Review Article
AMERICAN JOURNAL OF PHARMACY AND HEALTH RESEARCH
www.ajphr.com
2015, Volume 3, Issue 8
ISSN: 2321–3647(online)

Haemovigilance

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ABSTRACT

Haemovigilance is a continuous process of data collection and analysis of adverse reactions which occur during blood transfusion and it is used to investigate their causes and outcomes to prevent their occurrence or recurrence. It is a powerful risk monitoring system for blood transfusion and its ultimate purpose is to improve the quality and safety of transfusion therapy. It also proves that blood transfusion is relatively safe compared with the use of medicinal drugs as these blood components have reached a high safety standard.

Keywords: blood transfusion, adverse reactions, blood safety.

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Received 16 July 2015, Accepted 21 July 2015

Please cite this article as: Asadulla S *et al*., Haemovigilance. American Journal of Pharmacy & Health Research 2015.

INTRODUCTION

Haemovigilance is now universally recognized as an integral and prominent part of safety in blood transfusion, and increasing attention is being paid to haemovigilance in many countries. The World Health Organization (WHO) Global Database on Blood Safety Summary Report 2011[1] states that a national haemovigilance system was present in 13% of low-income countries, 30% of middle income countries and 78% of high-income countries (data based on 106 responding countries). An evidence base, for the improvement of transfusion practice is provided by National haemovigilance systems that displays the real risks and hazards of transfusion in a given community/country and allows for the dissemination of these findings and the instigation of appropriate actions, including educational processes to prevent recurrence. Haemovigilance acts a powerful tool for improving the quality of the blood transfusion chain and it primarily focus on safety, adequacy, accessibility and efficiency of blood supply through establishment of efficient, cost-effective and coordinated national systems. The transfusion of blood and blood components is a core part of healthcare service delivery to patients. While the use of blood and blood components can be lifesaving, there are also risks associated during transfusion like transmission of infectious disease (such as HIV, hepatitis B and C). To avoid these risks Haemovigilance is introduced.

History

Haemovigilance Programme has been launched on 10th December, 2012 under Pharmacovigilance programme of India and it started in 90 Medical Colleges across the country to track adverse reactions events and incidences associated with blood transfusion and Blood product administration (Haemovigilance). National Institute of Biologicals (NIB) is the coordinating center, for Biovigilance programme (BvP) as well as Haemovigilance across the country[2]. The word ‘haemovigilance’ (he´movigilance in French) was coined in France in 1991 in analogy to the already existing term ‘pharmacovigilance’. It is derived from the Greek word where ‘haema’ means blood and the Latin word ‘vigilans’ means watchful. The main aim of haemovigilance is to detect and analyze all untoward effects of blood transfusion in order to correct their cause and to prevent recurrence, thus improving the safety of blood transfusion. Both transfusion recipients and blood donors should be followed up in this process so as to detect any immediate and long-term effects of transfusion and blood donation respectively. The process is carried out from the donor selection and phlebotomy to the post-transfusion phase for monitoring the occurrence of adverse events. It was estimated that Indigenous Software –

Haemo-Vigil launched on 24th Jan 2013 & then 1st Haemovigilance Newsletter was published. In this regard a Core Group & Advisory Committee have already been constituted and first meeting of advisory committee was held on 29th Nov,2012 to finalize Haemovigilance Transfusion Reaction Reporting Form (TRRF) & Guidance Document and this Document Finalized by Advisory Committee on 7th Dec 2012.

There are 2760 licensed blood blanks in India, in February, 2015

The average annual blood collection is around 7-8 million units and this haemovigilance system extension to regional and global sharing of information will further enhance the process of learning for improvement.

Purpose of Haemovigilance

Haemovigilance system not only indicates how safety should be improved, but also documents the success of various measures.

The main purpose of Haemovigilance is:

1. To encounter the majority of the serious adverse reactions and also the events which occur in hospital.
2. To prevent the adverse reactions which occur due to clerical errors.
3. It is a system which may be used for the vigilance and surveillance of alternatives for allogeneic blood transfusion such as cell savers.
4. Haemovigilance systems and officers may be used to improve the quality of aspects of blood transfusion other than safety, such as appropriate use.
5. The type of organization of a haemovigilance system is of relative value, and it gives the best outcome.
6. Haemovigilance system will also be a benefit for vigilance and surveillance of the treatment with other human products such as cells, tissues and organs.
7. Standard protocols for the administration of blood are essential to minimize the potential for error.
8. Some adverse reactions such as anaphylactic reactions often are not avoidable and therefore have to be considered as an inherent risk of blood transfusion.
9. International collaboration has been extremely useful.
10. To report any adverse experiences with Blood Transfusion or Blood Products Administration and to provide health care.

Haemovigilance Programme of India

Centres for Pharmacovigilance Programme of India (HvPI)

According to HvPI, 2014 there are totally 134 centers in India i.e. Medical colleges/ hospitals/blood banks that are registered under National Coordinating Centre for HvPI for reporting adverse reactions for blood/ blood component transfusion.

Advice About Reporting

Report adverse experiences with Blood Transfusion or Blood Products Administration.

- **Who Can Report?**

Any health care professional (Doctors including Dentists, Nurses and Pharmacists) can report.

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

Indian Pharmacopoeia Commission – National Institute of Biologicals
Ministry of Health & Family Welfare – Govt. of India
HAEMOVIGILANCE
(Pharmacovigilance Programme of India)

TRANSFUSION REACTIONS REPORTING FORM FOR BLOOD & BLOOD PRODUCTS

For reporting of Transfusion Reactions by Healthcare Professionals

A) PATIENT INFORMATION * Mandatory Field

Patient initials*..... DOB/Age in years *:..... Blood Group *:____ Diagnosis .....Hospital Code No*.....
Hospital Admission No. *_____ Sex: * F ☐ M ☐
Date & Time of Transfusion *..... Date & Time of reaction*..... Date & Time of recovery.....

B) TRANSFUSION PRODUCT DETAILS*

Components	Select Components	Unit Number (transfused)	Expiry Date	Manufacturer	Batch Number	Indications	1st time / Repeat Transfusion (No. of Repeats)
Whole Blood							
Red Blood Cells							
Platelets Apheresis							
Platelets Pooled/ RDP							
Solvent detergent (SD) Plasma							
FFP							
Cryoprecipitate							
Any other							

Blood Products (Please Specify)	Manufacturer	Batch Number	Expiry Date

C) NATURE OF ADVERSE REACTIONS *

	Reactions	Please Tick (√)
1	Immunological Haemolysis due to ABO Incompatibility	
2	Immunological Haemolysis due to other allo- antibodies	
3	Non Immunological Haemolysis	
4	Transfusion Transmitted Bacterial Infection	
5	Anaphylaxis / Hypersensitivity	
6	Transfusion Related Acute Lung Injury (TRALI)	
7	Transfusion Transmitted Viral Infection (HBV)	
8	Transfusion Transmitted Viral Infection (HCV)	
9	Transfusion Transmitted Viral Infection (HIV-1/2)	
10	Transfusion Transmitted Viral Infection, other (Specify)	
11	Transfusion Transmitted Parasitic Infection (Malaria)	
12	Transfusion Transmitted Parasitic Infection, other (Specify)	
13	Post Transfusion Purpura	
14	Transfusion Associated Graft versus Host Disease (TAGvHD)	
15	Febrile Non Haemolytic Reactions(FNHTR)	
16	Transfusion Associated Dyspnea(TAD)	
17	Transfusion Associated Circulatory Overload (TACO)	
18	Other Reaction(s)	

D) OUTCOMES OF THE ADVERSE REACTIONS*

- Death following the adverse reactions ☐
- Recovered ☐
- Recovered with sequelae ☐
- Permanently disabled ☐
- Unknown ☐

E) REPORTER *

Name and professional Address: _____
_____
Pin Code : _____ Email: _____
Tel No. (with STD code)_____

Any other information .....

F) CAUSALITY ASSESSMENT*

Date of this report (DD/MM/YYYY)

➢ **Where to Report?**

The completed form should be returned to the nearest Medical College under Haemovigilance Programme or to NIB (National Coordinating Center)- Haemovigilance.

A list of nationwide Medical Colleges under haemovigilance programme is available at: http://www.nib.gov.in

➢ **What happens to the submitted information**

To the submitted information causality assessment is carried out at Medical Colleges under Haemovigilance Programme. The information collected in the Transfusion Reaction Reporting Form (TRRF) will be forwarded to National Coordinating Centre-Haemovigilance NIB, through software **(Haemo-Vigil)** developed in house by NIB's IT division. This data will be collated & analyzed to identify trends, recommend best practices and interventions required to improve patient care & safety. These recommendations will be forwarded to PvPI National Coordinating Centre IPC for onward transmission to Drugs Controller General (India), Central Drugs Standard Control Organization and these recommendations will be used to formulate safety related regulatory decisions on Blood & Blood Products Transfusion which will be communicated to various stakeholders. The information is submitted to the Advisory Committee of Haemovigilance Programme constituted by the Ministry of Health and Family Welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required[3]. This was the first time that data had been collected through the online system and automatically saved in a database in WHO. It had proven to be a very successful effort in the WHO survey.

Why do patients need blood transfusions?

The blood components are used to correct abnormalities in the blood, which cannot be corrected by any other means. Common reasons for transfusion of blood are:

•Due to blood lost because of an accident or surgery,

• Due to Anemia[4]

• Due to bleeding or clotting disorders.

Blood loss occurs when someone lose a significant amount of blood during an operation or an accident. In this condition the doctor wants to replace the blood loss with a blood transfusion immediately so that one do not suffer the serious effects of blood loss.

In case of anemia, the body does not have enough red blood cells to carry the oxygen that one can need because of this, the person may feel tired or breathless. Many cases of anemia may be

treated with medication, however not all cases respond and blood transfusion may be required. The medical team will best explain details about when and why the person need blood.

Steps to be taken to ensure that the blood is safe?

The Irish Blood Transfusion Service have many safeguards on our national blood supply. As all the donors are voluntary and unpaid and are the safest source of blood. Before giving blood, donors must answer detailed questions about their health and risk factors for diseases to ensure that they are in good health. Every unit is tested for infections which can be transmitted through blood, i.e. Hepatitis B and Hepatitis C, HIV I and 2 (the cause of AIDS), Syphilis and HTLV I and II. Important steps in the administration of blood components start with the correct identification of the patient and cross match sample and it ends with the collection and infusion of the right blood to the right patient at the right time. A quality management system should exist in each institution[5]. Each and every step is important and must be subject to the written procedures and quality management. All the staff must be trained and be familiar with procedures which should be regularly updated. Any breakdown in procedures should be investigated and corrected even if the recipient of the transfusion is unharmed[6].

Medical College/ Institute Haemovigilance focuses on fresh blood components and on the other following factors:

1. Red cells
2. Platelets
3. Fresh frozen plasma
4. Cryoprecipitate
5. Cryo-depleted plasma Whole blood
6. LPRBC
7. PRP
8. FFP
9. Blood Product (Name)
10. Batch No.
11. Manufacturer
12. Expiry[7]

Not only the blood components but also the patient's hospital medical records should contain the indication for the blood transfusion and the number of units required[8]. All blood and blood components for transfusion should be prescribed by a medical practitioner, preferably on a unit by unit basis[9] and Specialist advice may be needed on the need for cytomegalovirus (CMV)

seronegative or gamma irradiated components. Any medication to be given in conjunction with the transfusion must be prescribed on the drug chart. No other infusions, solutions or drugs should be added to any blood component as they may result in haemolysis or clotting[10].

Storage of Blood Components

The red blood cells and whole blood should **only** be stored in a designated controlled blood refrigerator.

• Plasma is stored frozen and thawed in the laboratory immediately before use.

• The Platelets should be stored at room temperature on a controlled agitator to avoid clumping, and should **never** be stored in a refrigerator.

• The time of removal of all components from the controlled storage should be logged – ideally electronically, or failing that, manually.

• Once a unit of blood has been removed from controlled storage the transfusion should be commenced immediately on delivery to the clinical area. If the transfusion cannot be initiated promptly, then the blood should be returned to the hospital transfusion laboratory for storage, unless the transfusion to the intended recipient can be completed within 4 hours. Blood should be returned to the hospital transfusion laboratory for documented disposal if out of controlled storage for more than 30 minutes[11].

• The transfusion of plasma and platelets should be commenced as soon as possible following issue from the laboratory and must not be stored outside the laboratory.

• The use of validated blood transport containers is recommended.

Pre-Transfusion Identification

Before starting the transfusion, the following checks are essential at the patient's bedside or wherever the patient is to be transfused. The checks should never be performed remote from the patient or at the nurse's station or in a side room.

Bedside Checklist

• Are the patient identification details identical on

- The patient's identity band?
- The compatibility label on the blood component pack?
- The compatibility report form sent with the blood component from the hospital transfusion laboratory?
- The patient's medical record?
- The prescription chart?

• Do these details match who the patient says he/she is?

- Patients who can communicate must be asked to state their surname, first name and date of birth.

• Are the ABO and Rh D group and donation number all identical on

- The IBTS label on the blood component pack?

- The compatibility label on the blood component pack?

- The compatibility report form sent with the blood component from the hospital transfusion laboratory?

• Do the details of the pack, compatibility form and prescription form, match any special Requirements for special types of blood components e.g. CMV seronegative, gamma-irradiated etc? If there are any discrepancies, the unit must not be transfused.

Pre-Transfusion Sampling

In pre-transfusion sampling the hospital policy should address the training needs of staff who undertake pre-transfusion sampling and provide detailed instructions on vene puncture and on the identification of patient and sample. Correct blood sampling techniques are vital to avoid haemodiluted samples being processed, which may further lead to incorrect clinical management/inappropriate.

Inspection of unit prior to administration

•Prior to administration check that the blood pack is in date and shows no sign of leakage, unusual colour or haemolysis.

• Check that the platelet packs do not show any clumping or appear unusually cloudy, as this may be a sign of bacterial contamination.

• If at any defect suspected during administration, contact the hospital transfusion laboratory for advice.

• If in doubt, do not transfuse the defect suspected blood packs.

Blood Transfusion can be fatal if incorrectly administered

• Errors occur most frequently in:

• Patient identification.

• Sampling/labeling of the pre-transfusion specimen.

• Removal of blood from the blood fridge before transfusion.

• Checking the identification of both the patient and the blood component at the bedside[12].

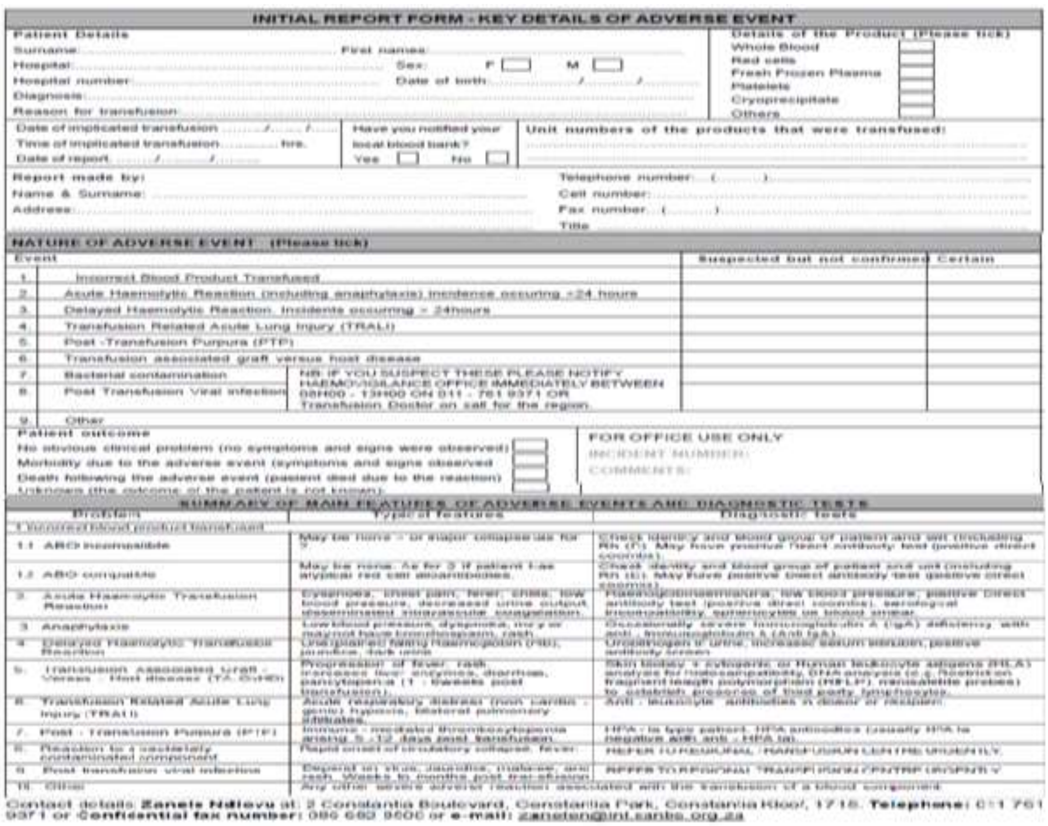
To avoid Adverse events

- ✓ Patients should be observed closely during the initial 15 min/50mls of a transfusion. Any symptoms, which may indicate a transfusion reaction including distress, pain at or near the transfusion site, loin pain, backache, fever, or dyspnoea, must be investigated as they could indicate a serious reaction. It is important to realize that signs and symptoms are not necessarily specific to a given type of reaction.
- ✓ In case of any defect, all suspected transfusion reactions should be reported immediately to the hospital transfusion laboratory. Immediate reporting is particularly very important
- ✓ Protocols should be in place to detect, investigate, and where possible prevent adverse reactions. Adverse reactions should be reported to the hospital transfusion laboratory and Transfusion surveillance officer(TSO).

Haemovigilance Adverse Event Report Form

This does not replace the normal procedure for reporting transfusion related adverse events. Reactions to fractionated products (e.g. albumin, IVI IgG) should be reported to NBI (National Bioproducts Institute).

Please Use This Form to Report Adverse Events Following Transfusion of Blood And Blood Products



INITIAL REPORT FORM - KEY DETAILS OF ADVERSE EVENT

Patient Details
Surname .... First names ....
Hospital .... Sex: F ☐ M ☐
Hospital number .... Date of birth ..../..../....
Diagnosis ....
Reason for transfusion ....

Details of the Product (Please tick)
Whole Blood ☐
Red cells ☐
Fresh Frozen Plasma ☐
Platelets ☐
Cryoprecipitate ☐
Others ☐

Date of implicated transfusion ..../..../....
Time of implicated transfusion .... hrs.
Date of report ..../..../....

Have you notified your local blood bank? Yes ☐ No ☐

Unit numbers of the products that were transfused: ....

Report made by:
Name & Surname: ....
Address: ....
Telephone number: (....) ....
Cell number: ....
Fax number: (....) ....
Title ....

NATURE OF ADVERSE EVENT (Please tick)

Event		Suspected but not confirmed	Certain
1.	Incorrect Blood Product Transfused		
2.	Acute Haemolytic Reaction (including anaphylaxis) incidence occuring <24 hours		
3.	Delayed Haemolytic Reaction. Incidents occurring > 24hours		
4.	Transfusion Related Acute Lung Injury (TRALI)		
5.	Post -Transfusion Purpura (PTP)		
6.	Transfusion associated graft versus host disease		
7.	Bacterial contamination		
8.	Post Transfusion Viral infection		
9.	Other		

NB: IF YOU SUSPECT THESE PLEASE NOTIFY HAEMOVIGILANCE OFFICE IMMEDIATELY BETWEEN 08H00 - 13H00 ON 011 - 761 9371 OR Transfusion Doctor on call for the region.

Patient outcome
No obvious clinical problem (no symptoms and signs were observed) ☐
Morbidity due to the adverse event (symptoms and signs observed ☐
Death following the adverse event (patient died due to the reaction) ☐
Unknown (the outcome of the patient is not known) ☐

FOR OFFICE USE ONLY
INCIDENT NUMBER:
COMMENTS:

SUMMARY OF MAIN FEATURES OF ADVERSE EVENTS AND DIAGNOSTIC TESTS

Problem	Typical features	Diagnostic tests
1 Incorrect blood product transfused		
1.1 ABO incompatible	May be none - or major collapse as for 2	Check identity and blood group of patient and unit (including Rh (D)). May have positive direct antibody test (positive direct coombs).
1.2 ABO compatible	May be none. As for 3 if patient has atypical red cell alloantibodies.	Check identity and blood group of patient and unit (including Rh (D)). May have positive direct antibody test (positive direct coombs).
2 Acute Haemolytic Transfusion Reaction	Dyspnoea, chest pain, fever, chills, low blood pressure, decreased urine output, disseminated intravascular coagulation.	Haemoglobinaemia/uria, low blood pressure, positive Direct antibody test (positive direct coombs), serological incompatibility, spherocytes on blood smear.
3 Anaphylaxis	Low blood pressure, dyspnoea, may or may not have bronchospasm, rash	Occasionally severe Immunoglobulin A (IgA) deficiency with anti - Immunoglobulin A (Anti IgA).
4 Delayed Haemolytic Transfusion Reaction	Unexplained falling Haemoglobin (Hb), jaundice, dark urine	Urobilinogen in urine, increased serum bilirubin, positive antibody screen
5 Transfusion Associated Graft - Versus - Host disease (TA-GvHD)	Progression of fever, rash, increased liver enzymes, diarrhoea, pancytopenia (1 - 6 weeks post transfusion).	Skin biopsy + cytogenic or Human leukocyte antigens (HLA) analysis for histocompatibility, DNA analysis (e.g. Restriction fragment length polymorphism (RFLP), microsatellite probes) to establish presence of third party lymphocytes.
6 Transfusion Related Acute Lung Injury (TRALI)	Acute respiratory distress (non cardio - genic) hypoxia, bilateral pulmonary infiltrates.	Anti - leukocyte antibodies in donor or recipient
7 Post - Transfusion Purpura (PTP)	Immune - mediated thrombocytopenia arising 5 - 12 days post transfusion.	HPA - 1a type patient, HPA antibodies (usually HPA 1a negative with anti - HPA 1a).
8 Reaction to a bacterially contaminated component	Rapid onset of circulatory collapse, fever.	REFER TO REGIONAL TRANSFUSION CENTRE URGENTLY
9 Post transfusion viral infection	Depend on virus, Jaundice, malaise, and rash. Weeks to months post transfusion.	REFER TO REGIONAL TRANSFUSION CENTRE URGENTLY
10 Other	Any other severe adverse reaction associated with the transfusion of a blood component	

Contact details **Zanele Ndlovu** at: 2 Constantia Boulevard, Constantia Park, Constantia Kloof, 1715. **Telephone:** 011 761 9371 or **Confidential fax number:** 086 680 9600 or **e-mail:** zaneleN@[illegible].sanbs.org.za

Recommendations to hospital/institutional level

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

1. Implement clinical guidelines on transfusion of blood and blood products based on national standards, including:

- Positive identification of patients prior to transfusion
- Transfusion triggers
- Standard blood ordering schedules
- Appropriate documentation of the transfusion process
- Blood utilization review
- Audit of clinical transfusion practice
- Traceability requirements.

2. Establish policies and procedures for all steps in blood transfusion chain including those for haemovigilance. These should be:

- Based on local, national or international standards
- Non-punitive
- Reviewed on regular basis.

3. Define quality indicators as measures of clinical practice and traceability including confirmation of transfusion; and collect and analyse the indicators data on regular basis for quality improvement.
4. Develop mechanisms of reporting of adverse transfusion events (reactions and incidents), including

- Adverse transfusion reaction forms and incident reporting form
- Protocol for further investigations of transfusion reactions
- Clear roles and responsibilities for reporting and follow up
- Regular review of adverse reactions and incidents by the hospital transfusion committee.

5. Allocate sufficient human and financial resources to establish an effective Haemovigilance system at hospital level.
6. Put in place mechanisms for providing training and education on haemovigilance and transfusion safety to all staff involved in the transfusion chain.
7. Establish and activate and maintain hospital transfusion committees.

8. Designate or appoint Transfusion Nurse or Haemovigilance Officer in hospitals to follow up on all reports of adverse transfusion events, to report to HTC and to the National Haemovigilance Office, where applicable.

CONCLUSION

Haemovigilance is an excellent quality indicator for the blood transfusion service. Without haemovigilance, it is impossible to identify the risk associated with a transfusion and consequently difficult for clinicians to assess the benefit/risk ratio and counsel pre-transfusion patients accordingly. For a successful national haemovigilance system health facility/ blood bank based professionals, a national coordinating body, regulatory/policy formulating body plays a prominent role to improve the blood safety and to minimize adverse effects. To promote blood safety and limit inappropriate blood use the standards guidelines for transfusion practice has to be followed and data collection, data validation and reporting around blood safety must be strengthened.

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