

# **BLOOD DONOR ADVERSE REACTIONS**

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## **CERTIFICATE**

This is to certify that this dissertation work “**BLOOD DONOR ADVERSE REACTIONS**” is an original work done by **Dr.KRISHNAMOORTHY.R**, a post-graduate student of MD Immunohaematology and Blood Transfusion, Department of Transfusion Medicine, The Tamilnadu Dr.M.G.R. Medical University, Chennai, during the period May 2005 to March 2008.

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## **INTRODUCTION**

Blood Donors are the backbone of a Blood Transfusion service. Ensuring the safety of Blood Donors is of utmost importance as is ensuring safe blood to the recipient. Since blood donors are altruistic volunteers, they should be protected as much as possible from adverse reactions. The reality that many first time donors do not return for donation can be explained by the occurrence of adverse reactions. Blood donor's physical experience affects the blood donor return rate . Efforts should be taken to retain adequate number of repeat donors. If the donors are ensured of a pleasant experience they will be motivated to become regular repeat donors. This can be accomplished by way of preventing adverse reactions in the donor.

### **PHYSIOLOGY OF BLOOD :**

The cellular elements of blood – white blood cells, red blood cells and platelets - are suspended in the plasma. The normal total circulating blood volume is about 8% of the body weight. About 55% of this volume is plasma (Ganong).

## **DONATION OF WHOLE BLOOD :**

The volume lost from a single unit donation is replaced within 48-72 hours. Red cell mass recovers more slowly, requiring 3-6 weeks (Mollison).

## **DONOR RECRUITMENT & RETENTION :**

Blood should be accepted only from voluntary non-remunerated, low risk, safe and healthy donors. Efforts should be directed towards encouraging and retaining adequate numbers of repeat donors. Donors should be appropriately recognized and felicitated for their contribution. The Blood bank should educate donors prior to collection of blood regarding the risk of transfusion transmissible infections.

## **DONOR SELECTION :**

Pre-donation counselling by trained staff should be made available maintaining privacy and confidentiality. Pre-donation information should include modes of transmission leading to risk behavior and self exclusion for patient's safety, alternative testing site, tests carried out on donated blood, confidentiality of test results and need for honest answers in view of window period.

A donor questionnaire should be prepared in English and local language which is simple and easy to understand to be answered by the donor. For donors who are illiterate, assistance should be given by donor registration staff. Medical officer should be responsible for reviewing the donor's health condition and performing physical examination of the donor. Demographic details such as name and address of donor, date and time of donor selection and donation should be registered. Consent should be obtained in writing from the donors after explaining the procedure, potential adverse reactions as well as the tests carried out on the donated blood.

#### **CRITERIA FOR SELECTION OF DONORS :**

Criteria for donor selection differ among countries. In the USA & UK, the minimum age for blood donation is 17 years. In India, the following should be observed as per the Drugs and Cosmetic Rules (1945) and the National Aids Control Organisation ( NACO ) guidelines in order to ensure that the blood donation will not be detrimental to the donors / recipients.

#### **PHYSICAL EXAMINATION :**

A medical officer should certify the donor fit for blood donation.



**GENERAL APPEARANCE :**

The prospective donor should appear to be in good health.

**AGE :**

Donors should be between the age of 18 and 60 years.

**HEMOGLOBIN OR PACKED CELL VOLUME :**

The Hemoglobin should be not less than 12.5 g / dl or the packed cell volume should be not less than 38 % .The screening should be carried out by using any appropriate and validated methodology.

**WEIGHT :**

Blood collection from donors weighing 45-55 kg should be 350 ml blood and from those weighing 55kg and above may be 450 ml.

**BLOOD PRESSURE :**

The systolic blood pressure should be between 100 and 180 mm of mercury and the diastolic pressure should be between 60 to 100 mm of mercury.

**TEMPERATURE :**

Oral temperature should not exceed 37.5\* C / 99.5 \* F.

**PULSE :**

Pulse should be between 60 to 100 beats per minute and regular .

**DONOR SKIN :**

The skin at the venipuncture site should be free of any skin lesion or scar indicative of addiction to narcotics or infection as well as marks of repeat venipuncture.

Examination of respiratory system, cardiovascular system and abdomen should be carried out if necessary.

**MEDICAL HISTORY :****CONDITIONS THAT AFFECT SAFETY OF DONORS :**

Before each donation questions should be asked to determine that the donor is in normal health and has not suffered or is not suffering from any serious illness.

## **PREGNANCY :**

Prospective donor should not be accepted during period of pregnancy and twelve months after full term delivery and also during lactation. Donors who have abortions should be deferred for six months .

Any donor who appears to be under the influence of alcohol or any drug abuse and who does not appear to be providing reliable answers to questions on their medical history should not be accepted for donation.

## **CONDITIONS THAT AFFECT SAFETY OF RECIPIENTS :**

Any donor on antibiotic therapy or other medications should be deferred after evaluating his / her suitability as donor.

## **INFECTIOUS DISEASES :**

Donors having history of malaria should be accepted after 3 months. Donors having history of jaundice should be deferred up to one year. Donors having history of being HBsAg, HIV / HCV antibody positive should be permanently deferred. Donors having intimate contact with HBsAg, HIV / HCV antibody positive individual should be deferred for one year. Donors having history of measles/mumps/chicken pox should be deferred for 8 weeks. Donors having history of influenza and upper

respiratory infection should be deferred till one week after treatment. Donors having history of diarrhea in preceding week particularly if associated with fever should be deferred . Private interview of each donor is essential to assess the risk of HIV infection due to high risk sexual behavior and unsafe sexual practice. Donors who give history suggestive of HIV infection such as swollen glands, persistent cough, unexplained weight loss, night sweats/fever, skin rashes and skin infections and prolonged diarrhea should be deferred permanently.

#### **VACCINATIONS :**

Individuals who have taken vaccinations against typhoid, tetanus, cholera, Hepatitis A should be accepted if free of symptoms. Those who have received Hepatitis B vaccination should be accepted after 7 days of vaccination. Yellow fever / measles / polio vaccinated individuals should be deferred for 2 weeks. Donors vaccinated for rabies should be deferred for 1 year. Those bitten by any animal should be deferred for 1 year. Those who had been administered Hepatitis B immunoglobulin should be deferred for one year.

## **SURGICAL PROCEDURES :**

Donors should be accepted one year after the recovery from major operations and six months after recovery from minor operations. Donors having history of receiving transfusion of blood or blood products should be deferred for 12 months.

## **DONATION INTERVAL:**

The interval between two whole blood donations should be atleast 12 weeks.

## **INFORMATION PROVIDED TO THE DONORS :**

### **Requirement of consent :**

Prior to blood donation the consent of the donor should be obtained in writing with the donor's signature or thumb impression after the procedure is explained and the donor is informed regarding testing of blood for all mandatory tests for safety of recipients. The donor should be provided an opportunity to ask questions and refuse consent.

## **POST-PHLEBOTOMY ADVICE :**

Donors should be given advice regarding post-phlebotomy care and cautioned as to possible adverse reactions. This should also be displayed in the blood collection / observation room.

## **INFORMATION OF TEST RESULTS :**

The Medical officer of the blood bank should inform the donor about any sero-reactive result of transfusion transmissible infection .Donors who are HIV sero-reactive should be referred to an Integrated Counselling and Testing Centre ( ICTC ) for post donation confirmation and counselling.

## **COUNSELLING AND REFERRAL :**

For ensuring blood safety, the blood bank should provide pre and post donation counselling services. All blood banks should train their donor organizers / medical officers to undertake counselling besides appointing a donor counsellor. Donors should be referred to appropriate medical services for follow up and treatment whenever necessary. All blood banks should procure a list of ICTC from their respective State Aids Control Societies.

## **METHOD OF BLOOD COLLECTION :**

A strict standardized procedure should be in use to provide maximum possible assurance of sterile product. The blood bags for collection of blood should be sterile, pyrogen free and disposable, with a closed system of collection as per standards. Multiple interconnected plastic bags should be used for blood component preparation (closed system). The anticoagulant solution should be sterile and pyrogen free.

## **VOLUME OF BLOOD DONATION :**

Volume of blood collected should be proportionate to the volume of anticoagulant with +/- 10% variation and should not exceed 10ml per kilogram body weight of the donor limited to a volume of 500 ml .Units of blood where volume collected is out of the permitted limits should not be used for transfusion.

## **DONOR REACTION :**

Necessary drugs and equipment should be available for treatment of donor reaction, if any. Donor collection staff should be trained in identification and management of donor reactions.

## **ADVERSE DONOR REACTIONS:**

Most donors tolerate blood donation very well, but adverse reactions occur occasionally. Personnel must be trained to recognize adverse reactions and to provide prompt treatment.

Syncope ( Fainting or vasovagal syndrome ) may be caused by the sight of blood , by watching others giving blood, or by individual or group excitement; it may also happen for unexplained reasons. Whether caused by psychologic factors or by neurophysiologic response to blood donation, the symptoms may include weakness, sweating, dizziness, pallor, loss of consciousness, convulsions, and involuntary passage of feces or urine. On occasion, the skin feels cold and blood pressure falls. Sometimes the systolic blood pressure levels fall as low as 50 mm Hg. The pulse rate often slows significantly. This can be useful in distinguishing between vasovagal attack and cardiogenic or hypovolemic shock in which cases the pulse rate rises.

Rapid breathing or hyperventilation may cause the anxious or excited donor to lose excessive amounts of carbondioxide. This may cause generalized sensations of suffocation or anxiety, or localized problems such as tingling or twitching ( Technical Manual- AABB ) .



## **MANAGEMENT OF ADVERSE DONOR REACTIONS :**

### **GENERAL :**

The tourniquet should be removed and the needle withdrawn from the arm if signs of adverse reaction occur during phlebotomy.

### **FAINTING or VASOVAGAL REACTION :**

Cold compresses should be applied to the donor's forehead or the back of the neck and the donor should be placed on his or her back with their legs raised above the level of their head. Tight clothing should be loosened and adequate airway should be ensured. Pulse, blood pressure and respiration should be monitored until the donor recovers. Some donors who experience prolonged hypotension may respond to an infusion of normal saline. The decision to initiate such therapy should be made by the Blood Bank Medical Officer.

### **NAUSEA AND VOMITING :**

The donor should be made as comfortable as possible and instructed to breathe slowly and deeply. Cold compress should be applied to the donor's forehead or the back of the neck . The donor's head should be turned to the side (to avoid aspiration ) and a suitable receptacle should be provided if the donor vomits and cleaning tissues should be kept

ready. After vomiting has stopped, water should be provided to rinse his or her mouth.

### **TETANY :**

Extremely nervous donors may hyperventilate, causing faint muscular twitching or tetanic spasm of their hands or face . The donor's attention should be diverted by keeping him engaged in a conversation to interrupt the hyperventilation pattern. If the donor is symptomatic the donor should be asked to cough . Oxygen should not be given.

### **HEMATOMA :**

The tourniquet and the needle should be removed from the donor's arm. Three or four sterile gauze pieces should be applied over the venipuncture site and digital pressure applied for 7 to 10 minutes with the donor's arm held above the heart level . Ice pack can be applied over the hematoma for 5 minutes if desired . If an arterial puncture is suspected pressure bandage should be applied.

### **CONVULSIONS :**

The donor should be prevented from injuring himself or herself. The donor should be held on the couch; if not possible, the donor should

be placed on the floor. A padded device should separate the jaws to prevent injury to the tongue. Adequate airway should be ensured . Blood Bank Medical Officer should be notified.

**Serious cardiac difficulties:**

Cardiopulmonary resuscitation must be carried out until medical help arrives. Emergency drugs, Oxygen cylinder and other equipments like emesis basins, towels should be made available.

**POST-DONATION INSTRUCTIONS :**

The donors should be given post-donation instructions as follows:

- a) Eat and drink something before leaving the donor site.
- b) Do not leave the donation site before instructed to do so.
- c) Drink more fluids than usual in the next four hours.
- d) Avoid consuming alcohol on an empty stomach .
- e) Do not smoke for 30 minutes.
- f) If there is bleeding from the phlebotomy site, raise the arm and apply pressure to the site.

- g) If fainting or dizziness occurs , either lie down, or sit with the head between the knees.
- h) If any symptom persist report to the blood bank or consult a doctor.
- i) Resume all normal activities if asymptomatic.
- j) Donors who work in certain occupations like construction work, operators of machinery, or persons working at heights should be cautioned that dizziness or fainting may occur if they return to work immediately after donating blood.
- k) Remove bandage after 4-6 hours.
- l) Maintain high fluid intake for several days to restore blood volume.

## **REVIEW OF LITERATURE**

Ogata H et.al ( 1980 ), have analysed the donor records of a hospital blood bank and have demonstrated a low incidence of vasovagal reactions(1.13%) and observed that donors of younger age and lower diastolic blood pressure were more prone to reactions and higher reaction rates were also associated with first time donation, time of the year and a particular phlebotomist.

Lin JT et.al ( 1982 ), observed from their study that convulsive syncope occurred in 0.03% of blood donors and was more common in men and some individuals appear to be predisposed to development of seizures in situations of global cerebral ischemia such as occurs in hypotension and bradycardia .

Pisciotta P et.al ( 1982 ), from the results of their study concluded that deferral of donors taking antihypertensive medication is not indicated when BP is normal, symptoms are absent and diuretics or similar agents are the only drugs used .

Pindyck J et.al ( 1987 ) showed that it is both clinically feasible and efficient to recruit healthy regular donors older than age of 66 years for blood donation.

McVay PA et.al ( 1990 ), from the results of their study opine that first time donation and female gender were the strongest predictors of donor reaction among autologous donors and elderly autologous donors were least likely to have reactions.

Kasprisin DO et.al ( 1992 ), in their study demonstrated that first time donors have a higher frequency of reactions (1.7%) than do repeat donors(0.19%) and that the number of prior donations was inversely proportional to the risk of reaction and ingestion of caffeinated beverages was associated with a reduced risk of reactions.

Krumholz A et.al ( 1995 ), in their study demonstrated that individuals with seizure or epilepsy are not at a greater risk for adverse reaction than the general population after blood donation and major restrictions on their participation as blood donors is not warranted .

Newman BH ( 1997 ) showed that accidental arterial puncture is very uncommon (1 in 100,000 ) and neurologic needle injuries occur approximately once in every 6,300 donations .

Janetzko K et.al (1998 ) showed that a single blood donation will not alter the physical fitness of otherwise healthy elderly people and no general reason was found for disqualifying blood donors aged 65 years from donating blood.

Trouern-Trend JJ et.al ( 1999 ), have observed from their study that donation related vasovagal reactions are a multifactorial process determined largely by age, weight & first time donor status and that adverse reaction rates were higher in the young , first time donors and low weight donors.

Sauer LA et.al ( 1999 ), from the results of their study conclude that a moderate dose of caffeine may attenuate donor reactions in first time female blood donors.

Ranasinghe.E et.al ( 2000 ), observed that incidence of bruising following venepuncture was 0.35% in males & 0.98% in females and this did not affect the donor return rate.

Bonk VA et.al ( 2001 ), conclude from the results of their study that among first time blood donors, audio-visual distraction may be an effective means of reducing vasovagal reactions.

Newman BH ( 2001 ) identified twelve cases of arterial punctures from 410,000 blood donations and fast blood flow rate ( $< 4$  min ) was the most common clinical feature and brachial artery aneurysm developed in one person in the study.

Newman BH et.al ( 2001 ), showed that syncopal reactions commonly occur at the refreshment table (61%) and preventive measures against trauma need to be applied.

Franchini M et.al ( 2002 ), observed that the frequency of vasovagal reactions was significantly lower in autologous and apheresis donations than in homologous donations, and that young age ,first time donation status, low body weight and pre-donation blood pressure were predictive factors of donor reactions.

Newman BH et.al (2003), demonstrated that post donation interview is a good tool for defining the blood donor's experience .

Newman BH (2003), identified that body weight is a very important determinant of vasovagal reaction rates in first time donors but previous successful blood donation appears to mitigate the effect of body weight on vasovagal reaction rates. It was also shown that vasovagal



reaction rate was inversely proportional to body weight in first time donors.

France CR et.al (2004), opine that blood donation reactions inventory is an effective method of assessing reactions that predict donor non-return and may be useful for future studies aimed at enhancing donor satisfaction & retention.

Hanson SA et.al (2004), demonstrated that predonation ingestion of about 500ml of water 30 minutes before donating blood may be a simple and cost effective strategy to enhance the donation experience and possibly increase donor retention .

Newman BH ( 2004 ) , in his study observed that the incidence of seeking outside medical care for an adverse event following blood donation is atleast 1 in 3400 blood donations.

Shehata N et.al ( 2004 ), from the results of their study confirm the safety of whole blood donation in regular donors who are 66-71 years of age. The rate of reactions decreased with increasing age and donation frequency.

Newman BH ( 2004 ), observed that 7% of donors experienced a vasovagal reaction and 2 to 4% of the phlebotomies were not successful in one particular study.

Danic B et.al ( 2005 ), have classified adverse effects of blood donation in to immediate or delayed events (or) local [ hematoma , nerve injury, arterial puncture injury, allergy, thrombosis] & general reactions [vasovagal reaction] .

Zervou EK et.al (2005), observed in their study that 0.87 % of donors had a vasovagal reaction and the possible reason for the lower incidence of adverse reaction was attributed to the fact that only physicians were responsible for the selection of donors .

France CR et.al ( 2005 ), opine that moderate and severe vasovagal reactions reduce the likelihood of repeat donation by 50 % or more.

Ohnishi H ( 2005 ), feels that apart from vasovagal reaction, other side effects occasionally caused by phlebotomy are hematoma, allergy, hyperventilation, air embolism and thrombosis.

Newman BH et.al ( 2005 ), suggested that the probability that a donor will have or not have a donor reaction can be estimated for a group, based on the donor's weight, age and first time donor status.

Newman et.al (2006 ), showed that donor reaction has the most negative impact on blood donor return rate and amelioration of adverse events has the potential to improve blood donor return rate.

Stewart KR et.al ( 2006 ), observed from the results of their study that phlebotomist's interpersonal skill can predict the experience of reactions among blood donors and a focus on the interpersonal skill of the phlebotomist can provide an additional avenue for improving donor's physical well being and satisfaction.

Goldman M et.al ( 2007 ) showed that regular blood donors may safely continue to donate past their 71<sup>st</sup> birthday.

Approximately 5% of vasovagal reactions progress to loss of consciousness ( syncope ). 60% of syncopal reactions occur at the refreshment table. 30 to 45% of syncopal reactions include involuntary tetany or tonic-clonic convulsive movements. These usually last for less than 30 seconds . 20% may last longer, up to a minute or two. A few donors may have associated urinary incontinence. Tetany can rarely occur without syncope .Some vasovagal reactions may resemble shock clinically except that the pulse is low rather than fast.

Adhesive tape , bactericidal solutions can cause contact allergic reactions. Serious systemic reactions after blood donation such as myocardial infarction and cerebrovascular accidents occur but are quite rare .These reactions may be coincidental events( Hillyer)

The most common adverse event after blood donation is the vasovagal reaction . 5 % of these reaction become more severe with loss of consciousness associated with a significant drop in systolic blood pressure and a pulse rate ranging from 40-60 beats per minute. Severe reactions may include convulsive movements and rarely fecal or urinary incontinence. These reactions are frightening but inconsequential in otherwise healthy donors ( Hillyer ).

Vasovagal reactions occur in 2-5% of blood donors. Syncope occurs in 0.08 to 0.34 % of donors. Tetany or convulsive activity develops in 25 % of these individuals with syncope. The risk is highest among those less than 20 years of age. Syncope occurs 5 times more often in first time donors than in repeat donors. The risk is also high in those weighing 110 to 120 pounds ( 50 to 54.5 kg ). Severe reactions, those resulting in hospitalization, occur at a rate of approximately 1 per 200,000 allogenic donations . Local nerve injuries represent an infrequent but annoying problem for donors (Rossi ).

The slow pulse rate (30-60 beats per minute) in the vasovagal attack is the most useful single indicator in differential diagnosis. Incidence of Tetany is 1 in 1000 donors and occurs characteristically in nervous subjects (Mollison ).

Donor reactions can be roughly grouped in to 3 categories as mild, moderate and severe based on the degree of severity (Denise M.Harmening ).

Approximately 2 to 5% of blood donors experience vasovagal reactions with syncope occurring in 0.1 - 0.3 % ( Wintrobe ).

The overall incidence of adverse reactions observed in most large blood banks is approximately 1.5 to 2 %. Most of these reactions are mild. Vasovagal reactions are not related to the volume of blood lost and may occur before blood is withdrawn ( Robert I.Handin ).

## **AIMS AND OBJECTIVES**

- 1) To study the frequency of occurrence of adverse reactions in voluntary whole blood donors.
- 2) To identify associated factors like age, sex, body weight, donation status in the causation of donor adverse reactions and
- 3) To formulate preventive strategies to avoid adverse donor reactions.

### **DESIGN OF THE STUDY:**

Observational study.

### **PERIOD OF THE STUDY:**

June 2005 to May 2007.

## **MATERIALS & METHODS:**

Voluntary whole blood donors who donated in the Blood Bank & in out-door camps of the Department of Transfusion medicine, The TN Dr. MGR Medical University, Chennai, during the period June 2005 to May 2007 were the subjects under study.

### **Donor selection procedure:**

Donors were selected as per the Drugs & Cosmetic rules(1945) of the Government of India and the National Aids Control Organisation (NACO) guidelines for donor eligibility and deferral were followed.

Donors were greeted warmly at the reception and those in the age group of 18-60 years were registered. Donors were first requested to answer the donor questionnaire and informed consent for donation and testing of collected blood was obtained in writing. Donor's medical history was elicited by the Medical officer and some donors were deferred based on their responses to the donor questionnaire and medical history.

Donors not deferred on the basis of medical history were subjected to a body weight check . Donors weighing < 45 kg were deferred and those weighing above 45 kg underwent Hemoglobin estimation by the Copper

sulphate ( Sp.gravity 1.053 ) method . Donors with Hb values <12.5 g/ dl were deferred while those with Hb values >12.5 g/dl were subjected to physical examination by the Medical officer.

Donors with :

- ❖ Pulse rate 60 -100 beats/min and regular rhythm ,
- ❖ Blood pressure in the range of 100/60 to 180/100 mm Hg,
- ❖ Respiratory rate between 16 to 20 per minute,
- ❖ Body temperature between 98.4 to 99.5 \* F and with no skin lesions at the venipuncture site ( cubital fossa ) were certified to be fit for blood donation by the Medical Officer . In any case, the Medical Officer's decision was final.

The eligible donors were given a unique donation number and the same was entered in the donor form; relevant entries were made in the donor register and the donor's signature obtained in the register also. The donation number was entered on the blood bag along with the date of collection.

Standard 350ml blood bags (Hindustan Latex) with 49ml of anticoagulant ( CPDA<sub>1</sub> ) were used .Blood bags chosen were either



single / double / triple .The donors were informed that irrespective of the blood bag used only 350 ml of blood will be collected .

### **BLOOD COLLECTION PROCESS:**

The donor was led to the donation couch and after verifying the donor identity as per the entries on the donor form and blood bag, the donor was made to lie down on the donor couch . The donor couch with a head-up tilt and facility to raise the foot end was used in the Blood bank and a flat couch was used at out-door blood collection sites.

The donor arm was scrubbed with a suitable disinfectant (Povidone iodine or isopropyl alcohol ) after applying the BP cuff . The BP cuff was inflated to about 60 mm Hg and the donor was made to squeeze a soft rubber ball (placed in the palm of the limb to be venipunctured) so that the veins would become prominent . The blood bag was placed in the Blood Collection Monitor. The antecubital vein was identified and the phlebotomy performed aseptically with the blood bag needle (16 G).

Once the blood started flowing down the tubing, the BP cuff pressure was reduced and the donor was instructed to squeeze the soft ball intermittently and gently to increase the rate of flow. The donor was

distracted from the blood collection process by keeping him engaged in a conversation with the phlebotomist.

Once 350ml of blood got collected ( in 7 to 10 min ) as shown by the display on the blood collection monitor, the squeeze ball was removed from the donor's palm and the BP cuff completely deflated and removed.

A plastic clip was applied to the tubing of the blood bag to stop the blood flow. The needle was then removed, a sterile cotton ball was placed over the venipunctured site and the donor asked to flex his / her elbow with the arm slightly raised. The donor was instructed not to get up from the donor couch until instructed.

After collecting blood samples in pilot tubes and uniform mixing, the blood bags were sealed using a di-electric tube sealer and placed in the transport box ( at camp sites ).

Once the blood stopped oozing from the venipunctured site, a medicated band-aid was applied. After about 10 min of observation, the donors were instructed to get down from the couch and led to refreshment area. The donors were given snacks and drinks and were instructed to remain there for atleast fifteen minutes. The donors were given post

donation instructions, thanked for the donation and were given a certificate of appreciation. The donors were instructed to report to the Blood Bank Medical officer if they experienced any adverse reaction like dizziness, fainting, convulsions, hematoma, bruise, sore-arm or fatigue, either on-site or off-site.

### **PROCESS OF OBSERVATION :**

Throughout the above mentioned process – from donor registration through blood collection, refreshment and until the donors leave the blood bank / camp site – donors were closely observed for the following signs and symptoms of an adverse reaction : anxiety, increased rate of respiration, pallor, sweating, dizziness, continuous yawning, nausea or vomiting, fainting, slow pulse rate, convulsions, abnormal movements and hematomas . Emergency drugs and Oxygen cylinder were kept ready for use in case of any emergencies.

### **MANAGEMENT OF ADVERSE REACTIONS :**

Adverse reactions, when observed, were managed appropriately and the donors monitored until recovery. The adverse events were recorded in the blood donor card . These donors were reassured and held under observation for another 30 minutes before they were allowed to

leave the blood bank / camp site. In case of any adverse reaction off-site, the donors were instructed to report to the Blood Bank Medical officer.

## **RESULTS :**

The following observations were made from the study :

Out of the total 2541 donors observed , 351 donations were made in the Blood Bank and 2190 were camp site donations. Except for four cases of therapeutic bleeding in the blood bank all other donations were allogeneic voluntary blood donations. As the University blood bank where this study was conducted is a stand –alone blood bank catering to the needs of Government & private hospitals in and around Chennai, there were no replacement donors.

1969 were male donors and 572 were female donors. 33 donors had an adverse reaction(1.3%) [Table 1 & Fig 1 ] out of which - 23 had a Vasovagal reaction (0.91%)- 22 (8 males & 14females) were in the age group 18-22 yrs and 1 was in a male donor in the 23-27 age group. 4 ( 1 male & 3 females in the age group 18-22 yrs) had nausea & vomiting (0.16% ) .2 developed Hematoma (0.07% ) (one was in a repeat male donor in the 28-32yrs age group and one was in a first time female donor in the 18-22 yrs age group).1 showed signs of Tetany (0.04% ) (in a male donor in the 18-22 yrs age group ) and 3 had transient seizures (0.12%) with loss of consciousness lasting a few seconds ( <10 seconds) [ Table 3

& Fig 3]. This Convulsive syncopal reaction was seen exclusively in male donors. 2 were in the 28-32 yrs age group and 1 was in the 18-22 yrs age group. There was no urinary or fecal incontinence in these donors.

All adverse reactions were observed only at camp sites and not even one occurred in the blood bank. Except for one case of Hematoma in a repeat male donor all other adverse reactions were observed in first time donors only. Most reactions were in the student population aged 18-22 yrs. Percentage of adverse reactions in female donors was 3.15% as compared to 0.76% in male donors.

Vasovagal reactions were more in female donors and in those weighing <55kg and occurred exclusively in first time donors and was more frequent in the hot summer months and in the age group 18-22 yrs and in those who had a lower predonation blood pressure. These donors developed a slow pulse rate ( <60 /min ) and complained of dizziness after donation.

Vasovagal reaction was 5 times more common in females (2.44%) than in males (0.46%). Tetany in one donor manifested as carpopedal spasm. This donor exhibited hyperventilation.

All adverse reactions occurred only after the blood collection process was over. Most adverse reactions occurred in the refreshment area except for the 3 donors who exhibited convulsive syncope even while lying on the donor couch (within 10 min of completion of blood collection). No donor complained of bruising or sore arm. In all cases of adverse reactions, recovery of the donor was complete & uneventful. None of the donors required any medicines for the adverse reactions. None of the donors who experienced an adverse reaction required hospitalization. No off-site adverse reaction was reported to the blood bank.

**AGE-WISE DATA OF DONORS : [Table 2 & Fig 2 ]**

18-22 YRS :	894 MALE, 383 FEMALE –	8 males & 14 females had vasovagal reactions,  1 developed hematoma,  1 had tetany,  4 had nausea & vomiting,  1 had convulsive syncope.
23-27 YRS :	471 MALE, 52 FEMALE -	1 male donor had vasovagal reaction
28-32 YRS :	226 MALE, 52 FEMALE -	1 had hematoma, 2 had convulsive syncope.
33-37 YRS :	151 MALE, 33 FEMALE –	No adverse reactions were observed.
38-42 YRS :	107 MALE, 21 FEMALE -	No adverse reactions were observed
43-47 YRS :	62 MALE, 12 FEMALE -	No adverse reactions were observed
48-52 YRS :	27 MALE, 16 FEMALE -	No adverse reactions were observed
53-57 YRS :	23 MALE, 3 FEMALE -	No adverse reactions were observed
58-60 YRS :	8 MALE , 0 FEMALE -	No adverse reactions were observed.

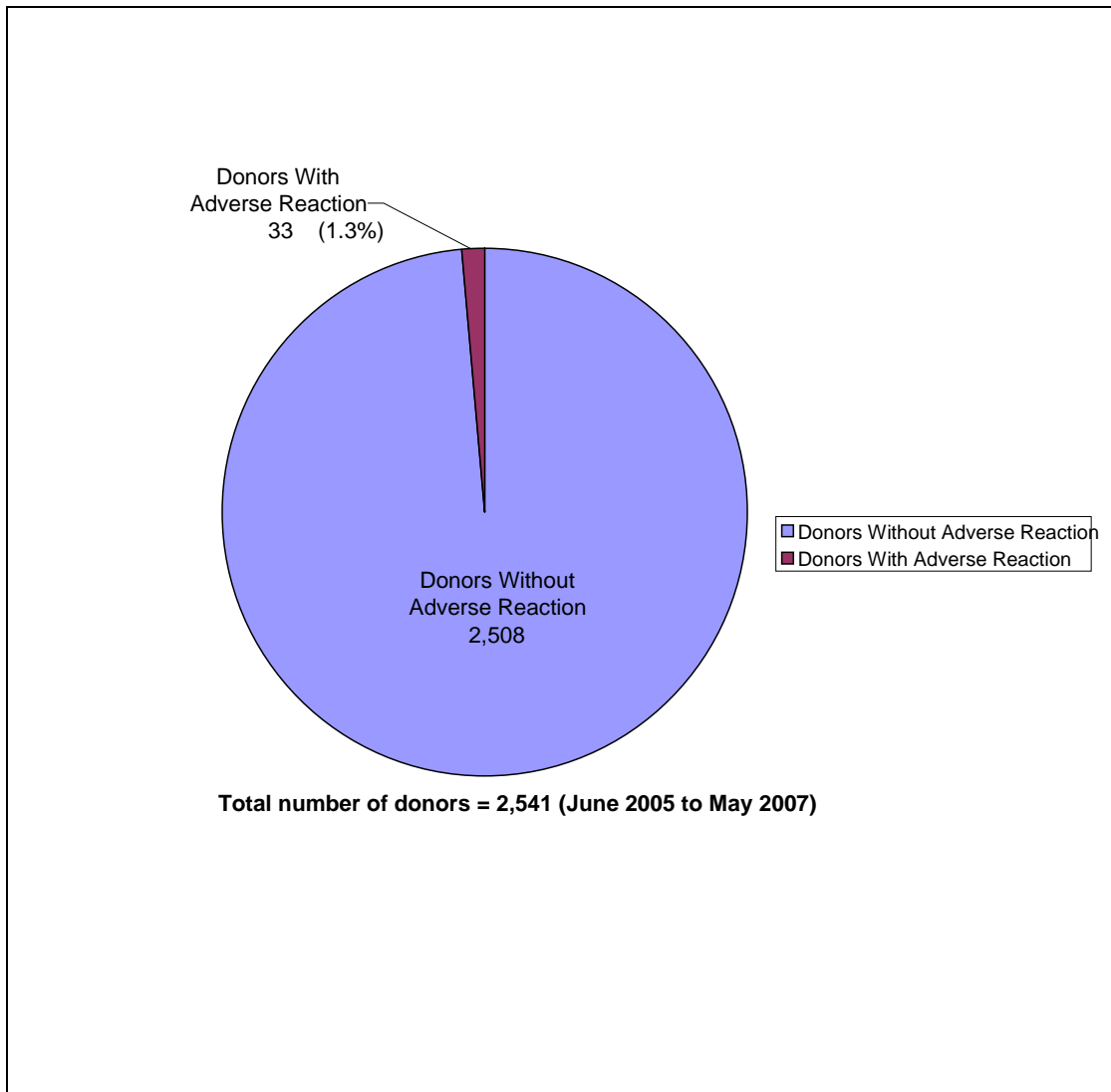


**TABLE 1**

**Total Number of Donors in the Study (June 2005 to May 2007)**

	<u>Male</u>	<u>Female</u>
Donors with adverse reaction	15	18
Donors without adverse reaction	1,954	554
<b>Total</b>	<b>1,969</b>	<b>572</b>
<b>Total number of donors (Male + Female) = 2,541</b>		

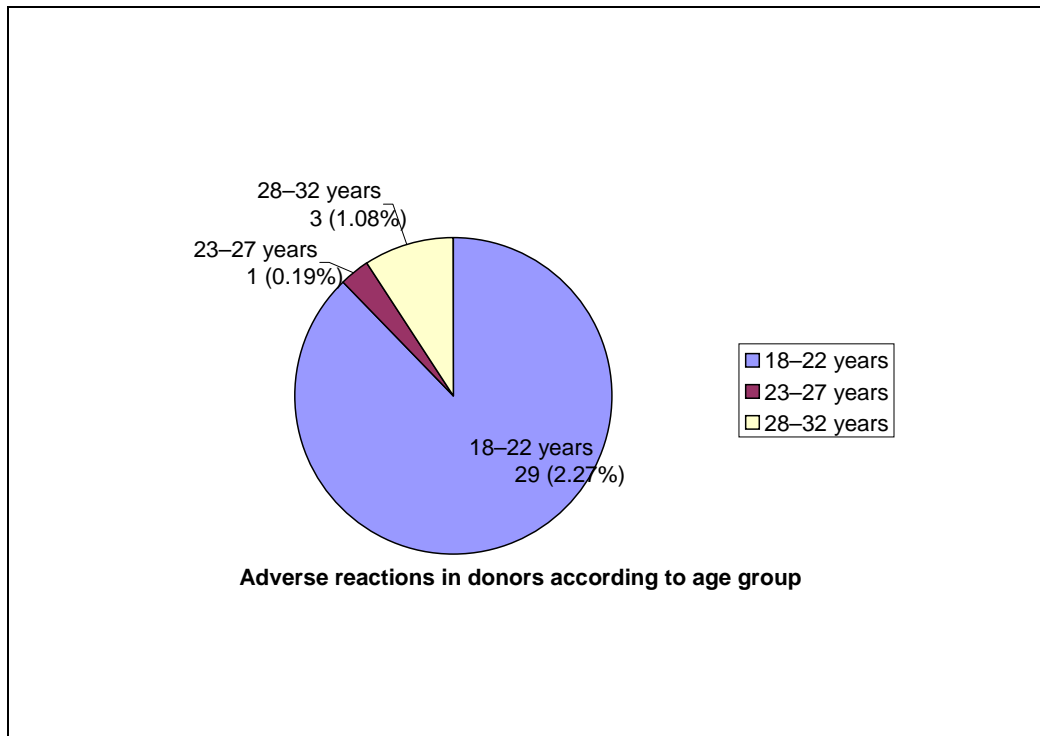
**FIGURE 1**



**TABLE 2****Age Distribution of Blood Donors (In years)  
June 2005 to May 2007**

	<u>Donors with adverse reaction</u>	<u>Donors without adverse reaction</u>	<u>Total number of donors</u>
18—22	29	1,248	1,277
23—27	1	522	523
28—32	3	275	278
33—37	0	184	184
38—42	0	128	128
43—47	0	74	74
48—52	0	43	43
53—57	0	26	26
58—62 **	0	8	8
Total	33	2,508	2,541
**(Donors up to 60 yrs of age only accepted for donation)			

**FIGURE 2**



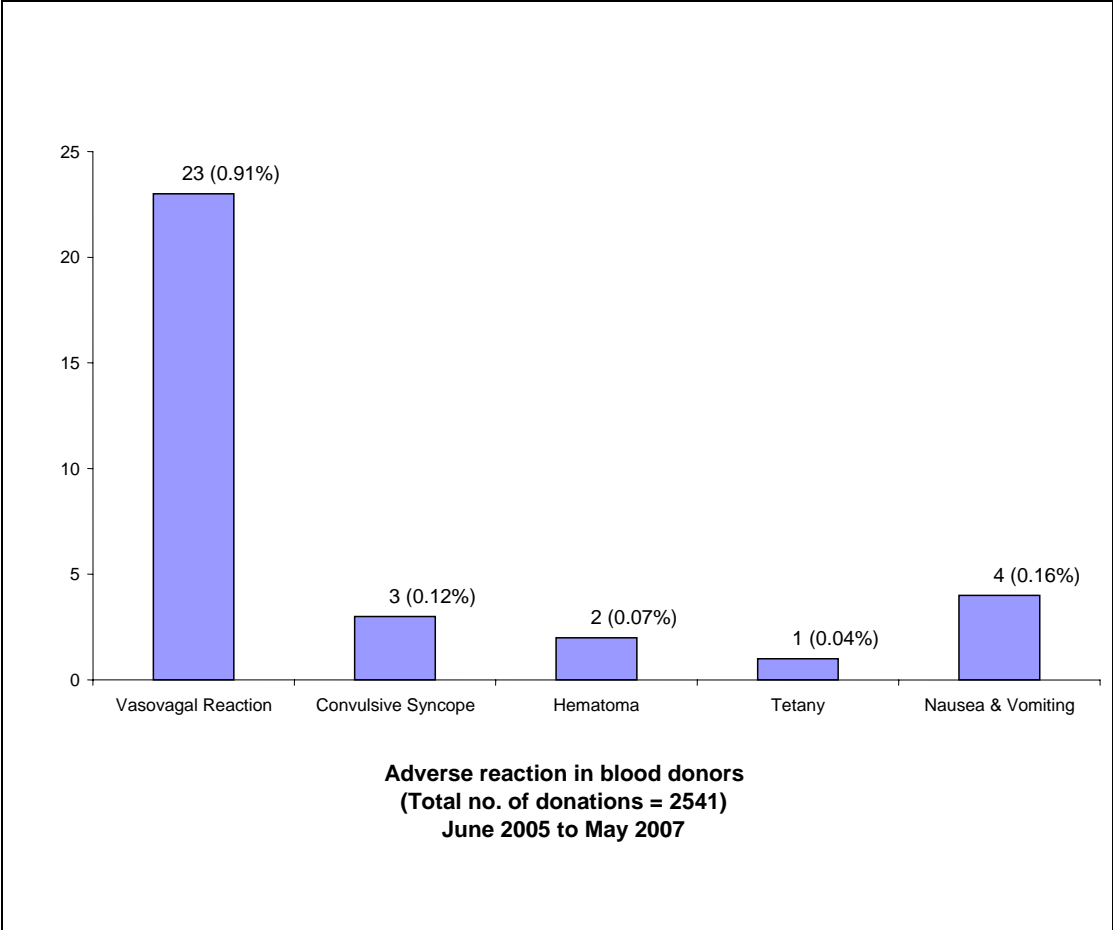
**TABLE 3**

**Adverse Reactions in Donors (June 2005 to May 2007)**

**Total Number of Donations = 2,541**

	<b>Male</b>	<b>Female</b>
Vasovagal Reaction	9	14
Convulsive Syncope	3	0
Hematoma	1	1
Tetany	1	0
Nausea & Vomiting	1	3
Total	15	18
<b>Total number of adverse reactions (15 + 18) = 33</b>		

**FIGURE 3**



# DONOR QUESTIONNAIRE



**The Tamilnadu Dr. M.G.R.  
Medical University**  
DEPARTMENT OF TRANSFUSION MEDICINE

DATE :-  

Donor Registration Number :
-----------------------------

## BLOOD DONOR CARD

Donor's Name :	Marital Status :
Father's/ Husband's Name :	Height / Weight :
Address :	Last meal Time :
Tel. No. :	
Date of Birth :	
Age / Gender :	
Occupation :	

GROUP	Rh

- |  |                                     |        |                          |  |
|--|-------------------------------------|--------|--------------------------|--|
| 1. Are you in good Health today ?  | <input checked="" type="checkbox"/> |        | <input type="checkbox"/> |  |
| Do you feel well ?   | <input type="checkbox"/>            | Yes/No | <input type="checkbox"/> |  |
| 2. In the past 3 months have donated blood (or) blood Products ? Date of last donation     | <input type="checkbox"/>            | Yes/No | <input type="checkbox"/> |  |
| 3. Have you ever fainted, had seizure, had any physical reaction to donate blood ?         | <input type="checkbox"/>            | Yes/No | <input type="checkbox"/> |  |
| 4. Do you have any cold, sore throat, asthma, active allergy ?                             | <input type="checkbox"/>            | Yes/No | <input type="checkbox"/> |  |
| 5. Are you taking any drug (or) medication ?   | <input type="checkbox"/>            | Yes/No | <input type="checkbox"/> |  |
| 6. Are you pregnant / breast feeding / menstruating ? (Female) <input type="checkbox"/> NA | <input type="checkbox"/>            | Yes/No | <input type="checkbox"/> |  |
| 7. Have you ever had Heart, Lungs (or) Liver disease ?                                     | <input type="checkbox"/>            | Yes/No | <input type="checkbox"/> |  |
| 8. Do you suffer from epilepsy, diabetes (or) high Blood Pressure ?                        | <input type="checkbox"/>            | Yes/No | <input type="checkbox"/> |  |
| 9. Blood diseases (or) bleeding tendency ?   | <input type="checkbox"/>            | Yes/No | <input type="checkbox"/> |  |

## DONOR QUESTIONNAIRE (contd)

10. Have you had dental Surgery in the last one month ?  Yes/No
11. Have you had malaria / fever in the last 3 months ?  Yes/No
12. Have you been vaccinated in the past 6 months  Yes/No
13. Have you had any surgical procedures (or) major illness in last 6 months ?  Yes/No
14. Have you had Jaundice / hepatitis in the past 2 years ?  Yes/No
15. Do you come under any of the following Categories  Yes/No
- (a) Recipient of blood and blood products in the past one year.
  - (b) Have you had any unexplained fever, Weight Loss, Night Sweats, enlarged lymph glands, persistant cough/diarhoea
  - (c) Any needle injury in the last 6 months.
16. Have you been deferred before ? What Reasons ?  Yes/No

### **DONOR CONSENT**

I am Voluntarily giving blood and it is non-remunerative, and not compelled by anybody. I have been informed and understood the procedure and risk of giving blood. The medical history which I gave is true and accurate. I understand the questions asked are for my protection as well as to protect the recipient of my blood donation. I am also aware that the blood is screened for transmissible diseases.

Date :

Donor's Signature

### **FOR BLOOD BANK USE.**

Hb.	Volume of Blood Drawn
Weight	Donor Reaction →
Temp	Serology Report .
Pulse	Blood Group
R.R.	Component : WHB / PC / PLT / FFP / Cryo
B.P.	Doctors / Nurse / Sign / :



## HEMOGLOBIN TESTING



## PHYSICAL EXAMINATION



## BLOOD COLLECTION AT A CAMP SITE



## MANAGEMENT OF AN ADVERSE REACTION



**BLOOD COLLECTION IN THE BLOOD BANK,**  
DEPARTMENT OF TRANSFUSION MEDICINE,  
THE TAMILNADU DR.MGR MEDICAL UNIVERSITY,CHENNAI-32.



## DISCUSSION

The incidence of vasovagal reactions was 1.3% in the present study as compared to 1.13% in the study by Ogata et.al . The other findings like higher reaction rates in first time donors and at a particular time of the year were also similar between the two studies. According to Ogata et.al, there was no significant sex difference ; in the present study vasovagal reaction rates were nearly 5 times higher in females ( 2.44%) than in males (0.46% ).

Convulsive syncope occurred in 0.03% of blood donors and was more common in men in a study conducted by Lin JT et.al . In the present study also, convulsive syncope was found only in men and at a rate of 0.12 % .The probable reason for the difference may be that marked individual variation may exist in the susceptibility of the central nervous system to ischemia as proposed by Lin JT et.al .

Adverse reaction rates in first time and repeat donors were 1.7 % and 0.19 % respectively in the study conducted by Kasprisin et.al. In the present study similar reaction rates were observed- 1.26 % in first time donors and 0.04 % in repeat donors.

Trouern Trend JJ et.al have observed that blood donation adverse reaction rates were higher in young donors , first time donors and low weight donors and the same has been recorded in the study by Franchini et.al. The results of the present study are in agreement with the above studies.

Incidence of bruising was 0.35 % in males and 0.98 % in females and this did not affect the donor return rate according to Ranasinghe.E et.al . In the present study bruising was not at all reported by the donors.

Newman BH et.al observed that vasovagal reaction rate was inversely proportional to body weight in first time blood donors.The observations made in the present study are similar.

In the study by Shehata N et.al, the highest rate of mild reactions was shown to occur in donors less than 20 years of age. In the present study also the mild reactions were found to occur more frequently in donors aged 18 to 22 years.

Vasovagal reaction rate was 0.87 % according to Zervou EK et.al and the possible reason for the lower incidence of reactions in donors than in other studies was attributed to the fact that physicians were

responsible for the selection of donors. The same holds good for the present study.

Hematoma is an occasional side effect of phlebotomy according to Ohnishi.H, and the 0.07 % of hematoma occurrence in the present study is in concordance with the above study.

Incidence of Tetany is 1 in 1000 donors (0.1% )according to Mollison. In the present study one case of Tetany ( 0.04%) with carpopedal spasm was observed.

The lower adverse reaction rates in the present study as compared to other studies could be due to proper donor selection ,screening criteria and the utmost care taken by the blood bank personnel in ensuring donor safety.

## **SUMMARY**

The frequency of the various adverse reactions like vasovagal reaction, convulsive syncope, tetany, hematoma, nausea and vomiting in whole blood donors has been studied and the percentage of adverse reactions in the study population has been compared with that of other studies and has been found to be less than in other studies.

The influence of factors like body weight, age, sex, donation status in the causation of vasovagal reaction has also been noted in the study. Vasovagal reaction was the predominant adverse reaction in the study. Vasovagal reaction was seen only in first time donors, more so in females and in those who weighed <55kg and in the age group 18-22 years and was more common in the hot summer months and in camp sites with inadequate aeration. Hematoma was as a result of the needle not being seated properly and the donor couch being uncomfortable at camp sites. Tetany was as a result of hyperventilation due to anxiety in a first time donor. The 3 donors who had transient seizures gave a history of sleep

deprivation on later questioning. These donors also exhibited hyperventilation and profuse sweating which could have been due to anxiety and the transient seizures and loss of consciousness could be a component of vasovagal syncope or due to hypoglycemia. All donor reactions were observed only at camp sites and not even one occurred in the blood bank.



## CONCLUSION

Preventive strategies to avoid adverse reactions in blood donors should include: a) proper elicitation of donor history like time since last meal, nature of their occupation & whether they had a good sleep on the day prior to donation b) proper screening procedures like ensuring adequate hydration of donors c) reassuring first time donors d) providing a comfortable couch at camp sites & proper phlebotomy techniques by an experienced phlebotomist e) ensuring adequate ventilation and a comfortable environment (preferably 24°C ) f) observing the donor for atleast 10 min post donation while he still remains on the donor couch and then sending him for refreshments and g) giving post donation instructions and h) donors experiencing adverse reactions should be moved to a separate area so that other donors do not get demotivated. At no point of time should a Donor be left unattended.

## **LIMITATIONS OF THE STUDY**

The period of study was limited to two years. As the Blood bank of the Department of Transfusion Medicine, The TN Dr.MGR Medical University, where the study was conducted, is a stand alone blood bank, blood collection from donors was predominantly at camp sites. As the camps were conducted mostly in educational institutions, student population[age group 18-22 yrs ] formed the majority of donors in the study.

Female donors were comparatively less in the study. Though donors were instructed to report to the blood bank if they experienced any adverse reaction after leaving the donation site, none was reported and since the present study was an observational study, no follow-up of the donors was done.

It is not known whether the donors who experienced adverse reactions turned up for subsequent donation as they might have donated elsewhere.

## **FUTUROLOGY :**

The study can be done on a larger number of donors over an increased time span. An interventional study can be carried out to find out the beneficial effect of predonation water ingestion or caffeine intake in the prevention of donor reactions. Specific questions like whether the donor had a good sleep on the previous day of intended donation can be included in the donor questionnaire and those donors who had inadequate sleep may be requested to turn up later for donation in order to avoid any risk of adverse reaction due to sleep deprivation. Strategies to enhance the donation experience and increase donor retention can be formulated. The effect of adverse reactions on the blood donor return rate can be studied. A case controlled multicentric study to ascertain the influence of age, sex, weight, donation status, blood pressure and pulse in the causation of adverse reactions can be carried out. As adverse reactions are more common in the younger age group and first time donors, the upper age limit for blood donation can be increased in case of regular repeat donors. This would significantly increase the donor pool.

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## ANNEXURES

### LIST OF CAMPS ATTENDED

<u>Date</u>	<u>Venue</u>
05.07.2005	C.L.Baid Mehtha College of Pharmacy,Chennai-96.
22.07.2005	D.B.Jain College, Chennai-96.
29.07.2005	V Friends Association,Chennai-92.
15.08.2005	AJS Nidhi School,Chennai-14.
24.08.2005	Valliammal College for Women, Chennai-102.
18.09.2005	Sri Sathya Sai seva samithi, Chennai-63.
21.09.2005	Meenakshi Dental College,Chennai-95.
20.11.2005	Swami, Chennai-4.
04.12.2005	Pudhiya Siragugal, Chennai-42.
21.12.2005	D.G.Vaishnava College, Chennai-29.
23.12.2005	Indian Bank , Chennai-35.
22.01.2006	Sri Sathya Sai seva samithi, Chennai-61.
03.03.2006	Tagore Engineering College ,Chennai-48.
15.03.2006	Vel R.S.Medical College,Chennai-62.
28.03.2006	Omayal Aachi College of Nursing,Chennai-54.

14.04.2006 St.Patrick's Church,Chennai-16.

21.05 2006 Tamilnadu Youth Congress,Chennai-88.

28.05.2006 Sathya Sai seva samithi, Chennai-63.

18.06.2006 Pudhiya Siragugal, Chennai-42.

09.07.2006 Swami, Chennai-4.

26.07.2006 Chellammal college for women,Chennai-32.

28.07.2006 D.B.Jain College, Chennai-96.

02.08.2006 Fathima Basheer College,Chennai-18.

15.08.2006 AJS Nidhi School,Chennai-14.

19.08.2006 Tamilnadu Youth Congress,Chennai-88.

10.09.2006 Sri Sathya Sai seva samithi , Chennai-44.

22.09.2006 Muthukumaran institute of technology,Chennai-69.

10.10.2006 D.G.Vaishnava College, Chennai-29.

11.10.2006 Govt. Arts College, Nandanam.

08.11.2006 C.L.Baid Mehtha College of Pharmacy,Chennai-96.

19.11.2006 Swami, Chennai-4.

17.12.2006 Pudhiya Siragugal,Chennai-42.

24.01.2007 Vivekananda College, Chennai-4.

04.02.2007 Harmony,Chennai-4.

16.02.2007 Anadocs, Chennai.

19.02.2007 Vel R.S.Medical College,Chennai-62.

20.02.2007 Vel R.S.Medical College,Chennai-62.

08.03.2007 Education Development Board,Chennai-35.

02.04.2007 Omayal Aachi College of Nursing, Chennai-54.

06.04.2007 St. Patrick's Church,Chennai-16.

26.04.2007 HDFC Ltd,Chennai-32.

06.05.2007 Swami,Chennai-4.

08.05.2007 IDBI,Chennai-35.

13.05.2007 Sri Sathya Sai Seva Samithi, Chennai-63.

21.05.2007 Tamilnadu Youth Congress, Chennai-88.

**BLOOD DONOR ADVERSE REACTION FORM**

**DEPARTMENT OF TRANSFUSION MEDICINE**  
**THE TAMILNADU DR. M. G. R. MEDICAL UNIVERSITY**

NAME OF THE DONOR :	
AGE / SEX :	
BODY WEIGHT :	
PRE-DONATION BLOOD PRESSURE: PULSE RATE:	
OCCUPATION :	
FIRST TIME / REPEAT DONOR :	
CAMP SITE / BB & DATE :	
SERIAL. NO. / DONATION. NO : VOLUME OF BLOOD COLLECTED:	
ADVERSE REACTION :	
MANAGEMENT :	

<b>Donor No:</b>	<b>Age/ Sex</b>	<b>Weight (in kgs)</b>	<b>BP (mm Hg)</b>	<b>Occupation</b>	<b>First time/ Repeat donor</b>	<b>Donor Reaction</b>
Donor 1	20/M	53	110/70	Student	First	VVR*
Donor 2	20/F	47	110/80	Student	First	VVR
Donor 3	18/F	48	100/70	Student	First	VVR
Donor 4	18/M	51	110/80	Student	First	VVR
Donor 5	20/F	53	110/80	Student	First	VVR
Donor 6	19/F	48	100/74	Student	First	VVR
Donor 7	18/F	51	110/80	Student	First	VVR
Donor 8	20/M	53	120/80	Student	First	VVR
Donor 9	20/F	52	110/74	Student	First	VVR
Donor 10	19/M	52	120/84	Student	First	VVR
Donor 11	19/F	54	120/80	Student	First	Nausea and Vomiting
Donor 12	30/M	64	120/84	Teacher	Repeat	Hematoma
Donor 13	19/F	50	110/80	Student	First	VVR
Donor 14	18/F	48	120/80	Student	First	VVR
Donor 15	19/F	49	110/70	Student	First	VVR
Donor 16	18/F	52	110/70	Student	First	Nausea and Vomiting
Donor 17	22/M	50	120/80	Student	First	VVR
Donor 18	22/F	57	110/78	Student	First	Hematoma
Donor 19	20/M	53	110/70	Student	First	VVR
Donor 20	18/M	51	120/74	Student	First	VVR
Donor 21	19/F	52	110/68	Student	First	VVR
Donor 22	23/M	54	120/80	Student	First	VVR
Donor 23	20/F	53	110/78	Student	First	VVR
Donor 24	19/M	51	110/74	Student	First	Nausea and Vomiting
Donor 25	19/F	51	112/68	Student	First	Nausea and Vomiting
Donor 26	20/F	53	108/70	Student	First	VVR
Donor 27	18/M	50	120/84	Student	First	Convulsive Syncope
Donor 28	19/M	47	120/78	Student	First	VVR
Donor 29	21/F	49	112/80	Student	First	VVR
Donor 30	21/F	57	104/64	Student	First	VVR
Donor 31	30/M	67	130/84	Foreman	First	Convulsive Syncope
Donor 32	21/M	73	124/80	Student	First	Tetany
Donor 33	32/M	60	120/74	Executive	First	Convulsive Syncope

\*VVR = VASOVAGAL REACTION