सत्यमेव जयते

Azadi Ka Amrit Mahotsav

राष्ट्रीय जैविक संस्थान
NATIONAL INSTITUTE OF BIOLOGICALS

GUIDANCE DOCUMENT FOR REPORTING BLOOD DONOR ADVERSE REACTIONS

NATIONAL BLOOD DONOR VIGILANCE PROGRAMME (NBDVP)

2022

National Institute of Biologicals

National Coordinating Centre - Haemovigilance Programme of India (NCC-HvPI)

Ministry of Health and Family Welfare (Govt. of India)

FOREWORD

Providing safe blood is a fundamental need for the health system of every country for which efficient blood transfusion services are important. With the impact being so immense and diverse, the regulatory network that governs and strengthens the procedures concerning the blood and blood products applications in health systems need to be robust, frequently monitored and updated. In this context Haemovigilance is an urgent need of the country to identify and prevent occurrence or recurrence of donor related adverse reactions, so as to increase the safety & quality of blood donations and make the donation environment more pleasant for donors.

This system includes monitoring, reporting investigation, identification and analysis of adverse reactions related to donation. The information thus collected will facilitate corrective and preventive actions to be taken to minimize the potential risks associated with blood donation, processing and donor care. Such information is also a key to introduce required changes in the applicable policies, improve standards, system and processes and assist in the formulation of guidelines.

A centralized Haemovigilance system involves all relevant stakeholders and coordinates various activities between the blood centres, donors, hospital health care professionals and transfusion committees, regulatory agencies and national health authorities. Extension of the Haemovigilance system to regional and global sharing of information by linking it to International Haemovigilance Network (IHN) will further strengthen it. The members of National Executive Committee, Haemovigilance Core Group, Expert groups for analysis of data have an important role to play in achieving the above objectives.

I am pleased to inform that elaborate guidance document for reporting blood donor adverse reactions under NBDVP have been developed herewith which will be useful tool for the blood centres, donors, hospital transfusion committees and health care professionals associated with the blood donation process. I would like to thank the Experts of HvPI who have been involved in bringing out this Guidance Document.

(Dr. Anup Anvikar)

Director, NIB

Dated:28/02/2022

PREFACE

The contents of this document are designed on the basis of various functional Haemovigilance systems in developed countries and modified as per the Indian scenario by Prof. Neelam Marwaha, Chairperson, National Executive Committee- Haemovigilance Programme of India (HvPI) & Former Head, Department of Transfusion Medicine, Post Graduate Institute of Medical Education & Research (PGIMER); Chandigarh, Prof. Debasish Gupta, Member, National Executive Committee- HvPI & Head, Department of Transfusion Medicine, Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Thiruvananthapuram; Prof. Ravneet Kaur, Member, Core Group- HvPI & Head, Department of Transfusion Medicine, Government Medical College and Hospital (GMCH), Chandigarh; Dr. Gopal Kumar Patidar, Associate Professor, Department of Transfusion Medicine, CNC Blood Bank, All India Institutes of Medical Sciences (AIIMS), New Delhi; Dr. Satyam Arora, Associate Professor, Department of Transfusion Medicine, Post Graduate Institute of Child Health (PGICH), NOIDA; Dr. Kshitija Mittal, Assistant Professor, Government Medical College & Hospital Chandigarh & Dr. Akanksha Bisht, Head-HvPI & Scientist Grade-II, National Institute of Biologicals (NIB), NOIDA. Further, the Guidance Document has been reviewed by Dr. Aseem K Tiwari, Director, Transfusion Medicine (Blood Centre), Medanta- The Medicity Hospital, Gurugram and Dr C. SHIVARAM, Consultant & Head-Transfusion Medicine, Manipal Hospital, Bangalore.

These guidelines are intended for reporting the Adverse Reactions related to Blood Donations by the Centres under National Blood Donor Vigilance Programme (NBDVP).

These guidelines are not to be quoted as a reference in any official communication except in the communication with the National Coordinating Centre (NCC) for Haemovigilance Programme of India, NIB.

It is the intent of NIB which is the National Coordinating Centre (NCC) for Haemovigilance Programme of India that Blood Donor Haemovigilance reports will contain no identifiable or re-identifiable data; that no donor, clinician, staff member or healthcare facility is identifiable from materials contained within the report.

This guidance document may be amended from time to time as per the requirements, after obtaining necessary approval from the competent authority.

	**Prof. Neelam Marwaha,** **Chairperson, National Executive Committee- HvPI &** **Former Head, Department of Transfusion Medicine,** **PGIMER, Chandigarh**
	**Prof. Debasish Gupta,** **Member, National Executive Committee- HvPI &** **Head, Department of Transfusion Medicine,** **SCTIMST, Thiruvananthapuram**

	**Prof. Ravneet Kaur,** **Member, Core Group- HvPI &** **Head, Department of Transfusion Medicine,** **GMCH, Chandigarh**
	**Dr. Gopal Kumar Patidar** **Associate Professor,** **Department of Transfusion Medicine,** **CNC Blood Bank, AIIMS, New Delhi**
	**Dr. Satyam Arora** **Associate Professor,** **Department of Transfusion Medicine,** **PGICH, NOIDA**
	**Dr. Kshitija Mittal,** **Assistant Professor,** **Department of Transfusion Medicine** **GMCH, Chandigarh**
	**Dr. Akanksha Bisht,** **Head-HvPI & Scientist Grade-II, NIB, NOIDA**
	**Dr. Aseem K Tiwari** **Director, Transfusion Medicine (Blood Centre)** **Medanta- The Medicity Hospital, Gurugram**
	**Dr C . SHIVARAM** **Consultant & Head-Transfusion Medicine,** **Manipal Hospital, Bangalore**

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1. Introduction

The first step in the transfusion chain is to collect blood and blood components from a donor. Donation of blood and blood components may sometimes result in a variety of adverse reactions in a few donors, and systemic surveillance of these donor adverse reactions (DARs) is known as donor haemovigilance. The Donor haemovigilance program's primary goal is to collect, analyse, and disseminate information on a pre-defined set of DARs. The obtained information will be utilised to create safer and more efficient blood collection systems for donors, and eventually to provide better services. In order to achieve its aims and objectives, the Haemovigilance Programme of India (HvPI) has enrolled numerous blood donation centres around the country, including medical colleges/institutions/standalone blood centres.

The National Blood Donor Vigilance Programme (NBDVP) is a division of the HvPI, which is also a member of the International Haemovigilance Network (IHN). This programme was introduced in India on 14th June 2015 and the reporting under the program started in June 2016.

2. Donor Haemovigilance

Donor Haemovigilance is the systematic monitoring of both immediate and long-term adverse reactions and incidents throughout the entire chain of blood donor care. It entails identifying, reporting, investigating, and analysing adverse reactions in blood donors due to donation. This haemovigilance system is also an important component of blood system quality control, triggering corrective and preventive measures for continuous quality and safety enhancement.

3. Objectives of reporting blood donor adverse reactions

The objectives of the National Donor Haemovigilance Programme of India are to:

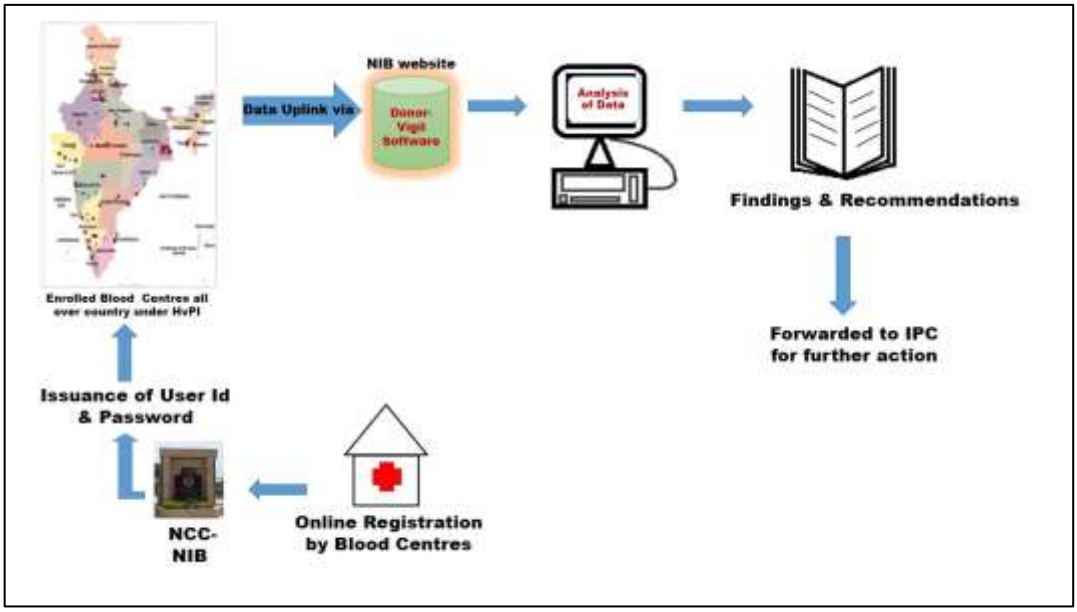
- Improve donor safety and satisfaction through monitoring, analysing, and researching adverse events
- Analyse risk factors, implement and evaluate preventive measures
- Provide evidence-based support for blood donation process improvement
- Reduce the frequency of adverse events
- Increase donation frequency

The national donor haemovigilance system aims to place a mechanism for data collection, validation with analysis, publication, and dissemination of reports, development of recommendations as well as monitoring their implementation. The ultimate aim of this national programme is to increase the confidence of donors and improve blood donor safety by:

- Identifying the trends in adverse events and reactions
- Determining risk factors and raising awareness
- Providing evidence for the development and amendment of policies to improve practices
- Guiding research

4. Donor-Vigil Software

- As part of the Haemovigilance Programme of India (HvPI), donor haemovigilance software is used to collect, compile and collate donor adverse reaction data from blood centres. The software was created in-house by the HvPI information technology (IT) team at the National Institutes of Biological, NOIDA (UP) and was unveiled on June 14, 2016, a year after the launch of the Donor Haemovigilance Programme on June 14, 2015, on the occasion of World Blood Donor Day, at Science City Kolkata in West Bengal, India
- National Institute of Biologicals has a web-based reporting system for adverse transfusion reactions and donor reactions via indigenously developed software(s). The reporting of donor reactions is done via Donor- Vigil Software in a uniform format i.e. Blood Donor reaction reporting form by enrolled centres using a unique use Id & password being provided by HvPI. The form is divided into five sections comprising of Donor Information, Details of Blood Collected, Adverse Reaction Details, Types of Complications, Outcomes & Imputability. The process flow of working of the National co-ordinating centre with the participant blood centres and analysis and recommendation forwarded to IPC for further action is shown in **Figure 1**.



IPC= Indian Pharmacopoeia Commission, NCC= National Co-ordinating centre NIB= National Institute of Biologicals

Figure 1: Process flow of National co-ordinating centre for Donor Haemovigilance Programme

5. Classifications and Definitions

The key needs of the donor haemovigilance system are having well-defined, evidence-based, and standardised definitions of DARs. These definitions are essential for each blood centre to appropriately identify, record, report a DAR as well as to establish a baseline DARs rate and also to evaluate risk factors for the same. This process also aids in determining the impact of mitigation strategies adopted to prevent DARs.

These definitions should be simple to use in a consistent manner and allow for international comparisons. International Haemovigilance Network in collaboration with the Association for the Advancement of Blood and Biotherapy (AABB) Donor Haemovigilance Working Group and the Donor Vigilance subgroup of the International Society of Blood Transfusion (ISBT) Haemovigilance Working Party developed the "Standard for Surveillance of Complications Related to Blood Donation" in 2014. These definitions served as the foundation for Continually Quality Improvements in the donation process as well as research on DARs. The Indian National Donor Haemovigilance Program incorporated ISBT's internationally approved definitions and categorization for DARs. (Table 1)

DARs may be caused by the phlebotomy procedure (local) or they might be the systemic (vasovagal) response. These reactions may lead to an incomplete blood collection and discomfort to the donor which may diminish the donor's likelihood of returning for future donation.

Table 1: Classification and categorization of donor adverse events/ reactions

A	Local Symptoms 1. Blood Outside Vessel • Haematoma (bruise) • Arterial Puncture • Delayed (bleeding/ Re-bleeding) 2. Arm Pain • Nerve injury / irritation • Other arm pain 3. Localized Infection/ Inflammation along the course of a vein • Thrombophlebitis • Cellulitis 4. Other major blood vessel injury- Serious conditions needing specialist medical diagnosis and attention • Deep Venous Thrombosis (DVT) • Arteriovenous Fistula • Compartmental Syndrome • Brachial Artery Pseudo aneurysm
B	Complications mainly with Generalized Symptoms: Vasovagal Reactions • Without Loss of Consciousness (LOC) • With LOC (Loss of Consciousness) < 60 sec • With LOC (Loss of Consciousness) > 60 sec • With Injury • Without Injury • Within Blood collection facility • Outside Blood collection facility
C	Complications related to Apheresis • Citrate reactions • Haemolysis • Air Embolism • Infiltration • Infiltration of IV fluids
D	Allergic Reactions • Local Allergic Reactions • Generalized allergic Reactions (Anaphylactic Reactions)
E	Serious Complications • Acute Cardiac Symptoms • Myocardial Infarction (MI) • Cardiac Arrest • Transient Ischemic Attack (TIA) • Cerebrovascular Accident • Death
F	Other Reactions

Definitions of donor adverse reactions

A. <u>Local Symptoms</u>

These DARs are directly caused by the insertion of the needle. Some of these are mainly characterized by the occurrence of blood outside vessels, whereas others are mainly characterized by pain.

A1: Complications mainly characterized by the occurrence of blood outside the vessels.

i. **Hematoma:** This condition is an accumulation of blood in the tissues outside the blood vessel characterised by bruising, discoloration, swelling, and local pain. Blood accumulation in deeper tissues can cause more severe pain and pressure syndromes. The symptoms are caused by blood flowing out of damaged vessels and accumulating in the soft tissues. Hematomas can also be caused by red cell infiltration of the soft tissues during the return phase of the apheresis procedure. Large hematomas, particularly those in deeper layers of the forearm, place pressure on surrounding tissues and can lead to other complications such as nerve irritation and injury as well as compartment syndrome, which occurs less frequently.

ii. **Arterial Puncture:** Arterial puncture is a puncture of the brachial artery or of one of its branches by the phlebotomy needle. It is often characterised by a rapid collection of bright red color which is brighter than venous collection. It may present with pulsation on needles and tubing. This may be associated with nagging pain in the elbow region. Due to the rapid blood flow, the risk of a large hematoma is increased by arterial puncture in contrast to venous punctures and thereby the risks of more

serious pain and pressure syndromes. The blood centre staff will need to pay more attention to arresting bleeding and prevent re-bleed by application of a pressure bandage without compromising blood flow to the distal forearm.

iii. **Delayed bleeding (re-bleeding):** This condition is characterized by leakage of blood from the venipuncture site after the initial bleeding has stopped. Re-bleeding may be related to pressure not being applied to the correct location or for an adequate duration, or premature removal of the bandage. After the donor has left the donation center, re-bleeding may be related to heavy lifting or strain to the donor's arm. Donors on certain medications, such as autologous donors on anticoagulants, may be at higher risk of re-bleed.

A2: Complications mainly characterized by pain

i. **Nerve Injury/ Irritation**: Injury or irritation of a nerve that may be hit directly by the needle at insertion or withdrawal, or there may be pressure on a nerve due to hematoma or inflammation of the soft tissues. It may present with radiating, often 'electrical' sharp pain moving away from the venipuncture site, and/or paresthesias such as tingling, burning sensations in the hand, wrist, or shoulder area, but away from the venipuncture site. Symptoms may arise immediately when the needle is inserted or withdrawn. In cases associated with a hematoma, pain may not be apparent immediately and may start when the hematoma has reached a sufficient size, sometime after insertion of the needle. Symptoms may be worse in certain positions or with certain arm motions. Rarely, weakness of the arm may develop.

ii. **Other Painful arm:** Pain in the arm is the primary symptom and may be described as an ache or heaviness in the arm, similar to that experienced after vaccination.

Pain here is not secondary to nerve irritation outlined above, or the presence of a large hematoma or other defined complications. Pain may be related to tissue injury, possibly due to hematoma in the deeper tissues. Pain in the arm is usually generalized, without characteristics of nerve irritation.

A3: Localised infection/ inflammations

i. **Localised infection/inflammation:** Inflammation along the course of a vein may progress to localised infection several days after phlebotomy. This may be due to clotting in the vein. Tissue damage and the introduction of surface bacteria into the deeper tissues with venipuncture may also cause this inflammation. Presentation is with warmth, tenderness, local pain, redness, and swelling at the site of phlebotomy. The site and the vein may feel tender, firm, and warm to the touch. Fever may be present. It may be of two types:

   a. Thrombophlebitis: It occurs in the superficial vein itself and extends along the course of the vein. The redness, swelling, and tenderness extend along the course of the vein.

   b. Cellulitis: The redness, swelling, and tenderness affect the soft tissues, and are not localized to the course of the vein.

A4: Other Major Blood Vessel Injury

i. **Deep venous thrombosis (DVT):** This refers to thrombosis of a deep vein in the donor's phlebotomy arm. Superficial venous thrombosis may progress into the deeper veins of the donor's arm. DVT can also occur in the absence of previous

signs and symptoms of superficial thrombosis. These donors may have an additional risk factor for thrombosis, specifically the use of oral contraceptives. It is characterised by swelling and pain in the upper arm.

ii. **Arteriovenous fistula:** Acquired channel forms between the lacerated vein and artery (due to venipuncture laceration) immediately post-venipuncture, or during the healing process. It may be caused by an arterial puncture. It is characterised by pulsating mass with a palpable thrill and associated bruit. If there is excessive blood shunting, the affected region may be warm, and the distal part of the arm may be cold. The distal veins may be dilated and may pulsate.

iii. **Compartment syndrome:** This is characterised by increased intra-compartmental pressure caused by blood deposition in the frontal deep areas of the forearm, resulting in muscle and soft tissue necrosis. It is characterised by a painful arm, particularly when moving, swelling, paraesthesia, and partial paralysis.

iv. **Brachial artery pseudoaneurysm:** Collection of blood outside the artery, contained by adventitia of the surrounding tissue alone is called pseudoaneurysm May follow a traumatic arterial puncture or a large hematoma following an arterial puncture. It can be characterised by a pulsating mass in the arm, as well as pain and paraesthesia.

B. Complications mainly with generalized symptoms: Vasovagal Reactions

A vasovagal reaction (VVR) is characterised by a general sense of discomfort and weakness, as well as anxiety, dizziness, and nausea, which may progress to loss of consciousness (fainting). It can be caused by both physiological and psychological factors. The autonomous nervous system causes the reaction, which is further triggered by psychological factors and the amount of blood removed in comparison to the donor's total blood volume. It can happen before, during, or after donation, and it can happen within or outside the blood donation complex.

Usually present as discomfort, weakness, anxiety, light-headedness/dizziness, nausea, chills, sweating, vomiting, pallor, hyperventilation, rapid or a slow pulse. Hypotension and loss of consciousness (LOC) may occur and can be accompanied by loss of bladder or bowel control or convulsive movements. Reactions may occur before (rare), during, or immediately after phlebotomy, when the donor stands up, in the refreshment area, or after the donor has left the collection site. Vasovagal reactions are divided into a few subgroups:

a. Without loss of consciousness (LOC):
b. With the loss of consciousness (LOC): The donor faints for
    i. Less than 60 seconds
    ii. More than 60 seconds

- Based on injury:
    a. With Injury- Injury caused by fall or accident due to a vasovagal reaction
    b. Without Injury
- Based on the location:

a. On collection facility: When symptoms occur within the blood donation centre/ area, before the donor has left the donation site (in the area within which staff can observe the donor and be responsible for the care of donors with complications)
b. Outside collection facility: Symptoms occurred after the donor has left the donation site

C. Complications related to apheresis

a. **Citrate Reaction:** It is a type of neuromuscular hyperactivity caused by a decrease in ionized calcium levels as a result of the infusion of citrate anticoagulant during the apheresis procedure. It is characterised by numbness or tingling of lips and fingertips, feeling of vibrations, numbness, and tingling of fingers, metallic taste, chills, shivering, light-headedness, feeling of tightness, muscle twitching, rapid or slow pulse, shortness of breath. Symptoms may progress to carpopedal spasms and vomiting, and in severe reactions, to generalised muscle contractions (tetany), shock, irregular pulse, and cardiac arrest.

b. **Haemolysis during apheresis procedure:** Donor red cells may get damaged in the return line of the apheresis kit releasing haemoglobin. It may be caused by faulty/ malfunctioning valves, kinks or obstructions in the tubing, incorrect kit installation, or other equipment failure affecting the extracorporeal circuit. It can also be due to incompatible replacement fluids, such as dextrose D5W. It is characterised by pink or red plasma, blood in the tubing of apheresis kit or filter may appear dark. The donor may notice pink or red urine after donation.

c. **Air embolism:** Air bubbles are injected into the apheresis donor circulation. Air can enter the apheresis kit tubing due to improper priming of the tubing, equipment failure, faulty kits, or incorrect manipulation by staff. This air can circulate in the pulmonary or arterial circulation, reducing blood flow in the lungs or brain. It is distinguished by a bubbling sound at the site of the venipuncture, a cough, dyspnoea, apprehension, sweating, chest pain, confusion, tachycardia, hypotension, nausea, and vomiting.

d. **Infiltration:** Intravenous solute (saline, albumin solution) enters the extravascular tissues during volume replacement (can happen during any apheresis procedure like plasmapheresis or even plateletpheresis if the needle is improperly positioned). The needle is no longer positioned in the intravascular space, so fluids enter the surrounding tissues. Signs and symptoms may include swelling of the tissues at the venipuncture site.

e. **Unable to return red cells**: Due to an emergency termination of the apheresis procedure, red blood cells in the apheresis kit are not returned to the donor. It might be due to technical errors in the equipment or severe donor reaction. It could result in a loss of nearly one unit of packed red blood cells from the donor.

D. Allergic reactions

a. **Localised allergic reaction:** Red or irritated skin at the venipuncture site. Allergens or irritants in disinfection solutions for the arm (such as iodine or chlorhexidine), latex gloves, or the adhesive bandage cause the reaction (bandage adhesive dermatitis). It is characterised by itching, redness, raised rash, or hives at the venipuncture site, the bandaged site, or the entire skin disinfection area. The reaction can occur immediately after the donation or within hours or days.

b. **Generalised allergic reaction**: Anaphylactic reactions typically begin shortly after the apheresis procedure and can sometimes quickly progress to cardiac arrest (extremely rare). It may be because some donors are sensitive to the ethylene oxide gas which is used to sterilise apheresis collection kits. Apprehension, anxiety, flushing, swelling of the pupils, lips, or tongue, cyanosis, cough, wheezing, dyspnoea, chest tightness, cramps, nausea, vomiting, diarrhoea, tachycardia, hypotension, and altered mentation are all symptoms that may present.

E. Other serious complications related to blood donation

- **Major cardiovascular event (MCE)**

  Acute cardiac symptoms (other than myocardial infarction or cardiac arrest).

  Myocardial infarction

  Cardiac arrest

  Transient Ischemic Attack

  Cerebrovascular accident

  Death

  Major cardiovascular events, including death, may occur hours after attending the collection centre for blood donation. This is very rarely reported.

F. Other complications

Other systemic reactions or complications that do not fit into the above may be considered in these categories. For example, chest pain may have been investigated as angina, but was actually musculoskeletal, or transmission of infection to a donor through erroneous re-use of equipment.

Grading of Imputability:

Imputability refers to the strength of the relation between donation and the DAR (or complication in the donor). Imputability of harm should be assessed, i.e., the extent to which the harm detected is likely to have been caused by the process of donation. (Table 2)

Table 2: Details of terms used to define the imputability

Definite or Certain	Conclusive evidence beyond reasonable doubt that donation caused the complication (DAR)
Probable or Likely	Clearly in favor that the donation caused the complication (DAR).
Possible	Evidence is indeterminate that complication adverse reaction (DAR) could be caused by donation or by other reason
Unlikely or Doubtful	Clearly in favor that "other" reason is the cause of the complication (DAR) adverse reaction
Excluded	Conclusive evidence beyond reasonable doubt that reasons other than donation caused the complication (DAR)

6. Severity Grade Tool (SGT):

The severity grading subgroup was formed in January 2018 by the AABB Donor Hemovigilance Working Group, the ISBT Donor Haemovigilance Working Group, and the chair of the Plasma Protein Therapeutics Association (PPTA) Medical Policy Committee (representing the source plasma collection industry) to undertake the task of developing the Severity Grading Tool (SGT) for blood donor adverse events.

The severity grade is intended to be used in conjunction with the standard definitions of DARs developed by ISBT. This grading tool is designed to improve objective severity assessment based on the management strategy used to manage the adverse event. More consistent reporting with minimum inter-and intra-observer variation in reporting of severity with help in a more reliable comparison of research results among the reporting centres. This will also help us highlight the priority areas for research in donor care and safety. This grading tool assigns severity grades 1-3 with 1 through 3 approximately corresponding to mild, moderate, severe. (Table 3)

Some terms to understand and apply the tool:

- **Outside Medical Care (OMC):** In this donor is evaluated and/or treated by Emergency Medical Response (EMR), Health Care Professional (HCP), or outside the hospital by ambulatory service or in hospital emergency room (ER) without being admitted to the hospital.
- **Hospitalization:** Admission to the hospital for more than 24 hours.
- **Surgery:** Any procedure that required regional (spinal, block), inhalation, or general anaesthesia. The simple sutures, staples, butterfly closure are NOT considered surgery.
- **Activities of Daily Living (ADL):** Including household tasks, doing necessary business, shopping, going to work or school, or getting around for other purposes.
- Choose the highest applicable severity grade; for example, if a vasovagal reaction caused a fall and the donor was taken to the emergency room where she required sutures (Grade 2) to repair a laceration on her arm and was also diagnosed with a concussion (Grade 3), the final severity assignment would be Grade 3.

Table 3: Definitions and general considerations for severity grading tool:

Categories	Grade 1	Grade 2	Grade 3
A.1. Blood outside vessel -Haematoma - Arterial puncture - Delayed bleeding	- No OMC - Localized to the venipuncture site	- OMC (EMR, ER, Urgent care), No hospitalization, or - ADL ≤2 weeks, or - Generalized beyond venipuncture site	- Hospitalization, or - ADL -2 weeks, or - Severe sequelae, or - Surgical intervention
A.2. Arm Pain - Nerve injury/irritation - Other arm pain	- No OMC - Duration ≤2 weeks	- OMC (EMR, ER, Urgent care), - No hospitalization, or - Duration -2 weeks to ≤6 months, or - ADL ≤2 weeks	- Duration - 6 months, or - ADL -2 weeks
A.3. Localized infection/inflammation of vein or soft tissue -Superficial thrombophlebitis -Cellulitis	-No OMC	-OMC (EMR, ER, Urgent care), -No hospitalization, or -ADL ≤2 weeks, or -Resolved with oral antibiotics	-Hospitalization, or -ADL -2 weeks, or -Resolved with IV treatment
A.4. Other major blood vessel injury -Deep venous thrombosis -Arteriovenous fistula -Compartment syndrome -Brachial artery pseudoaneurysm			-Diagnosis is medically confirmed, or -Treated with anticoagulant therapy, or -Required surgical intervention
B. Vasovagal reactions -Vasovagal reaction, no loss of consciousness (LOC) -Vasovagal reaction, loss of consciousness (LOC)	-No OMC	-OMC (EMR, ER, Urgent care), -no hospitalization, or -ADL ≤2 weeks, or -Suture of laceration(s), or -IV rehydration	-Hospitalization, or -ADL -2 weeks, or -Fracture(s), medically confirmed concussion, a dental injury requiring dental procedure, e.g., cap/crown, dental implant, bridge, tooth extraction, dentures
C. Related to apheresis -Citrate reaction -Haemolysis -Air embolism -Infiltration	-No OMC -Citrate toxicity (including carpopedal spasm) resolved with or without oral calcium	-OMC (EMR, ER, Urgent care), no hospitalization, or -ADL ≤2 weeks, or -Citrate toxicity requiring intravenous calcium	-Hospitalization, or -ADL -2 weeks, -Abnormal cardiac rhythm medically diagnosed

D. Allergic Reaction -Local allergic reaction -Generalized (anaphylactic) reaction	-No OMC -Managed with over-the-counter medications—topical steroids, antihistamine	-OMC (EMR, ER, Urgent care), no hospitalization, or -Generalized reaction including bronchospasm, Laryngospasm managed with inhalation or oral bronchodilator and/or autoinjector (EpiPen)	-Hospitalization, or -Generalized reaction, including bronchospasm, laryngospasm, or anaphylaxis, requiring management with intravenous steroids and/or epinephrine, but NOT intubation or tracheostomy
E. Other serious complications -Acute cardiac symptoms -Myocardial infarction -Cardiac arrest -Transient ischemic attack -Cerebrovascular accident (Stroke)			-Diagnosis is medically confirmed
F. Other	-No OMC -No injury	-OMC (EMR, ER, Urgent care), no hospitalization, or -Duration -2 weeks to ≤6 months, or -ADL ≤2 weeks	-Hospitalization, or -Duration - 6 months, or -ADL -2 weeks, or -Surgical intervention
OMR: Outside Medical Care, EMR: Emergency Medical Response, HCP: Health Care Professional, ER: Emergency Room, ADL: Activity of Daily Living			

A donor can sometimes experience multiple adverse events. In such situations, assigning a severity grade requires discretion.

- If more than one type of donor adverse reaction, each donor adverse reaction has to assign a separate grade.
- If the donor's adverse reaction is related or difficult to differentiate, use the highest applicable severity grade.

7. Submission of data in Donor haemovigilance software:

7.1. Website:

7.1.1. Access the website for the National Institute of Biologicals on URL:- http://nib.gov.in/haemovigilance.aspx

7.1.2. Select Donor-Vigil Software on this website (Figure 2).

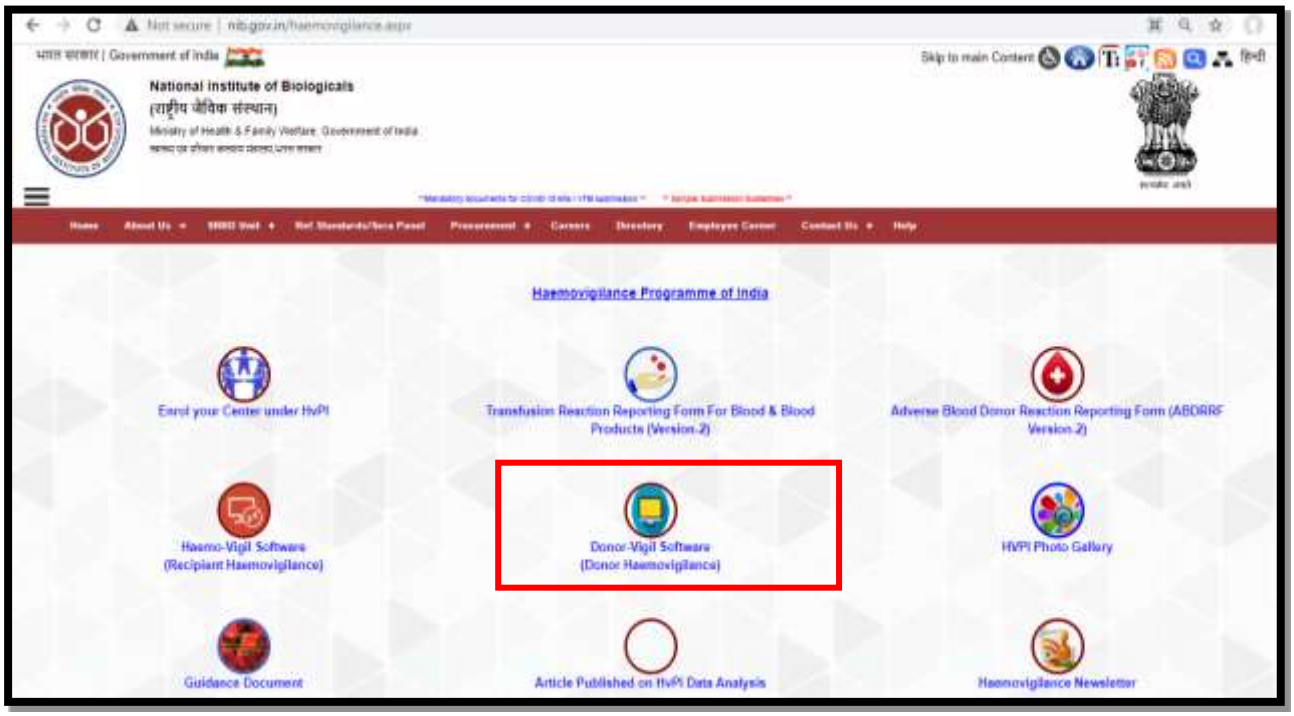


Figure 2: Donor-Vigil software on the website

7.2. Login by user ID and Password: After registering, log in to the Donor-Vigil Software using the user ID and password given by the Haemovigilance Programme of India. (Figure 3)

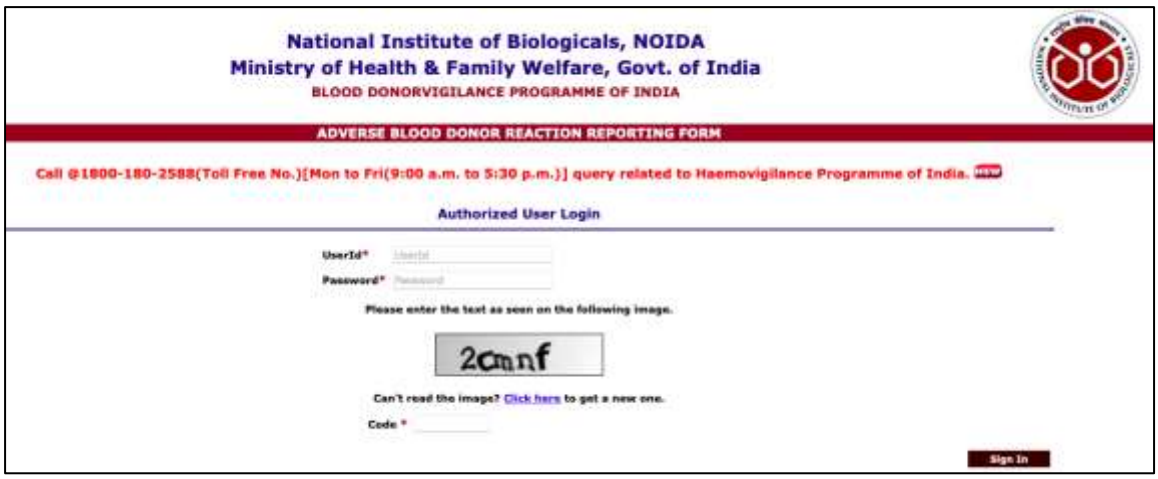


Figure 3: Login by user ID and Password

7.3. Adverse Blood Donor Reporting form: After logging in, the screen will display a message in yellow colour box with red which will guide you to filling the report, nil report, or denominator data accordingly in the software. After that clicking on the left side on the option, i.e. donor reaction reporting form a blank adverse blood donor reaction reporting form will open. (Figure 4) This form is divided into four sections: donor information, blood collection details, adverse reaction details, and type of complications. The outcome and imputability are also shown on the screen. All fonts highlighted in red ink are necessary fields.

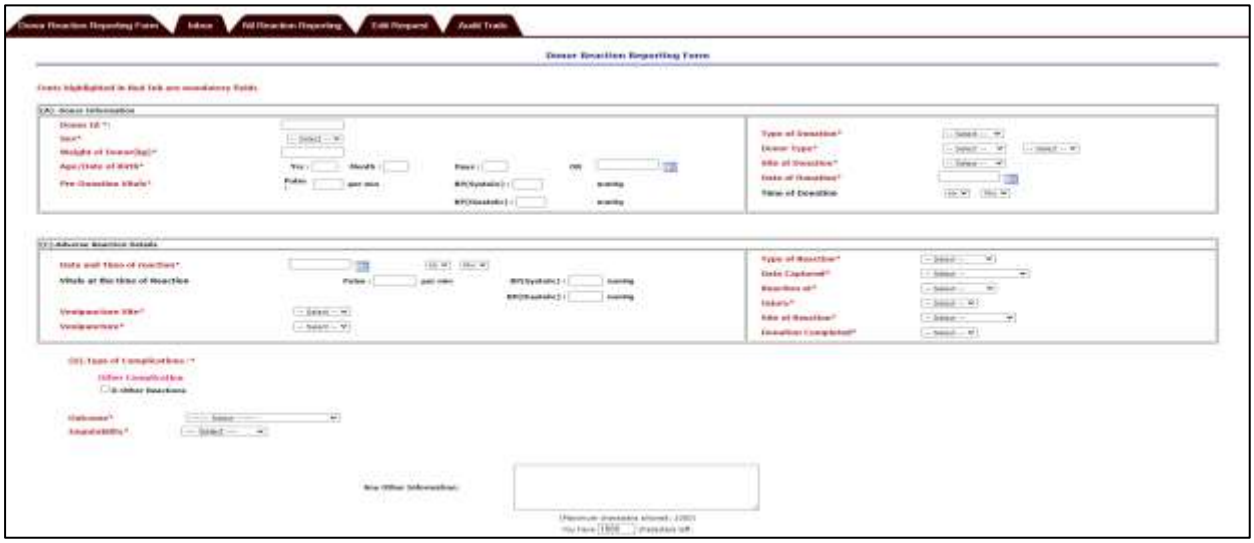


Figure 4: Donor reaction reporting form

7.4. Donor Information: In this donor demographics and type of donation are to be filled. (Figure 5) Begin by entering the Donor ID. This is the unique donor identification number provided by the blood centre to each blood donor at the time of blood donation. This will aid in tracing the donor details if an error is made.

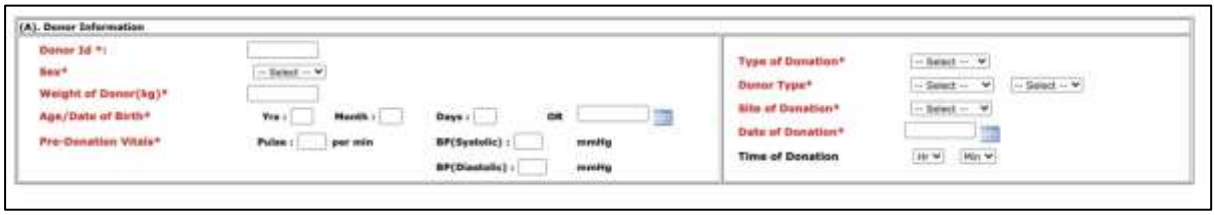


Figure 5: Donor information

7.5. Gender Information: This is filled out by choosing the gender of the blood donor from the dropdown menu next to the sex column. (Figure 6) This will aid in identifying genders that are predisposed to a high risk of some specific adverse reaction during data analysis.

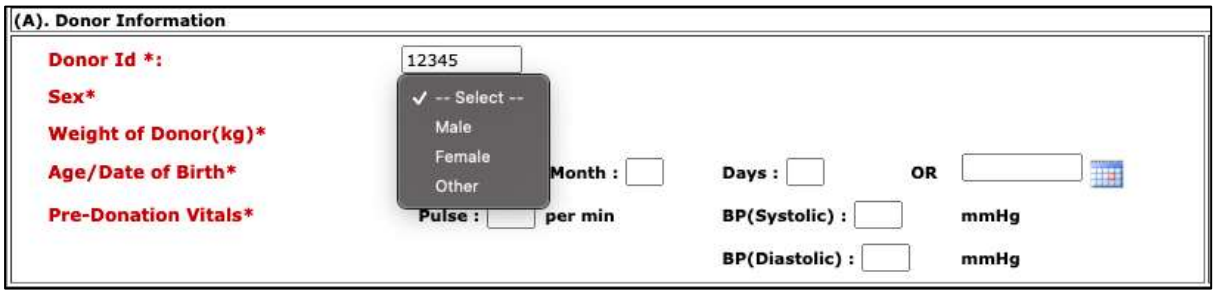


Figure 6: Gender information

7.6. Weight of donor: According to the Drug and Cosmetic Act March 2020 amendment, the minimum weight for 350 mL, 450mL whole blood, and apheresis donation is 45 kg, 55 kg, and 50 kg, respectively. If there is a difference between the type and amount of blood donation and the weight of the blood donor, the final data may be invalid at

the time of data validation. This would also aid in identifying weight groups of donors who are at high risk for some specific form of adverse reaction.

7.7. Age or Date of Birth of donor: According to the Drug and Cosmetic Act March 2020amendment, the minimum and maximum age for blood donation is 18 and 65 years, respectively, and the upper limit for apheresis is 60 years. If there is a difference between the type of donation and the age of the donor, the final data may be invalid at the time of data validation. This would also aid in identifying the age of donors who are at high risk for some specific form of adverse reaction. By choosing the calendar option in front of the Age/Date of Birth option, can enter the date of birth.

7.8. Pre-donation vitals: Pre-donation vitals like pulse and blood pressure need to enter in order to observe any variation in pre-donation and vitals at the time of adverse reaction.

7.9. Type of Donation: This is to be entered by dropdown selection for whole blood and apheresis in front of the type of donation column. (Figure 7)

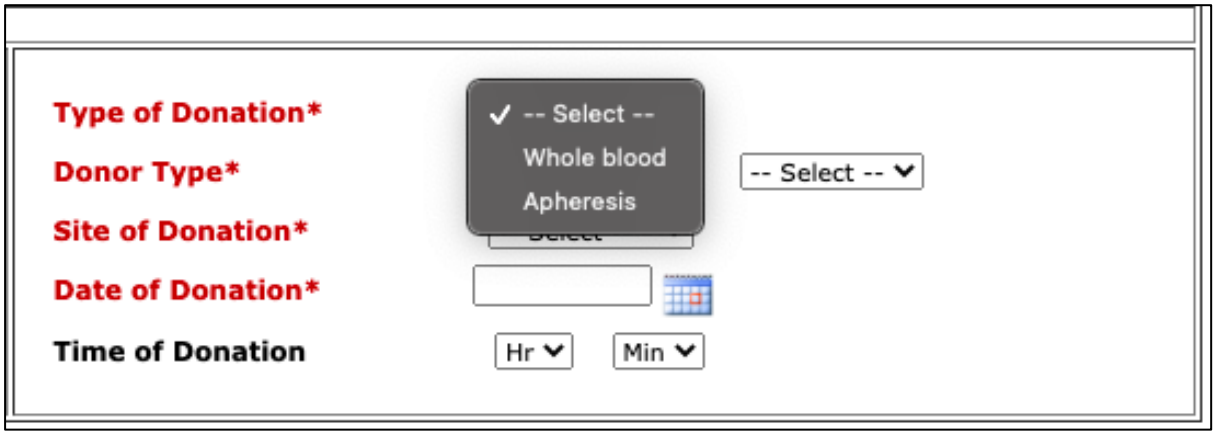


Figure 7: Type of Donation

On selection of whole blood donation, section (B) regarding whole blood details of blood collected will be opened in that lot number, manufacturer and expiry date of blood bag has to be entered. (Figure 8)

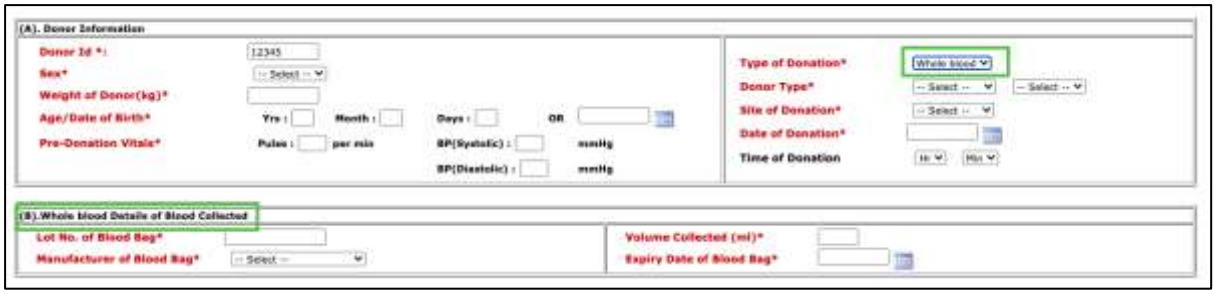


Figure 8: Whole blood details of blood collected

On selection of apheresis donation, another dropdown near to that will be opened to select a type of apheresis donation like a platelet, plasma, red blood cells, granulocyte, peripheral blood stem cells, and COVID-19 convalescent plasma. Along with that section (B) regarding apheresis details of blood collected will be opened in that lot number, and the expiry date of the kit has to be entered. (Figure 9)

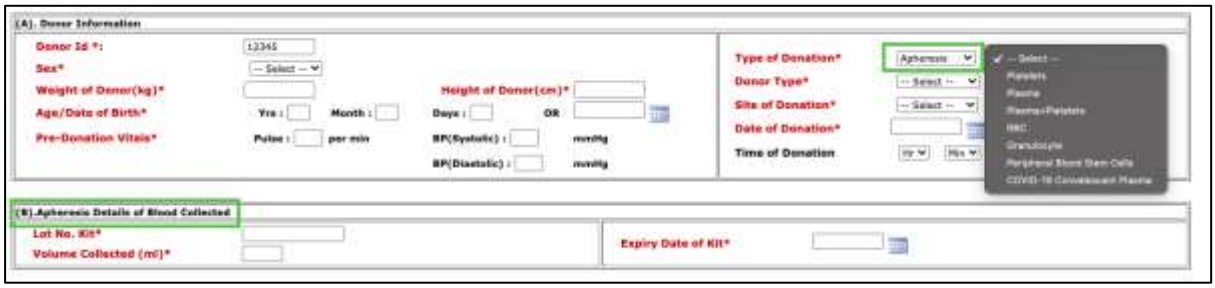


Figure 9: Apheresis details of blood collected

7.10. Donor Type: This is entered through two dropdown menus in front of the donor type, the first for voluntary, replacement, family, and autologous donation, and the second for the first-time and repeat donation. (Figure 10 & 11) This would also aid in identifying groups of donors that are at high risk for some specific form of adverse reaction.

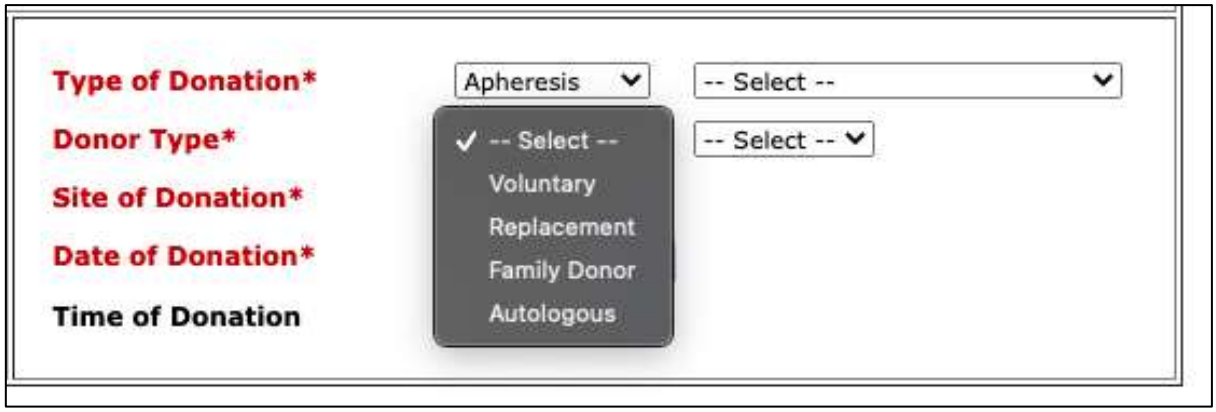


Figure 10: Type of donation (1)

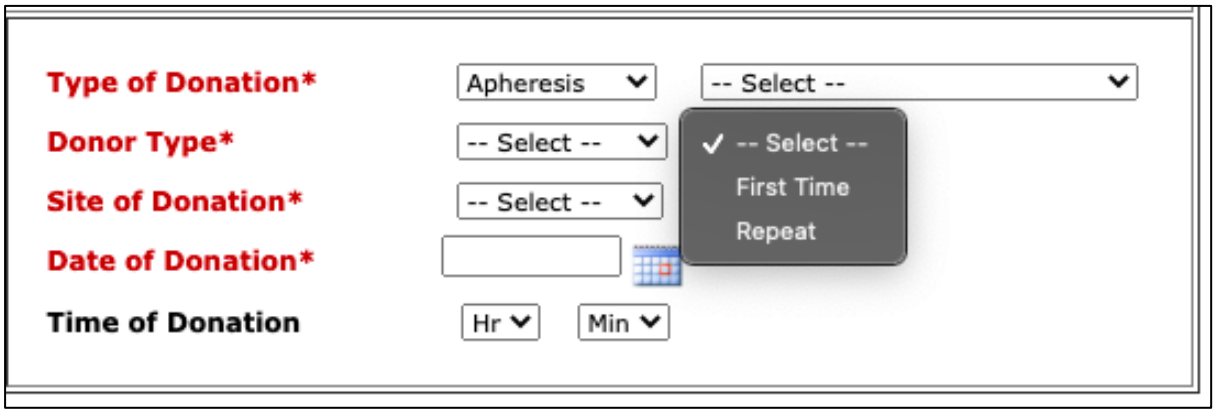


Figure 11: Type of donation (2)

7.11. Site of Donation: This is entered by selecting a dropdown menu in front of the donation column's location. (Figure 12) The correct entry would aid in identifying the type of adverse reactions that occurred at any particular blood donation site.

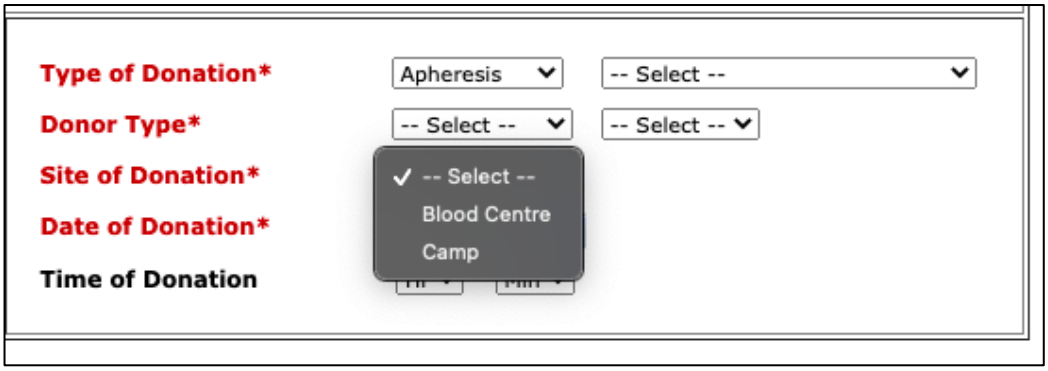


Figure 12: Site of donation

7.12. **Date and Time of Donation:** Enter the date of blood donation in the format DDMMYY. It must be in a match or before the date of the adverse reaction, otherwise, it will be invalid during data validation. Enter the time of blood donation in HR and Min formats by using the dropdown menu in front of the time of donation column. (Figure 13)

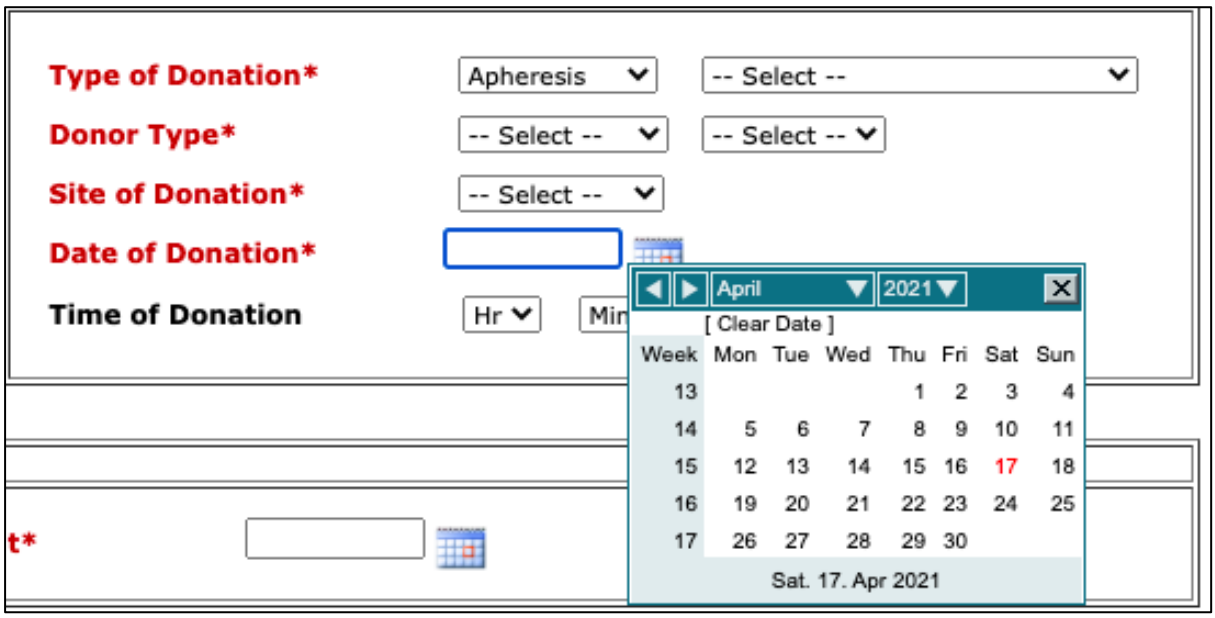


Figure 13: Date and time of donation

7.13. **Blood collection details:** Following the selection of whole blood donation, section (B) pertaining to whole blood specifics of blood collected will be opened, in which the lot number, manufacturing, and expiry date of blood bag must be entered. (Figure 14) For the manufacturer of a blood bag, select one name from the drop-down menu of the different manufacturer names.

While section (B) regarding apheresis details of blood collected will be opened in that lot number, and the expiry date of the kit has to be entered for apheresis donation.

Along with that for both types of blood donation, the volume collected has to be entered. This is the volume collected at the time of reaction like 50 ml, 100 ml, or so on not the volume of blood bag used for collection (350/450 ml). If there is a disparity between the amount collected and the time gap between donation and reaction time, such as 350 ml of blood collected within two minutes, the data would be invalid.

Figure 14: Whole blood details of blood collected

7.14. Adverse reaction details: In this basic detail about adverse reaction has to be entered. (Figure 15)

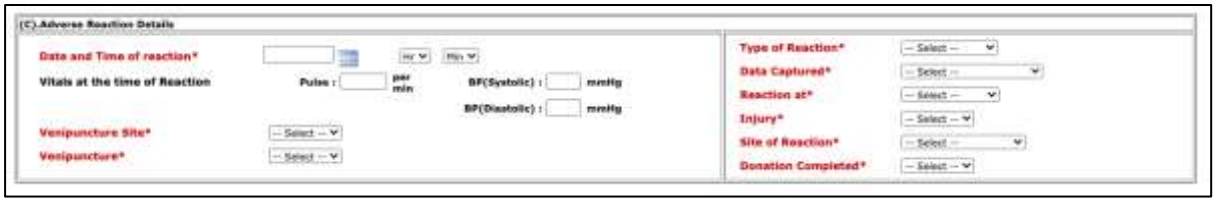


Figure 15: Adverse reaction details

Enter the date and time of the adverse reaction in the format DDMMYYYY and Hr and Min by using the calendar and dropdown menu, respectively. This timeline must come after the blood donation timeline. This timeline is also significant when analysing the volume collected, as well as the difference in donation and reaction time, as previously discussed. Unexpectedly longer or shorter length differences can lead to data invalidation.

7.15. Venipuncture Site: This is entered by using the dropdown menu in front of the venipuncture spot. (Figure 16) This is important in the context of a medicolegal situation.

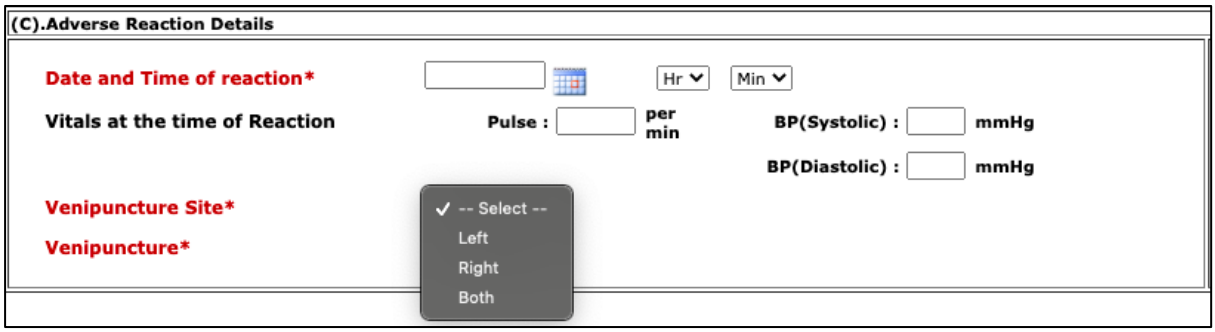


Figure 16: Venipuncture Site

7.16. Number of venipuncture: Enter by selecting a venipuncture from the dropdown menu. (Figure 17) The number should be correctly filled in.

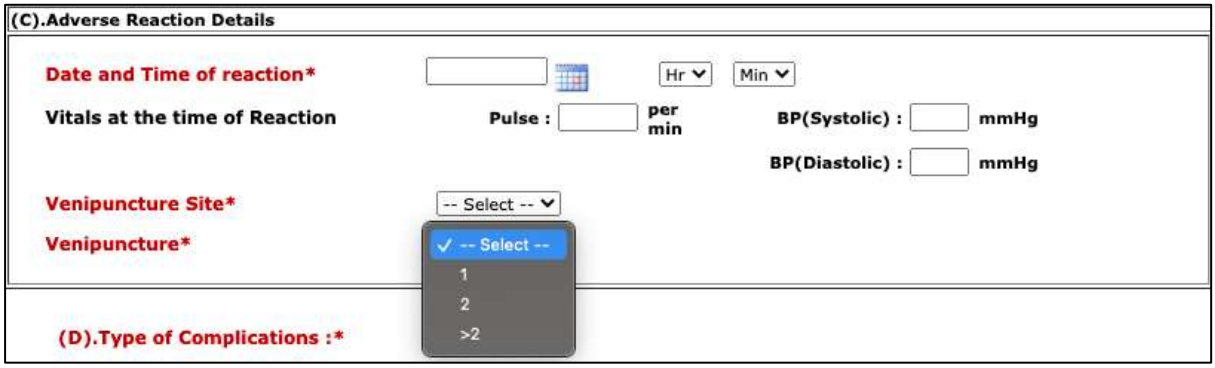


Figure 17: Number of venipuncture

7.17. Type of Reaction: It must be entered by selecting a localised, generalised, both, and other reaction from the dropdown menu next to the type of reaction. (Figure 18)

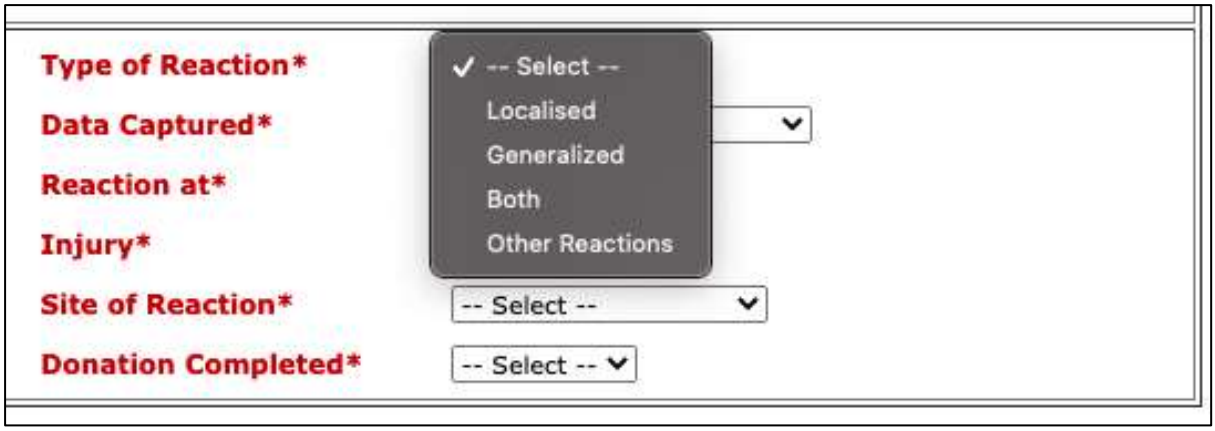


Figure 18: Type of reaction

Following the selection of a localised reaction, options for localised complications are shown in section (D) type of complications. (Figure 19)

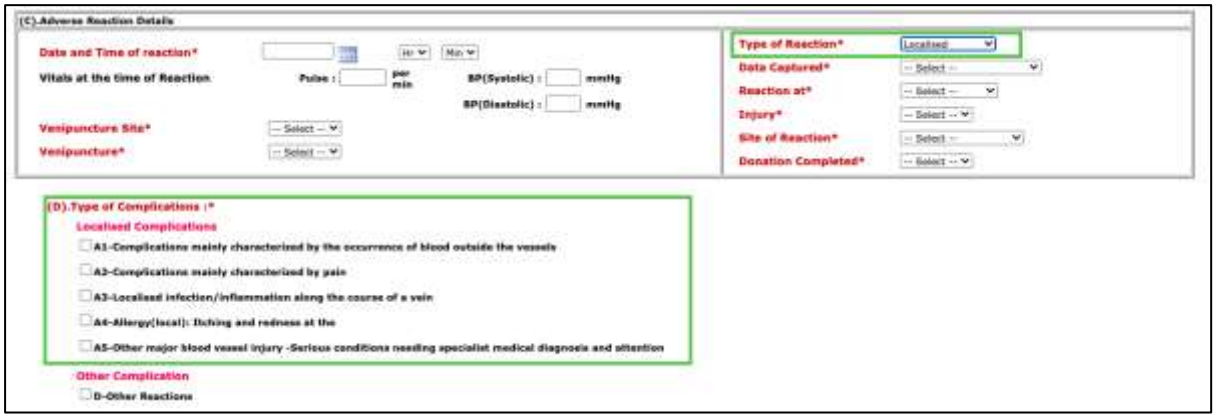


Figure 19: Localised Complications

Following the selection of a generalised reaction, generalised complications choices will be shown in section (D) type of complications. (Figure 20)

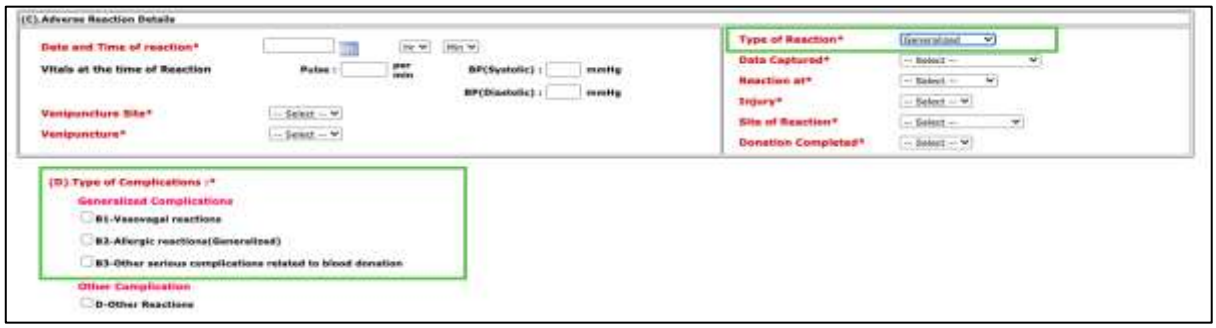


Figure 20: Generalised reaction

On the selection of both reactions, options of both localised and generalised complications will be displayed. (Figure 21)

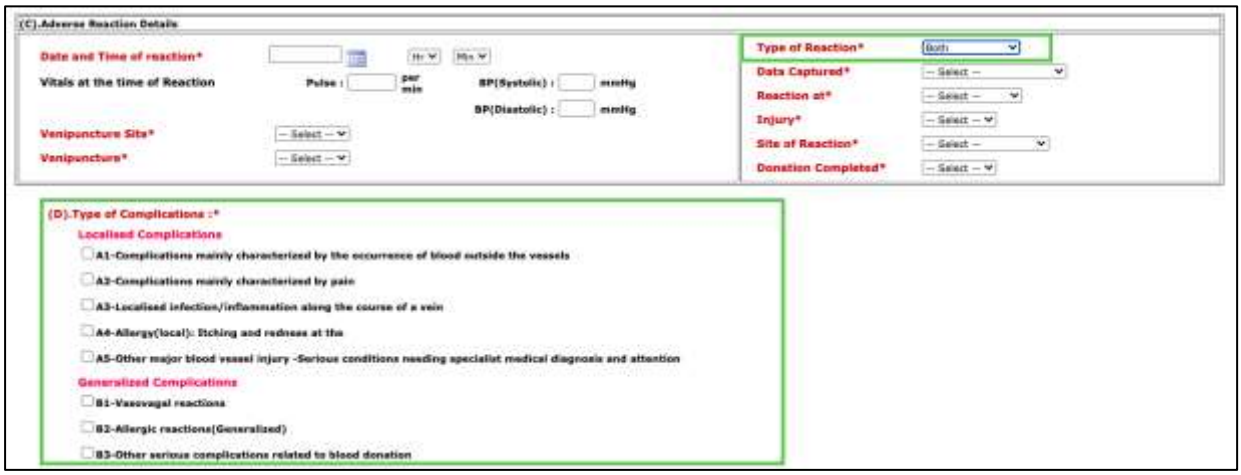


Figure 21: Both localised and generalised reaction

When apheresis donation is selected in the type of donation column in section (A), the choice for Apheresis complication is shown, along with localised or generalised complication (depending on selection) in section (B) (D). (Figure 22)

Figure 22: Apheresis Complications

While on the selection of other reactions, an option only for other reactions will be displayed. (Figure 23)

Figure 23: Other Complication

7.18. Data Capture: Data capture sites,

7.18.1. Onsite means collection of donor adverse reaction data at the site of blood donation either at a blood centre or camp. The gap between donation and reaction may be less than 60 minutes for it to be considered for "onsite" data captured.

7.18.2. Call back by donor means donor himself called back to blood centre to give information regarding adverse reaction after blood donation, and

7.18.3. Call back by blood centre means blood centred called back to blood donor to know well-being and donor inform about an adverse reaction. The gap between donation and reaction may be more than 6 hours for it to be considered for "Call back by blood centre" data captured.

This is to be entered by a selection of dropdown against data capture. (Figure 24) Data would be invalid if the data capture site is onsite and the donation reaction gap is long like more than 6-8 hrs because it is to be unlikely that blood donors at the donation site till this long time. Similarly, it would be invalid if the donation reaction gap is less than 10 minutes and data is obtained via a call back by the donor or a call back by the blood centre.

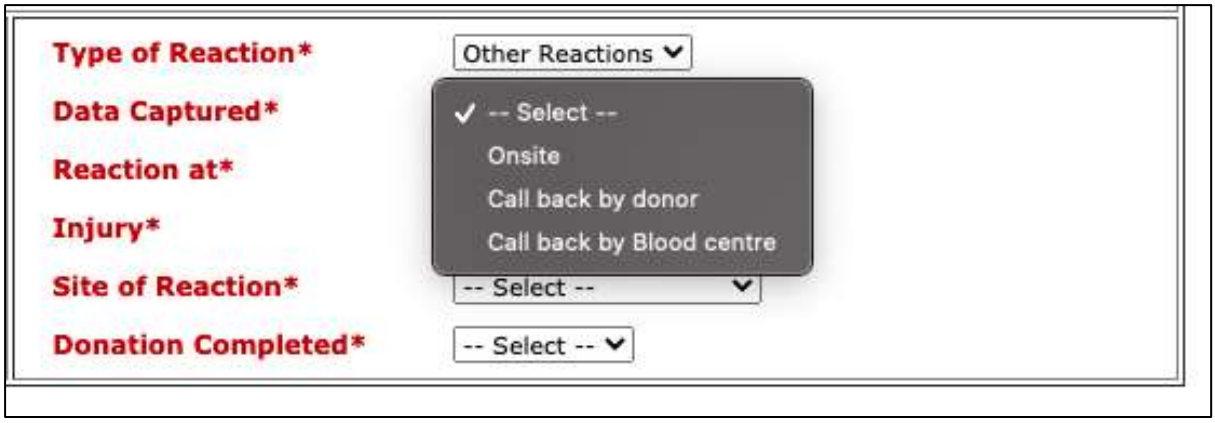


Figure 24: Data captured

7.19. Reaction time: This is to be entered by selecting the pre-donation, during donation, and after donation dropdowns in front of the reaction at column. (Figure 25) Pre-donation reactions are reactions that occur prior to blood donation, such as during a medical examination or questioning, or prior to needle insertion for blood donation. In that case, there is no need to enter blood collection information in section (B) whole blood/apheresis bag collection details.

If pre-donation reaction and blood collection information are entered, the data will be invalid. Similarly, if the reaction after donation and volume collected is entered as 0 (zero) ml, the data would be invalid.

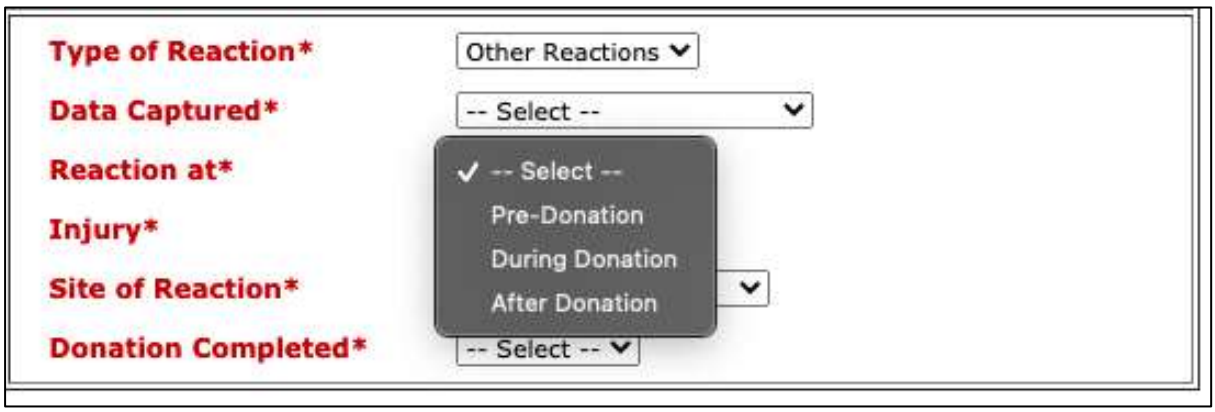


Figure 25: Time of reaction

7.20. **Injury:** Injury as a result of an adverse donor reaction is entered through a "Yes" or "No" dropdown against that. (Figure 26) Injuries may manifest as either localised or generalised adverse reactions. Details about the injury can be entered in the other details column at the bottom of the form.

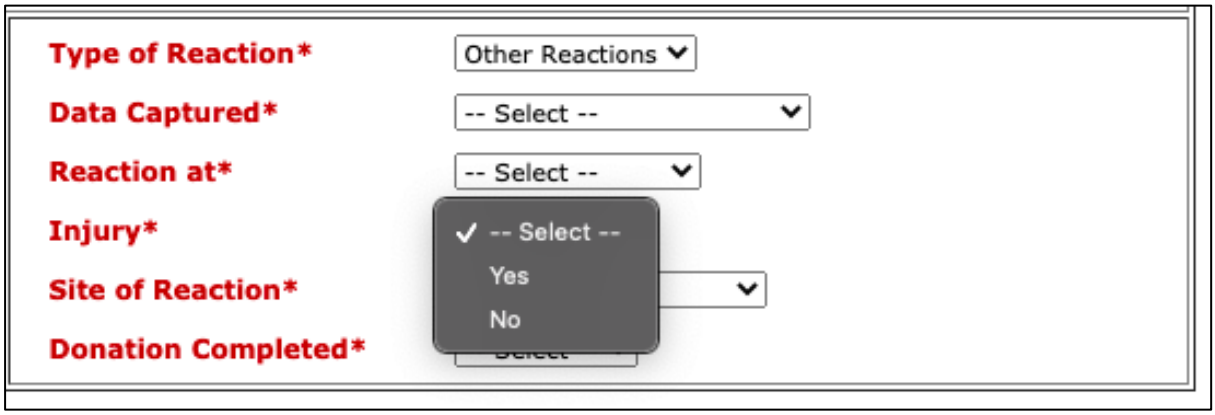


Figure 26: Injury details

7.21. **Site of reaction:** This is the site where adverse donor reaction is observed the first time, it is to be entered by the selection of dropdown in front of that. (Figure 27) Data would be invalid if the reaction at donation site and donation reaction gap is more than 6-8 hrs or similarly if the reaction at outside donation site and donation reaction gap is less than 10 minutes.

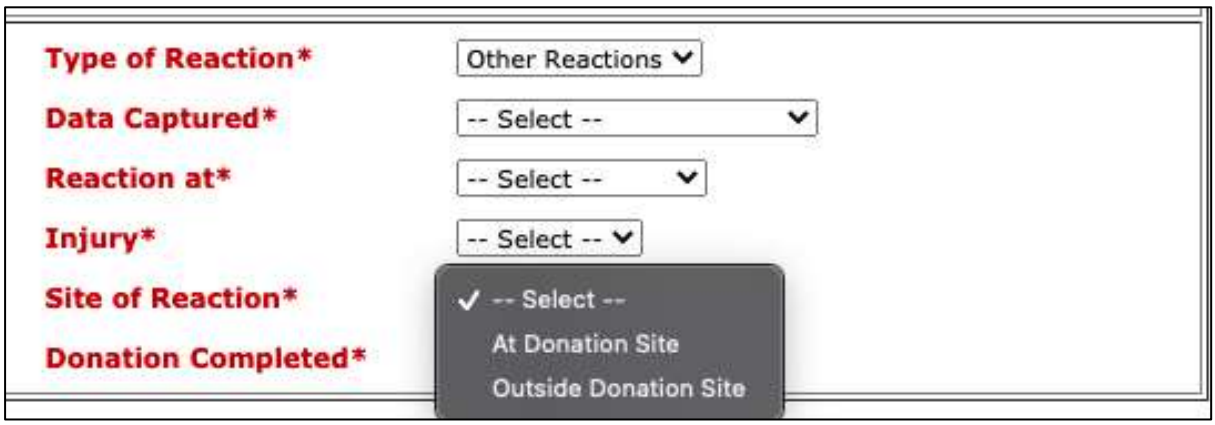


Figure 27: Site of reaction

7.22. Donation status: Status of blood donation either "completed" or "not completed" is to be entered by selecting the dropdown option "Yes or "No" in front of the donation completed column. (Figure 28) Data would be invalid if the donation is completed but the volume of whole blood collected is less than the volume of blood bag used and the donation reaction gap is too shorter like one to 2 minutes. Data would also be invalid if the volume collected entered as 350/450 ml but donation status incomplete.

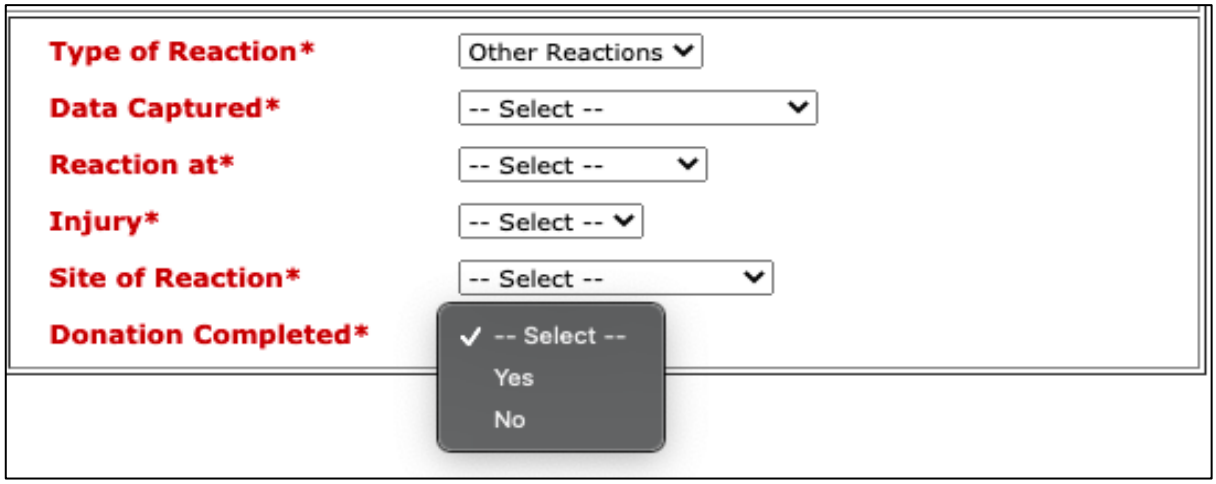


Figure 28: Donation Status

7.23. Localised complications: On selection of localised complications in section (B), options of entry for localised complications will be displayed. (Figure 29) Multiple options can be selected if the donor experienced more than one type of localised complication.

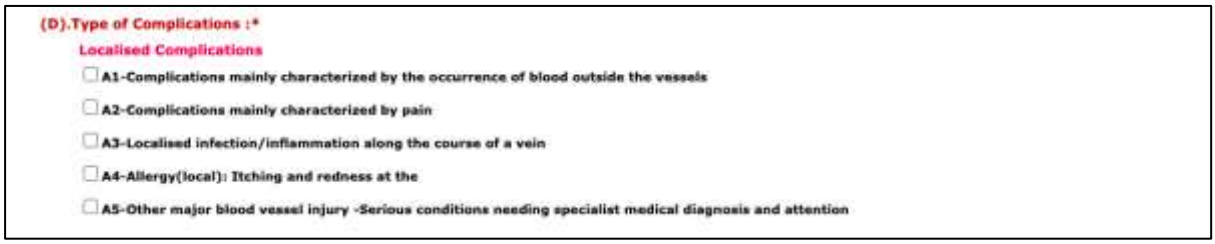


Figure 29: Localised complications

If the donor has a localised complication in the (A1) category: complications primarily characterised by the presence of blood outside the vessels, choose that choice again. (Figure 30) Three separate reactions will be displayed: haematoma, arterial puncture, and delayed bleeding. Choose the reaction alternative that the blood donor has had. If more than one type of donor reaction has occurred, many options can be selected.

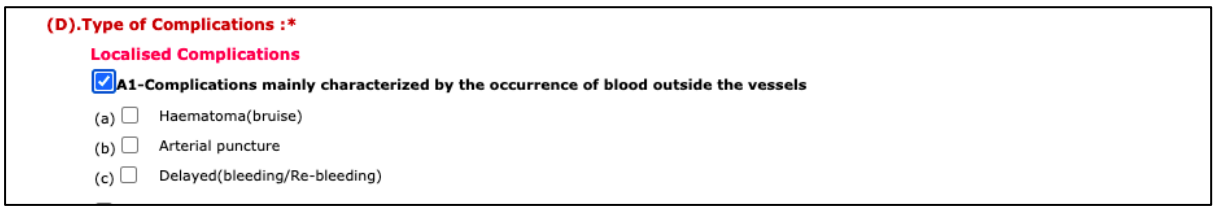


Figure 30: Complications primarily characterised by the presence of blood outside the vessels

After selecting delayed (bleeding/re-bleeding), a dropdown menu will appear to choose the timing of the delayed bleeding; choose one of the options. (Figure 31) Data could be invalid if the donation reaction gap exceeds 30 minutes and the delayed bleeding time occurs within 30 minutes of the donation, or vice versa.

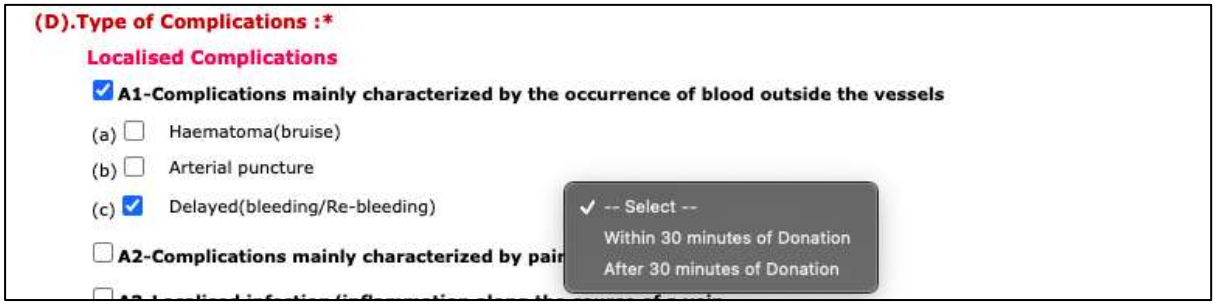


Figure 31: Delayed bleeding or rebleeding

When option (A2) complications characterised primarily by pain are selected, two choices will be displayed; choose any one of them based on the reaction encountered by the blood donor. (Figure 32)

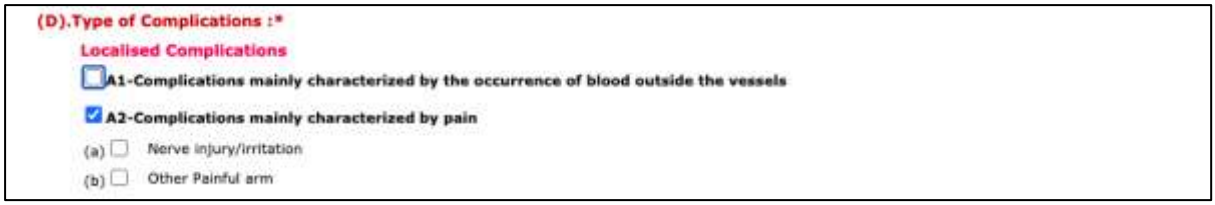


Figure 32: Complications characterised primarily by pain

When choice (A3) Localised infection/inflammation along the course of a vein is selected, two choices will be displayed; choose either one of them based on the reaction encountered by the blood donor. (Figure 33)

Figure 33: Localised infection/inflammation along the course of a vein

On selection option (A4) allergy (Local), a dropdown menu will display, and on the selection of that three options will be open, select one of them according to reaction. (Figure 34)

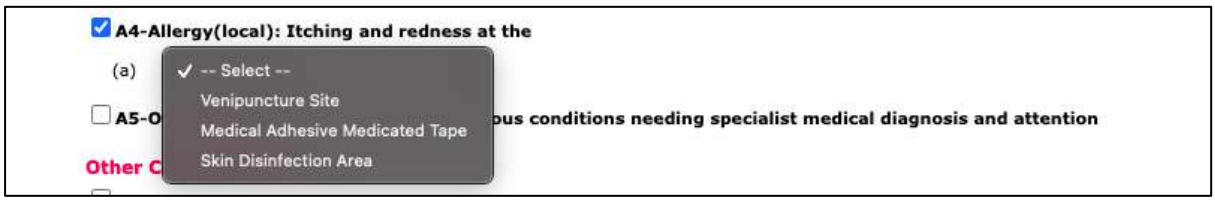


Figure 34: Local allergy

On selection of option (A5) Other major blood vessel injury, four options will get displayed, select any one of them according to reaction. (Figure 35)

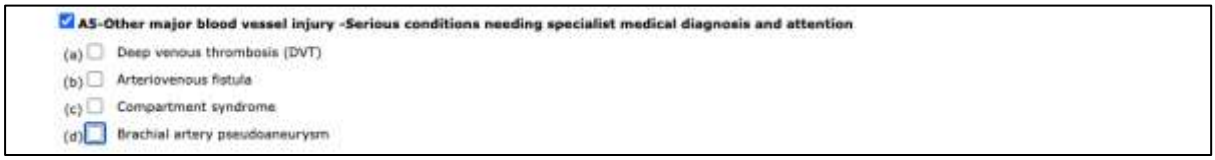


Figure 35: Other major blood vessel injury

7.24. Generalised Complications: On the selection of generalised complications in section (B), options of entry for generalised complications will be displayed. (Figure 36) Multiple options can be selected if the donor experienced more than one type of generalised complication.

Figure 36: Generalised complications

On selection of option (B1) vasovagal reactions, symptoms of vasovagal reactions will get displayed, multiple options can be chosen in symptoms. On selection of option (r) loss of consciousness, again a dropdown menu of time of LOC will appear, have to select any one of them according to symptoms. (Figure 37)

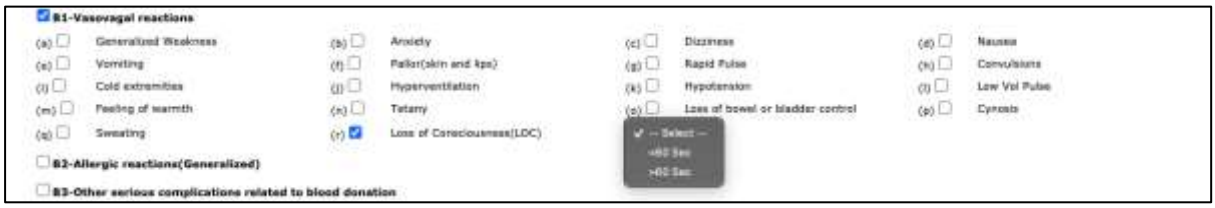


Figure 37: Loss of consciousness

On selection of option (B2) allergic reactions (Generalized), symptoms of generalized allergic reaction will get displayed, multiple options can be chosen according to symptoms. (Figure 38)

Figure 38: Generalized allergic reactions

On selection of option (B3), other serious complications will display, can choose any one or multiple according to reaction. (Figure 39)

Figure 39: Other serious complications

On the selection of both types of reactions in section (B), options of entry for both localised and generalised reactions will be displayed. Multiple options can be selected if the donor experienced more than one type of reaction.

7.25. Apheresis Complications: When apheresis donation is selected in section (A) type of donation, the option for apheresis complication appears. If the donor had more than one type of reaction, can choose multiple options. Along with that, a Yes/No dropdown menu in front of apheresis complication appears. If the donor has apheresis problems during apheresis donation, the "Yes" option in the dropdown menu must be selected. If the donor had only a localised or generalised reaction during apheresis donation and no apheresis complication, the choice "No" must be selected. (Figure 40)

Figure 40: Complications related to apheresis

When option (a) citrate reaction is chosen, symptoms of the citrate reaction will be displayed; any or all of the symptoms can be selected depending on donor symptoms. Along with the prophylactic calcium choice, a "Yes" or "No" option from the dropdown menu must be selected. (Figure 41)

Other options in apheresis complications can be chosen based on donor reaction, and multiple options can also be chosen based on donor reaction.

Figure 41: Prophylactic calcium choice

7.26. Other Complications: If the donor has experienced any other complications in addition to or instead of the reactions specified on the form, choose, and specify another reaction choice. (Figure 42)

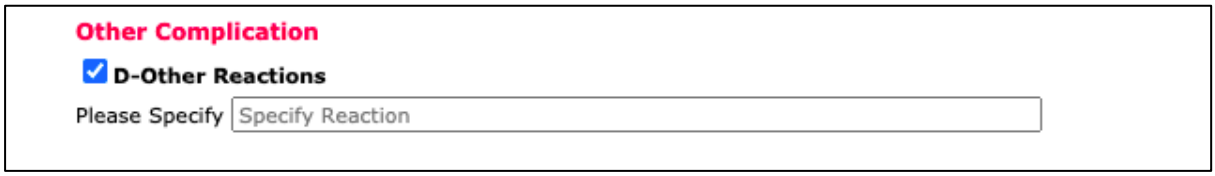


Figure 42: Other complication

7.27. Outcomes: Entering adverse reaction outcomes is achieved by selecting a choice from the dropdown menu in front of the outcome column. (Figure 43) If a reaction is resolved on the donation site and there is a donation-reaction delay of more than one day, or if a reaction is resolved on follow-up and there is a donation reaction gap of 12 hours or less, data would be invalid.

Figure 43: Outcome

7.28. **Imputability:** To perform an imputability entry, select from the drop-down menu in front of the imputability column. (Figure 44) The data could be invalid if the reaction has a clear association with blood donation and the imputability is entered as excluded on unlikely. When we keep the cursor on individual Imputability you will find the definition of each Imputability which will help you select the Imputability.

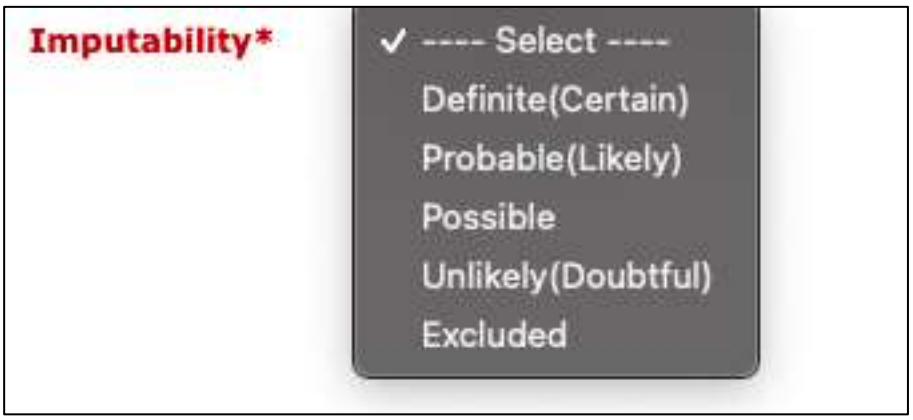


Figure 44: Imputability

7.29. **Other Information:** If any additional information is to share with the National coordinating centre regarding the reaction, it can be added to any other information section. (Figure 45) This option can be used to provide information about any

additional adverse reactions not included in the form. Do not enter any information about the treatment of adverse reactions.

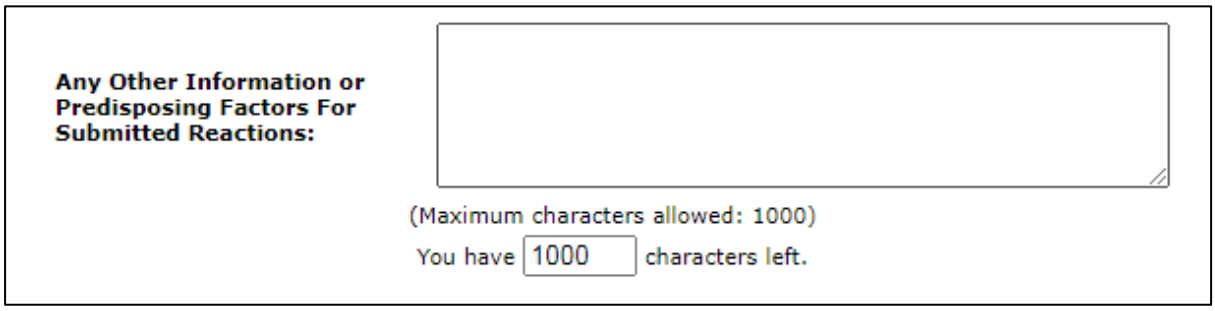


Figure 45: Any other information

7.30. Save or Preview: After completing the form, data can be rechecked by selecting the preview option, and data must be saved by selecting the save option after confirmation of entry. (Figure 46)

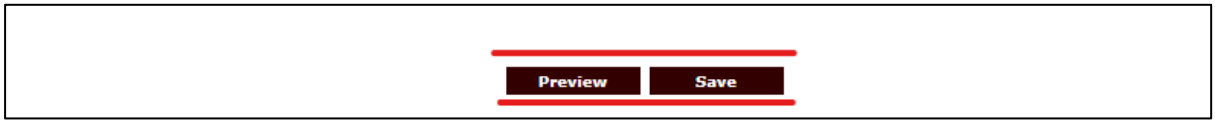


Figure 46: Save & Preview

7.31. Denominator data entry: After entering adverse reaction data for the entire month, denominator data for that month must be entered by choosing the Inbox option at the top. (Figure 47) As one of the objectives of capturing the denominator data is to calculate the various rate of occurrence of DARs. Appropriate reporting of the denominator data is equally important for the reporting centre. NOTE:- Denominator option appeared after date 25th of every month below the saved form for a particular month.

Figure 47: Choose inbox for denominator data

In the Inbox option select list of saved/submitted donor reaction reporting forms (Figure 48)

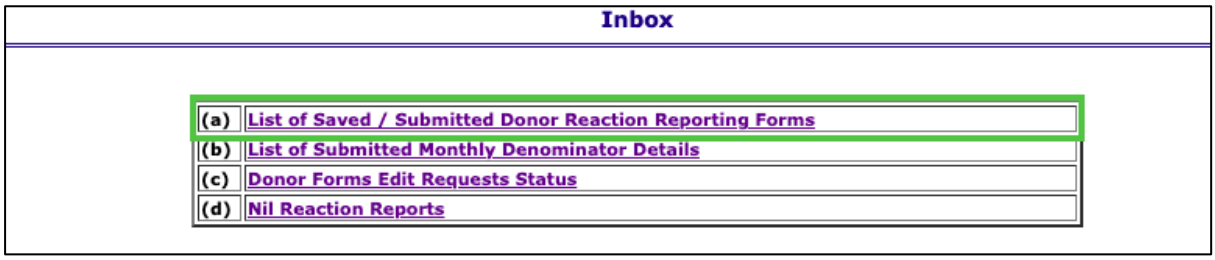


Figure 48: List of saved/submitted donor reaction reporting forms

In that further select list of saved donor reaction reporting form (Figure 49)

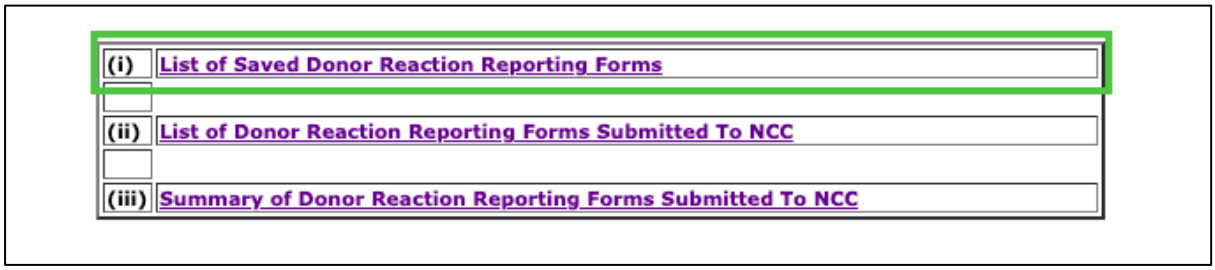


Figure 49: List of saved donor reaction reporting form

Select the month and year for which denominator data is to be entered from the list of saved donor reaction reporting forms. (Figure 50)

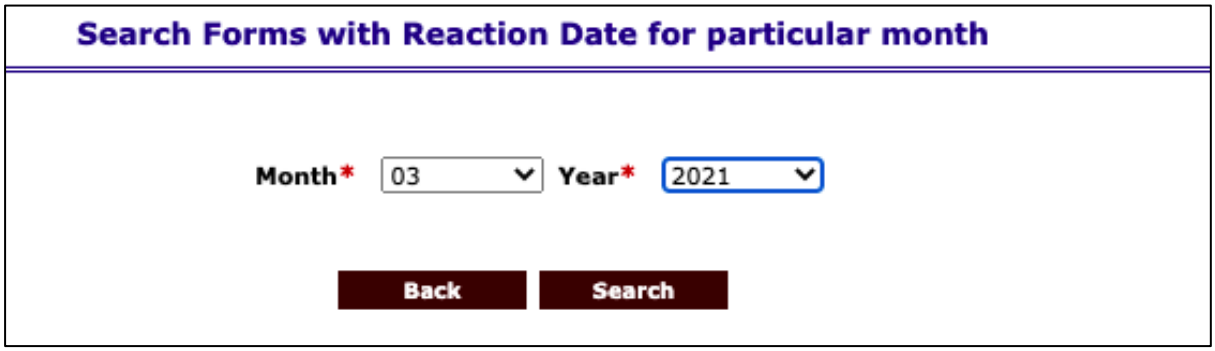


Figure 50: Month and year entry

After searching the particular month entry, select proceed to denominator form for entry of denominator data. (Figure 51)

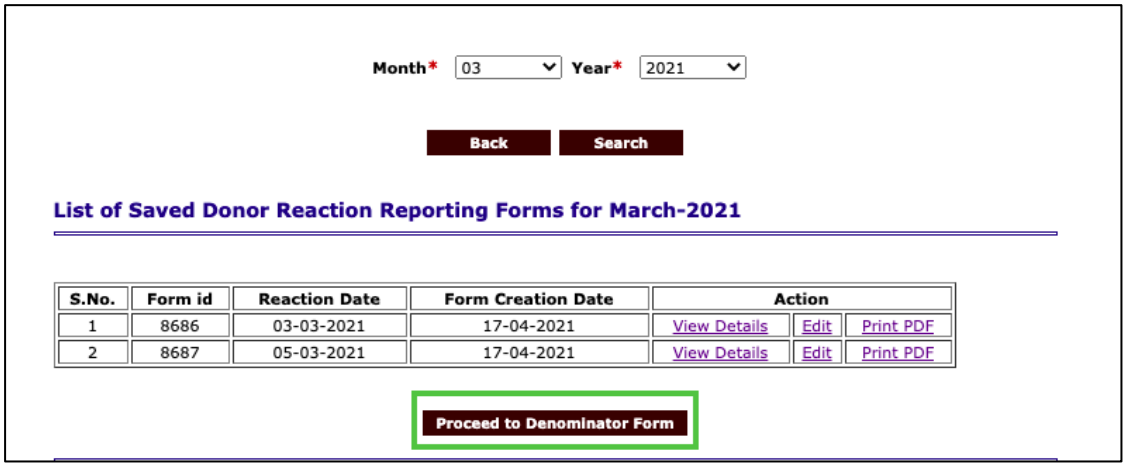


Figure 51: Proceed to denominator form

When you select the denominator form, blank denominator data for that month will be shown. In that form, enter the denominator data for that month. (Figure 52)

The total number of genders of donors, type of donation, donor types, and site of donation should be the same as the total donation for that month.

Figure 52: Denominator form

On selection of whole blood, the number of 350- and 450-ml bags will display. (Figure 53) Enter the number of 350- and 450-ml bags used in that particular month. A total number of 350 ml and 450 ml blood bags should be the same as the total whole blood collected.

Figure 53: Whole blood details

Similarly, on the selection of apheresis, different types of apheresis procedures will display. (Figure 54) The total number of different procedures should be the same as the total apheresis procedure.

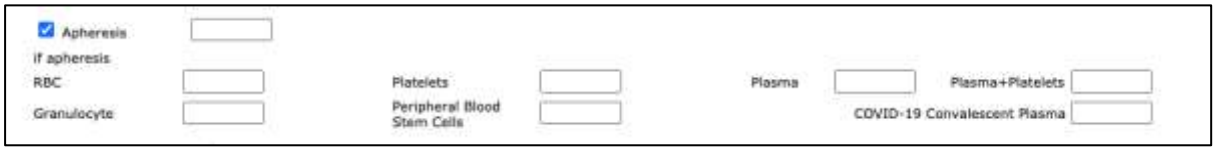


Figure 54: Apheresis details

7.32. Nil reaction reporting: if there was no donor adverse reaction in any particular month, the nil reaction reporting form has to be entered with denominator details of the respective month. (Figure 55)

Figure 55: Nil reaction reporting

7.33. Edit request: Select the edit request option if there is an error in the data entry of the donor adverse reaction form. (Figure 56, 57 & 58) Edit requests for monthly

denominator data or individual adverse reaction data including nil reaction data may be submitted with a justification for the edit.

Figure 56: List for edit

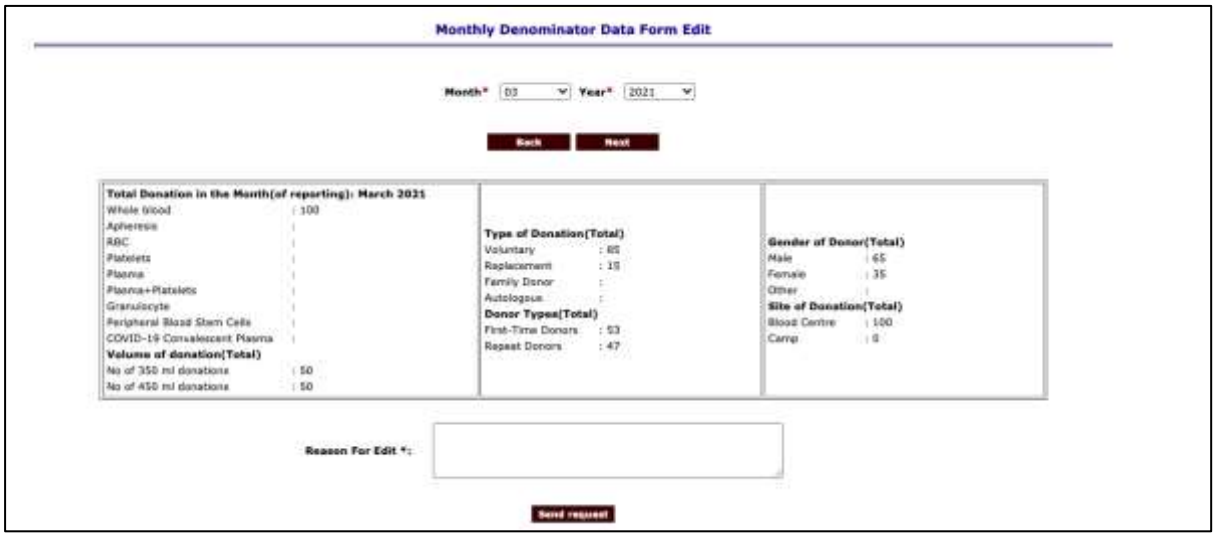


Figure 57: Edit request form

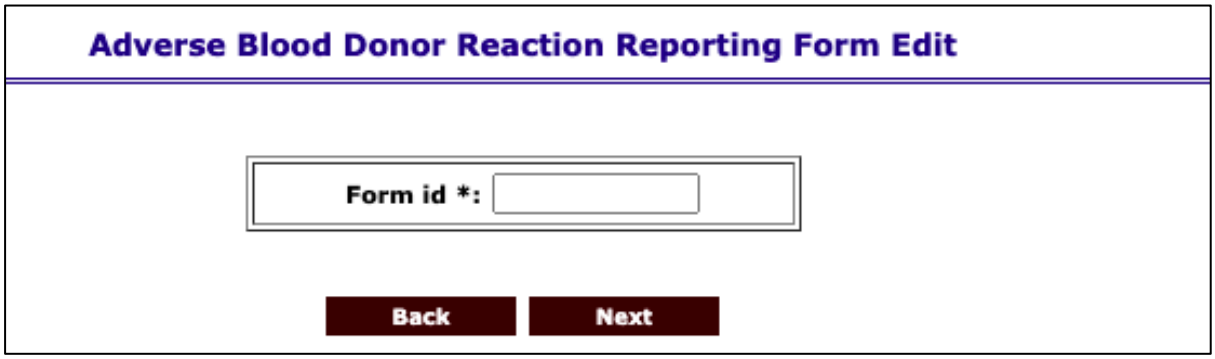


Figure 58: Form ID for adverse blood donor reaction reporting form

7.34. Submitted data summary: After submitting all of the data for a month, the data description can be viewed in the submitted data entry section. (Figure 59 & 60) It is possible to save or print it for future reference.

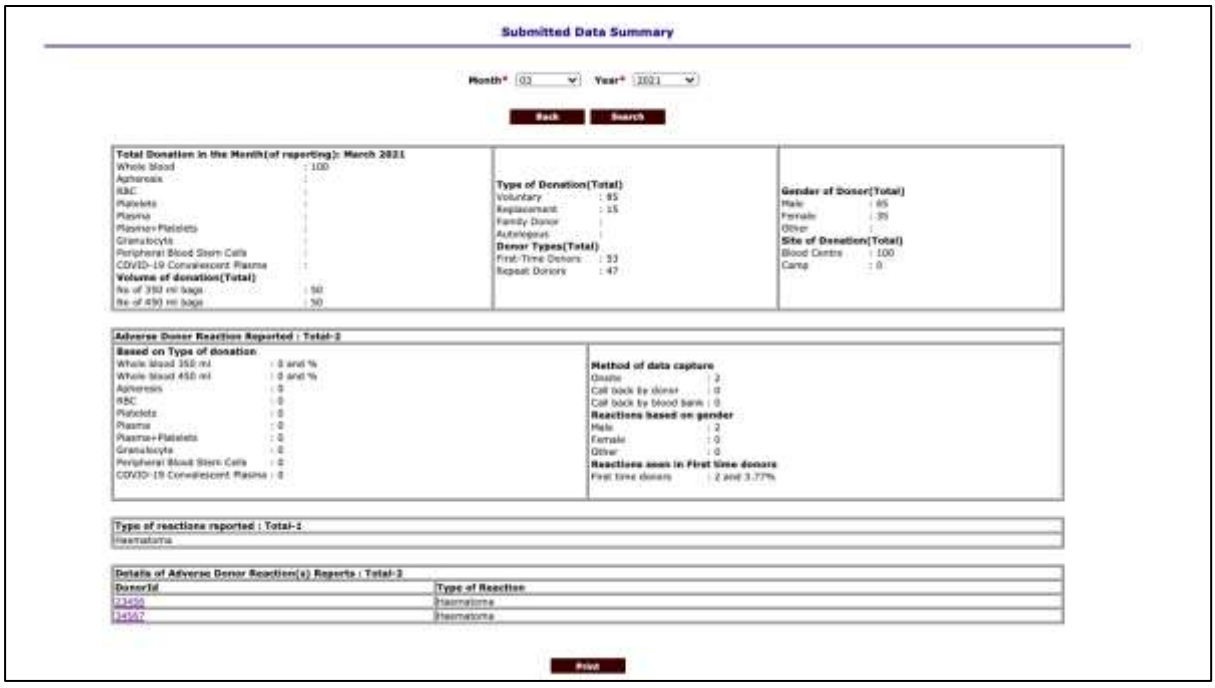


Figure 59: Submitted data summary

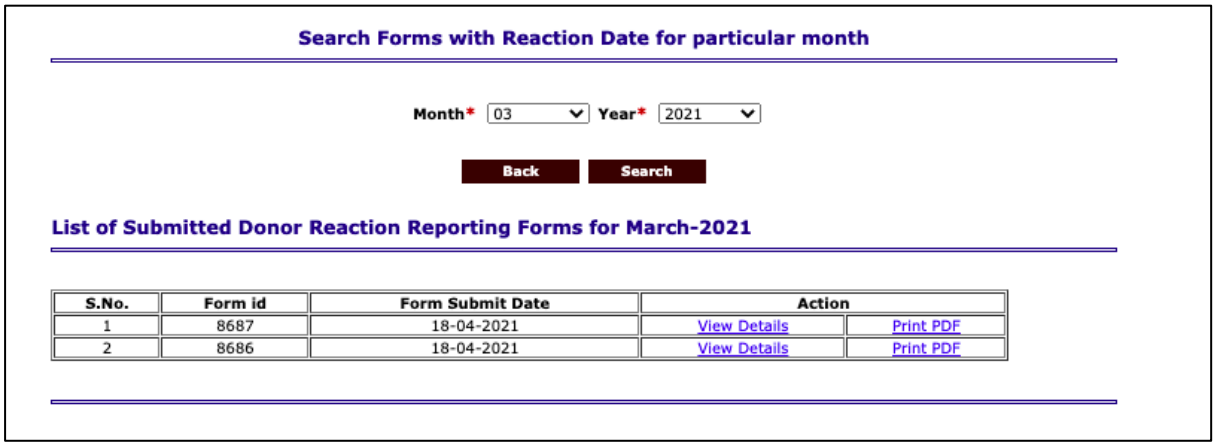


Figure 60: List of submitted donor reaction reporting forms

8. Data Validation

The Haemovigilance committee of Donor HvPI analyses data on a yearly basis. Any discrepancy in data may result in the removal of both the denominator and the numerator from the final analysis. Any discrepancy in denominator data, such as if the sum of donations at the dimension level does not match the total for that month/year, will result in the elimination of that range of denominator data. The corresponding donor adverse reactions reported during that specified month/year, are also omitted from the analysis (numerator data). The difference in denominator data may be caused by one of the following factors:

- Total donations are not reported in the denominator data for a given donation month/year for which there is a reported reaction in that organization.
- Donations not reported for specific dimension classes (such as total male or female donations; total first time or repeat donation; total whole blood or apheresis donations and total 350 ml or 450 ml bags used) for the given month/year for all donations that have a reported reaction that falls in that category.
- The total donations for given dimension classes do not tally with the total donations for the month/year.

The numerator data were also checked for errors and inconsistencies. Errors in the numerator data, primarily due to invalid, incomplete, inappropriate, or duplicate DAR entries, were also excluded from the review. Following table no. 4 elaborates on the type of errors reported while submitting a donor reaction report. Some of the elaborated errors are being improved with the introduction of new version of the reporting form (version 2) and some checks introduced in the software.

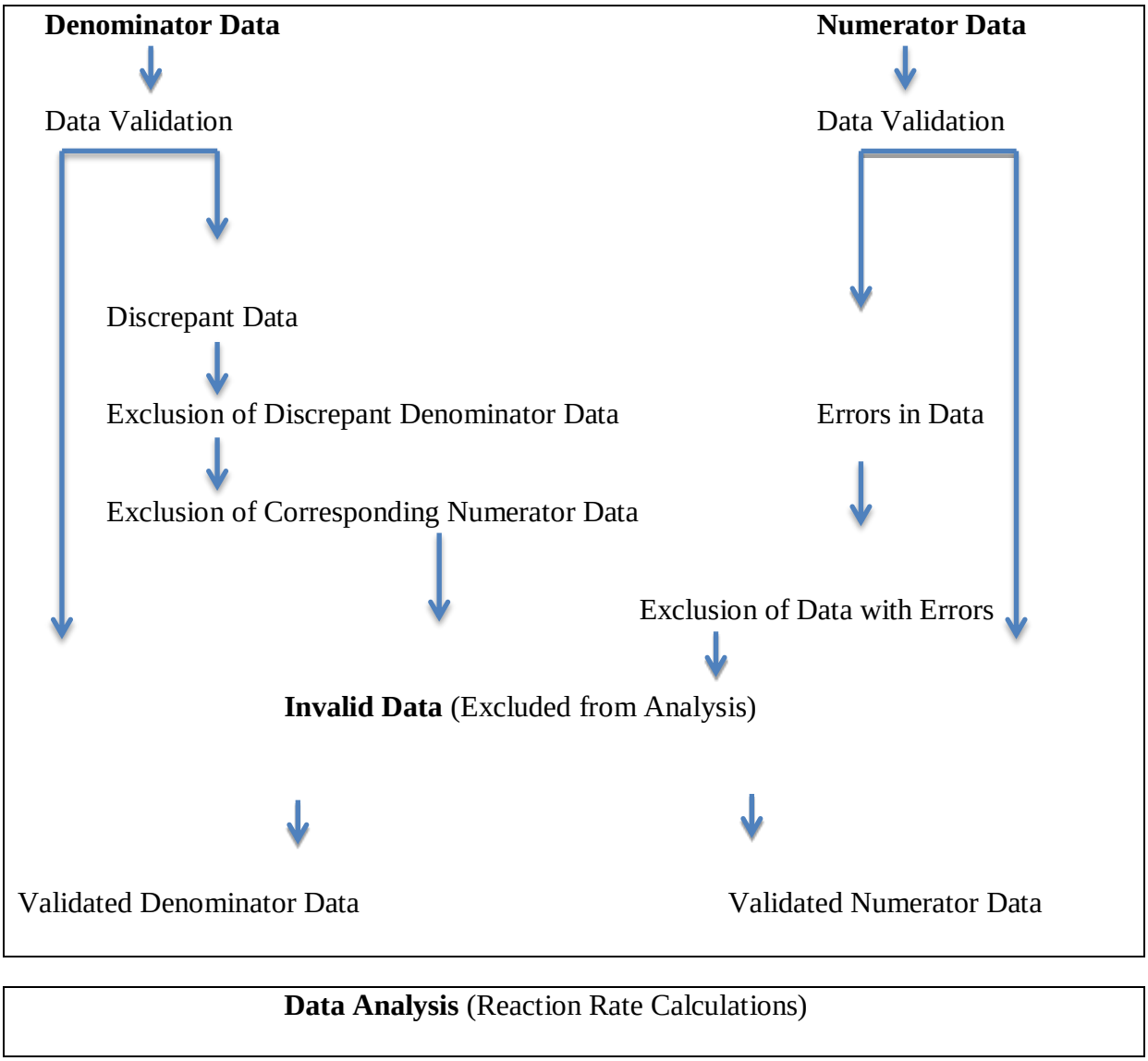
Table 4: Type of errors reported while entering the donor reaction details

Section of the reporting form	**Elaboration on the error**
Donor Information	• Incomplete or missing data • Date entered – out of range (e.g., Age <18yr or Age > 65; weight <45 kg etc.)

Collection Details	• Incomplete or missing data
	• Date of expiry of bag/ kit before the date of donation
	• Apheresis kits details submitted for whole blood donations
	• Gap between donation and reaction
	  ○ Short gap (0-5 min) reported for (Donor/ blood bank call back, DAR outside blood center, volume collected > 100 ml and donation completed with a gap of 0-3 min.
	  ○ Long gap (> 1 hour) reported for pre-donation reactions, data captured onsite and reaction at donation site etc.

Type of Complication	• Apheresis reactions or generalized reactions reported for whole blood donations • Pre donation reactions reported as localized or apheresis reactions • Duplicate entry • Generalized Reactions ○ Vasovagal Reactions: Multiple selections in the symptoms, incomplete submission of data on LOC, site of reaction and history of injury.
Imputability	Excluded or unlikely for local complications such as hematoma

Figure 61: Flowchart for the process of cleaning and validation of the data submitted to Donor-Vigil Software



9. Responsibilities of stakeholders

9.1.Responsibilities of Medical Officer of donation centre

- To correctly recognize the possible adverse reaction in a blood donor
- Fill out the Donor adverse reactions reporting form with the specifics of the adverse reaction.
- After an adverse reaction, manage and monitor the donor.
- Encourage blood donors to report any delayed adverse reactions after they leave the blood donation region.
- Educate the staff working in the donation area or the blood donation camp to correctly recognize the reaction/ event, manage the event and report to the blood center in charge.

9.2.Responsibility of blood centre or department of Transfusion Medicine

- To assure the completeness of donor adverse reaction reporting form
- To assess the imputability of the donor adverse reaction
- To report the details of adverse reaction as per the donor adverse reaction reporting form in the Donor Haemo-Vigil Software
- To report the monthly details of the denominator data like total collection, type of collection, type of donors, types of blood bag used, etc.
- To educate the staff and donors about the risk of an adverse event after a blood donation and the importance of reporting it to the national pragramme.

9.3.Responsibilities of NIB, National Co-ordinations centre- donor HvPI

- Review completeness, quality check, and causality assessment
- Collection, collation, and analysis of donor haemovigilance data and

forward it to MoH & FW

- Compilation of data and flagging major issues for deliberation by the Haemovigilance advisory committee.
- To monitor the function of centres under HvPI and quality of data received from the blood centres
- Preparation of guidance documents and training manuals etc.
- Providing training to the centres under HvPI.
- Publication of haemovigilance newsletters
- Communicate recommendations of hemovigilance advisory committee to MoH & FW

9.4.Responsibilities of Ministry of Health and family welfare (MoH & FW), Govt. Of India

- Forward recommendation of Haemovigilance Advisory Committee to MoH & FW.

9.5.Responsibility of Central Drugs Standard Control Organisation(CDSCO)

- Formulate safety-related regulatory decisions.
- Communication of blood and blood components transfusion safety-related decisions to stakeholders.

9.6. Ethical aspects of Haemovigilance

Ethics in haemovigilance plays as important a role as in other aspects of medicine. The informed consent obtained from a donor needs to be after due diligence that the donor understands the donation process and the reasonably common complications associated with it. Blood collected must be used for the purpose stated in the donor form. Additional risks that might be associated with specialised components such as double yield single donor apheresis platelet, granulocyte collections, peripheral blood stem cells (PBSC) collection though not addressed in this document must form a part of the donor informed consent. Collection of blood for research or commercial use or use of excess plasma for fractionation must form a part of informed consent. NIB and CDSCO on the other hand must ensure that the data collected is strictly used for Continual Quality improvements of National blood transfusion services and ensure strict confidentiality of donor and blood centre data without any punitive action.

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National Institute of Biologicals- National Coordinating Centre-HvPI

National Institute of Biologicals

Ministry of Health and Family Welfare, (Government of India)

Office :A-32, Sector-62, Near NH-24, Noida - 201309, (U.P.) **E-mail :** haemovigilance@nib.gov.in

Tel.: 0120-2400072, 0120-2593612 **Fax:** 0120-2403014 **Website :** http://nib.gov.in/

Toll Free No. : 1800-180-2588 [Mon to Fri (9:00 a.m. to 5:30 p.m.)]

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