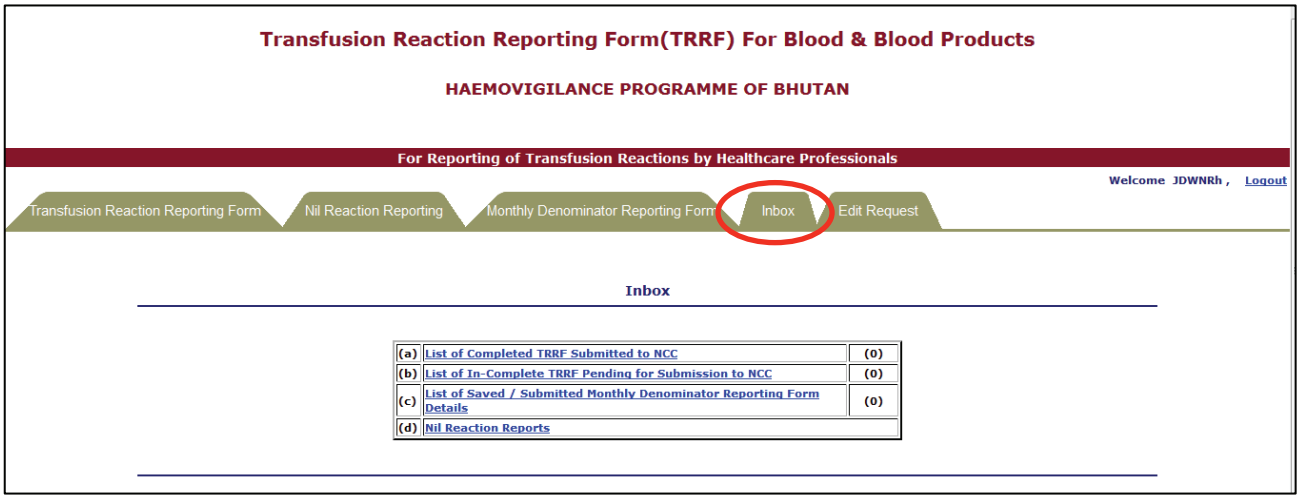
STEP-9



- Click on the **"Monthly Denominator Reporting Form"**tab to openthe same& start entering the following:
- Select **"Month"** and **"Year"** from the drop down menu.
- Enter the **"No. of Units Issued"** in selected month & year by the centre for respective products.
- In case of **"Any other"** enter name of the product along with no. of unit issued by the centre.
- Select the submit button whether **"Yes"** or **"No".**
- If select **"Yes"** then denominator form will be submitted to NCC, by clicking on the **"Submit"** button or user can exit by clicking on the **"Exit"** button.
- If select No then denominator form will be saved by clicking on **"Save"**, or user can exit by clicking on the **"Exit"** button.
- Submitted & Saved form can be view under Inbox tab list of **"List of Saved/ Submitted Monthly Denominator Reporting Form Details".**

Tab 4. INBOX

STEP-10

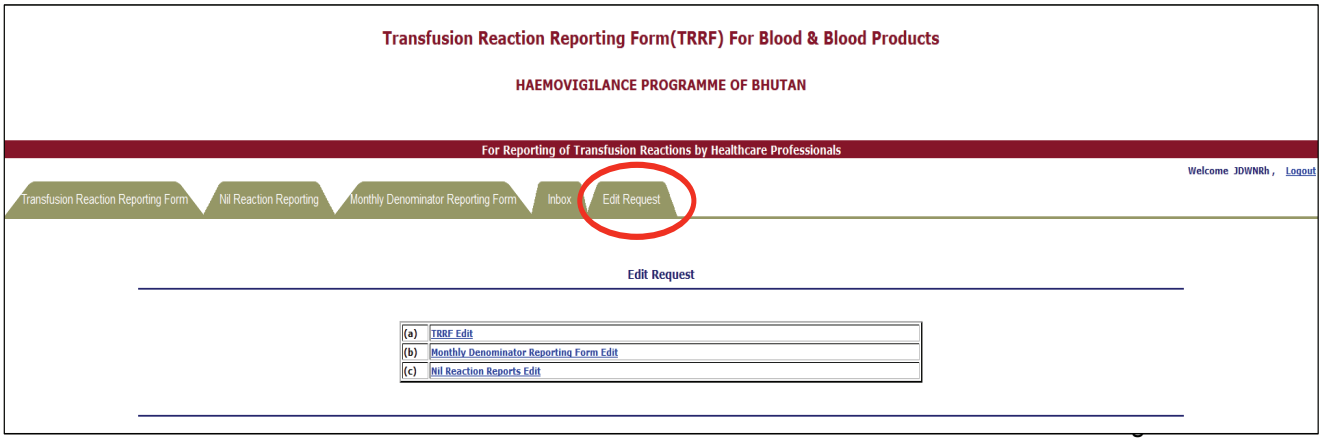


a) **List of completed TRRF submitted to NCC with total no. of forms.**
b) **List of In-complete TRRF pending for submission to NCC with total no. of forms.**
c) **List of Saved/ SubmittedMonthly Denominator Reporting Form Detailswith total no. of forms.**
d) **Nil Reaction Reports**

Click on the **"Inbox"** tab and page shows the following information as given below.

Tab 5. EDIT REQUEST

STEP-11



- Once TRR Form submitted cannot be changed, if required click on the Edit Request tab then page opens with following details:
  1) **TRRF Edit**
  2) **Monthly DenominatorReporting Form Edit**
  3) **Nil Reaction Reports Edit**
- Click on one of the link for which user want to send request to NCC for edit, then the form for edit request will open.
- In case of wrong entry in the TRRF click on the **"TRRF Edit" tab** & similarly for others edits.
- In"Form Edit Request". Enter the **Form Id** No. of TRRF for which Edit option is required then click on next tab to open the Form for Edit Request.
- Enter the reason for edit in space provided for the same.
- Click on the Send Request Button then TRRF at the bottom submitted to NCC for edit request.
- Once NCC receives the edit request after review of the request NCC approves & activate the Edit Option for the User to correct the form.

All Tab highlighted in Red Ink are Mandatory Fields

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