



National Institute of Biologicals
Ministry of Health & Family Welfare, Govt. of India
NATIONAL BLOOD DONOR VIGILANCE PROGRAMME



(Haemovigilance Programme of India)
Adverse Blood Donor Reaction Reporting Form

I) Donor Information

Donor Id _____	Type of Donation: (a) Whole Blood, (b) Apheresis — (1. RBC, 2. Platelets, 3. Plasma, 4. Plasma + Platelets)
Sex _____	Donor Type: (a) Voluntary, (b) Replacement, (c) Family Donor (1. first-time, 2. repeat)
Weight of Donor (KG) _____	Venipuncture: (a) 1, (b) 2, (c) >2
Age/Date of Birth _____	Data Captured: (a) Onsite, (b) Call back by donor, (c) Call back by Blood Centre
	Site of Donation: (a) Camp (b) Blood Centre

II) Details of Blood Collected

Lot No. of Blood Bag _____	Volume of Blood Collected (ml) _____
Manufacturer of Blood Bag _____	Expiry date of Blood Bag _____
Date & Time of Donation _____	Date & Time of Reaction _____

III) Type of Complications (Refer Annexure I)

- A1-Complications mainly characterized by the occurrence of blood outside the vessels**
- (a) Haematoma (bruise)
 - (b) Arterial puncture
 - (c) Delayed(bleeding/Re-bleeding)
- A2-Complications mainly characterized by pain**
- (a) Nerve injury/irritation
 - (b) Other Painful arm
- A3-Localised infection/inflammation along the course of a vein**
- (a) Thrombophlebitis
 - (b) Cellulitis
- A4- Other major blood vessel injury -Serious conditions needing specialist medical diagnosis and attention**
- (a) Deep venous thrombosis (DVT)
 - (b) Arteriovenous fistula
 - (c) Compartment syndrome
 - (d) Brachial artery pseudoaneurysm
- B-Complications mainly with generalized symptoms: Vasovagal reactions**
- (a) LOC(Loss of Consciousness) < 60 sec
 - (b) LOC(Loss of Consciousness) > 60 sec
 - (c) Without loss of consciousness (LOC)
 - (d) With injury
 - (e) Without injury
 - (f) Within Blood collection facility
 - (g) Outside blood collection facility
- C-Complications related to apheresis**
- (a) Citrate reaction
 - (b) Haemolysis
 - (c) Air embolism
 - (d) Infiltration of IV fluids
- D-Allergic reactions**
- (a) Allergy (local)
 - (b) Generalised allergic reaction (anaphylactic reaction)
- E-Other serious complications related to blood donation**
- (a) Acute cardiac symptoms
 - (b) Myocardial infarction(MI)
 - (c) Cardiac arrest
 - (d) Transient Ischemic Attack(TIA)
 - (e) Cerebrovascular Accident
 - (f) Death
- F-Other Reactions**

IV) Outcomes

V) Imputability (Refer Annexure II)

- | | |
|--|--|
| <input type="checkbox"/> Resolved | <input type="checkbox"/> Definite (Certain) |
| <input type="checkbox"/> On Follow Up | <input type="checkbox"/> Probable (Likely) |
| <input type="checkbox"/> Recovered with Sequelae | <input type="checkbox"/> Possible |
| <input type="checkbox"/> Permanently Disabled | <input type="checkbox"/> Unlikely (Doubtful) |
| <input type="checkbox"/> Death following the Adverse Reactions | <input type="checkbox"/> Excluded |
| <input type="checkbox"/> Unknown | |



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Annexure I

Donor Complication Form

Reference Document (Type of complication)

A 1. Complications mainly characterized by the occurrence of blood outside the vessels.

a) Haematoma (bruise)

Bruising/discolouration Redness/warmth Swelling Local pain/tenderness

Nerve irritation/injury

b) Arterial puncture

Bright Red blood Pulsating needle/tubing. Blood bag fills rapidly (< 4 min).

Weak pain (elbow). Radial pulse weak/absent.

c) Delayed bleeding/ Re-bleeding

Inadequate Pressure at venipuncture site Inadequate duration of pressure (< 10 min)

Heavy lifting or strain to the donor's arm. Donor medications (anticoagulants/aspirin)

A2. Complications mainly characterized by pain

a) Nerve injury/irritation

Radiating, sharp pain moving away from the venepuncture site,

Paraesthesias- tingling, burning sensations in the hand, wrist or shoulder area

Onset of symptoms-on needle insertion or withdrawal

Delayed pain when accompanied by haematoma.

Worsening of symptoms in certain positions or with certain arm motions.

b) Other Painful arm

Arm pain described as ache or heaviness in the arm(Like vaccination)

Absence of nerve irritation

A 3. Localised infection/inflammation along the course of a vein

Symptoms localized to phlebotomy site

Warmth tenderness Local pain Redness Swelling (at the site of phlebotomy)

Fever Present/absent

a) Thrombophlebitis: Symptoms along course of vein

b) Cellulitis: The redness, swelling and tenderness affect the soft tissues

A4. Other major blood vessel injury -Serious conditions needing specialist medical diagnosis and attention

a) Deep venous throosis (DVT) Swelling and Pain in upper arm Signs of superficial inflammation/thrombosis(See A3) Additional risk factor of thrombosis(ExOC pills)

b) Arteriovenous fistula Pulsating mass Palpable thrill/Associated bruit
 Affected area-warm Distal area -feels cool Distal veins-dilated& pulsatile
 Related to arterial puncture Related to venous laceration.

c) Compartment syndrome Painful arm Swelling(Haematoma) Paresthasias

Partial paralysis. Muscle and soft tissue necrosis.

d) Brachial artery pseudoaneurysm

Pulsating mass in the arm. Pain and paraesthesias. Haematoma(large)

May follow Arterial puncture (A1)



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B. Complications mainly with generalized symptoms: Vasovagal reactions

- Generalized Weakness Anxiety Dizziness Nausea Vomiting
 Pallor (Skin and lips) Cold extremities Hyperventilation Hypotension Vomiting
 Rapid Pulse Low Vol Pulse Feeling of warmth Vomiting
 Convulsions Tetany Twitching Vomiting

- a) LOC (Loss of Consciousness) < 60 sec b) With injury c) Within Blood collection facility
 LOC (Loss of Consciousness) > 60 sec without injury Outside blood collection facility
 Without loss of consciousness (LOC)

C. Complications related to apheresis

[] a) Citrate reaction

- Numbness/tingling/vibrations-lips, fingers Metallic taste Vomiting
 Chills/ shivering light-headedness Muscle twitching Carpopedal spasm
 rapid or slow pulse, Irregular Pulse shortness of breath.
 Tetany(generalized muscle contractions) Shock Cardiac arrest

[] b) Haemolysis

- Pink or red plasma Blood in lines Pink or red urine

[] c) Air embolism

- Bubbling sound or feeling at venipuncture
 Cough Dyspnea Apprehension Sweating Chest pain Confusion
 Tachycardia, Hypotension, Nausea Vomiting.

[] d) Optional category: Infiltration of IV fluids []-Swelling at venipuncture site

D. Allergic reactions

[] a) Allergy (local)

- Itching and redness at the ()venepuncture site ()Bandage site or () Skin disinfection area. Raised rash or hives that may expand to cover a larger area of the arm.
 Occurrence ()Soon after donation () Hours later () Days later.

[] b) Generalised allergic reaction (anaphylactic reaction)

- Occurs soon after reaction Cardiac arrest
 Apprehension/Anxiety Flushing, swelling of eyes, lips or tongue cyanosis cough
 wheezing Dyspnea Chest tightness cramps, nausea, vomiting, diarrhoea,
 tachycardia Hypotension altered mentation.

E. Other serious complications related to blood donation

Major cardiovascular event (MCE) (Upto 24hours after donation.

- a) Acute cardiac symptoms (other than myocardial infarction or cardiac arrest).
b) Myocardial infarction(MI) c) Cardiac arrest Transient Ischemic Attack(TIA)
d) Cerebrovascular accident e) Death



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Annexure II

IMPUTABILITY LEVELS (Grading of complication severity and Imputability strength of relation between donation and complication)

The Imputability levels are given below:

- **Definite (Certain):** when there is conclusive evidence beyond reasonable doubt for the relation.
- **Probable (Likely):** when the evidence is clearly in favour of a relation.
- **Possible:** when the evidence is indeterminate for attributing the complication to the donation or an alternative cause.
- **Unlikely (Doubtful):** when the evidence is clearly in favour of attributing complication to other cause.
- **Excluded:** when there is conclusive evidence beyond reasonable doubt that the complication can be attributed to causes other than the donation.



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Denominator Data About All Donor

1. Total donations in the month (of reporting)		
Whole blood[] Apheresis[] If apheresis RBC[] Platelets[] Plasma [] Plasma + Platelets[]		
2. Gender of Donor (Total) Male [] Female []		
3. Donor Types (Total) First-time donors [] Repeat donors []		
4. Volume of donation		
No of 350 ml donations []	No of 450 ml donations[]	others