

## MEDICO-LEGAL ASPECTS OF BLOOD TRANSFUSION

### Abstract

Deaths are not common but they do occur rarely during blood transfusion. Whenever such incidence happens it poses a great problem to the medical persons. Management and investigation of serious adverse reaction poses a great challenge. Most of the medico-legal problems faced by the doctors are due to the reason that medical records are not properly maintained and there is lack of informed written consent. Patients and their relatives are not prepared to face the adverse reactions particularly death during this process of administration. Whenever such an incidence happens; there is a lot of hue and cry against the doctors. Only proper and timely investigation of the case by the persons well conversant with such investigations can solve the crisis. Recommendations are provided to reduce the unpleasant effects on the career of medical professional by proper handling of blood transfusion cases.

**Keywords:** Adverse effects; blood transfusion, blood reaction

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### Introduction

Consent for accepting blood transfusion is of paramount importance like any other procedure on the human body. The comment "Every human being of adult years and sound mind has a right to determine what shall be done with his own body and the surgeon who performs operation without his (patient's) consent commits assault for which he is liable in damages" [1] equally applies to blood transfusion.

Blood transfusion is beneficial in many circumstances and may even be life saving. Blood transfusion must be carried out only on precise indications [2] and these indications must be mentioned in the files.

For the safety of blood transfusion step by step procedure must be adopted which should include informed consent, immune-haematological results, specific prescription about quantity and quality of blood product. [3] In an emergency procedure may be changed but it must be documented. Fact of the blood transfusion must be recorded in the hospital file and this hospital file should be kept in safe custody for a particular period of time as per the laws of the land e.g. in France it is kept for 30 years. The need of blood transfusion has been described as normal cases, special cases, urgent cases and emergency cases. [2]

Transfusion nurses are specially trained in blood transfusion but their availability may not be in all the circumstances. Blood transfusion can be done by nurse or midwife but clinician must be able to intervene quickly if need arises. [3]

Ethics in blood transfusion are very important and must be followed for safe blood transfusion procedure. In 1980 international society of blood transfusion endorsed first code about the ethics of blood transfusion. [4] This code was adopted by WHO which was later modified in 2000. Only volunteered donations should be accepted and used for patients requiring blood transfusion as Supreme Court has banned professional blood donors. [5]

Jehovas witnesses believe in not using the blood and blood products to save their lives even when it is indicated therapeutically. Blood transfusion against the religious beliefs is problem in emergency situations particularly when the victim is unconscious. It is better to inform the patient about transfusion before operations. [6]

### Adverse reactions

Earliest blood transfusion was carried out in 1492 on Pope Innocent VIII to save his life and blood was taken from three 10 years old boys. In this process of transfusion Pope as well as three boys died. [5] It gradually progressed to modern day almost safe well accepted procedure through stages of animal blood transfusion, haemolytic reactions, development of blood groups and cross matching and knowledge of blood carried infections.

Adverse reactions to blood transfusion are not uncommon. This may vary from mild to lethal. Some of these reactions can be prevented and others cannot. These reactions may be acute which occur within 24 hours or may be delayed for days or months. Blood transfusion reactions may be immune mediated or non immune mediated. [7]

There may be haemolytic (intravascular or extra-vascular) or febrile non-haemolytic immune mediated acute reactions. Other such reactions may be allergic or even anaphylactic reactions. TA –acute lung injury is also seen due to this.

Non immune mediated acute blood transfusion reactions may be seen as physical or chemical damage to RBCs, hyperkalemia and circulatory overload. If the infused blood contains bacteria then there may be bacterial contamination.

Haemolytic reaction can also be result of immune mediated delayed onset and due to this post transfusion purpura, Imuomodulation and alloimmunization are seen. Transfusion related graft vs host disease is also observed in this group. Hepatitis B & C, HIV 1&2, syphilis, Malaria and iron overload can be other delayed adverse effects

### **Treatment of Transfusion reaction**

Treatment in these cases must be done as early as possible to avoid charges of negligence. But blood should never be administered without the consent of the person. If the person has ever expressed consent against blood transfusion it should not be carried out as it may result in unfavourable court decisions.[8] In case of transfusion reactions immediately stop the blood transfusion and start the supportive treatment. It is very important to take care of allergic reactions, hypotension, renal failure, hypokalemia and, DIC and start treatment for infections if indicated. It is important to maintain a record of the treatment. Maintaining record is as important as giving treatment in such cases.

### **Investigation of Transfusion reaction**

Investigation in cases of adverse reactions should be done without delay to reach at informative and valuable conclusions. First thing to see is there is no clerical error in collecting blood or transfusion blood to a wrong person. Blood grouping from the bag and patient should be repeated to rule out any error in grouping. Regrouping is performed on blood samples from the blood bag/tube, pre transfusion and post transfusion samples. Usually ABO and Rh grouping is done on cells and serum grouping is also done. Re- cross matching is performed also on blood samples from the blood bag/tube, pre transfusion and post transfusion samples for IgM and IgG major and minor antibodies by saline, enzymes and IAT. Red cell antibody screening is also performed for pre and post transfusion samples.

Amount of unutilized blood in the bag should be noted carefully and naked eye examination of this blood should be noted. Color and special features of the blood in the bag/tubing of the bag should always be noted and noted that it is normal/purple/clotted to rule out bacterial contamination or haemolysis. Always check the patient's plasma color of the pre and post- transfusion blood samples. Pink color indicates free hemoglobin due to destruction of RBCs and yellow or brown color indicates bilirubin. Ascertain levels of total free and conjugated levels of bilirubin in post transfusion samples. For this pre transfusion and post transfusion blood samples should be collected, preserved and analyzed. Other tests on pre and post transfusion samples may also help at reaching a conclusion. Increased non-conjugated bilirubin levels post-transfusion samples (5-7hours to 24 hours), decreased hemoglobin, increased methemoglobin and free hemoglobin levels are also good pointers to blood reaction.

Pre and post transfusion compatibility, IgG loaded erythrocytes, antibodies against blood group antigens, anti A or anti B isoagglutinins, ABO and other than ABO incompatibilities need to be tested. Direct antiglobulin test should be done on the blood of patient as negative test will rule out incompatibility. This blood should be drawn as early as possible as negative test will also be there if it is performed after several hours or if it is non hemolytic reaction. In case of doubtful results; repeat cross match of pre-transfusion and post-transfusion blood sample of patient with donor's blood by saline, enzyme and IAT methods. Blood should be screened for irregular antibodies. Special test may be indicated in case of detection of irregular antibodies and identification of antibody should be done if possible.

Bacterial smear and bacterial culture of donor's blood should be performed to rule out bacterial contamination.

Investigation in fatal cases will depend upon the cause of the complication.[2] Assessment of lethal blood transfusion errors is a multidisciplinary challenge involving forensic medicine, pathology and immune-histochemical and immuno-haematological aspects to detect the incompatible foreign red blood cells in the samples collected during autopsy.[9]

Patients urine collected after blood transfusion reaction should also be checked for free hemoglobin.

All these tests should be preferably counter checked by senior technician if performed by junior technician.

We should rule out both immune and non immune blood transfusion reactions and then also should find about intrinsic red cell defects.

When investigating about negligence of the treating physician treatment line should also be checked to see that proper supportive treatment has been given for hypotension, renal failure, hyperkalemia disseminated intravascular coagulation and bacterial contamination.

For investigation of delayed onset transfusion adverse effects mean time and time range between administration and sero-conversion must be taken care of infectious diseases. For HIV it is 22 days and 6-38 days, for HCV it is 98 days and 56-189 days, For HBsAg it is 56 days and 24-128 days and HTLV it 51 days and 37-72 days respectively.[7]

### **Discussion**

There is 2% - 5% lethal outcome in blood transfusion in spite of 1: 12,000 – 1:36,000 wrong blood transfusions. [9]

Due to inherent dangers in blood transfusion number of legal actions has increased in foreign countries since 5 decades back. [10] It is more likely that this will further increase in the future in India because of more legal awareness and many people successfully suing the doctors to get financial compensation.

### **Recommendations**

Doctor must be aware of the legal basis of blood transfusion. To avoid legal complications the professionals dealing with blood transfusion must follow the national and international guidelines. There should always be a written manual/standard operating procedure of procuring, issuing and administering transfusion for each institution. From the experience in the medico legal field it is recommended that following points should be carefully followed:

1. Always take an informed consent.
2. This consent should always be in writing and preferably it should be a witnessed consent and it will of great value in case there is death due to adverse reaction.
3. Blood sample sent for grouping and matching should be properly labelled and this fact should be recorded in the case file. Request for the blood requirement should preferably be on the proforma of the blood bank or of the institution and all the details should be filled correctly.
4. Always keep the records that from where blood for transfusion was obtained grouped and matched.
5. Please see that all the required tests have been done on the blood which is being transfused.
6. Check the label properly for blood group and see that this is meant for that particular patient only.
7. Do not administer blood and drugs through a common administration set or inject drugs into blood bag or use a small bore needle for blood transfusion.
8. In case of blood transfusion reactions always treat promptly and document all the treatment of the patient. Attending clinician/nurse must be aware of the sign/symptoms of adverse blood reactions. With platelet infusion particular attention should be towards ill effects of bacterial contamination as platelets are stored at 20<sup>0</sup>-24<sup>0</sup> C.
9. Always inform the blood bank in case of adverse reaction along with sign and symptoms of the patient.
10. In case of death do not panic and always inform the police and keep the patient record securely.

### **Conclusions**

Taking care of the all the recommendations will minimize the gravity of the medico-legal adverse effects on the career of the medical person. Proper documentation of the steps taken after the adverse reaction will go a long way in saving the reputation of the medical professionals. Blood transfusion is a well accepted procedure in modern day clinical practice and one should not be afraid of stray cases of litigation due to adverse affects of blood transfusion but the need of the hour is to be well conversant with the law of the land and follow the ethics of blood transfusion

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