Steps to Take When Transfusion Reaction Occurs

- Steps in Transfusion Reaction
  - Stop transfusion immediately
  - Leave the needle in the vein, begin saline infusion
  - Obtain vital signs
  - Begin oxygen administration
  - Carry out brief physical examination
  - Obtain a new blood sample and send to blood bank for compatibility testing

- Inspect plasma of the collected sample for evidence of haemolysis
- Obtain urine sample if the patient can void
- Obtain a chest X-ray if pulmonary symptoms are prominent
- Make preliminary assessment of the situation
- Begin definitive treatment based on initial assessment

Immunologic Complications of Transfusion

- Immunologic complications
  1. Immunisation to blood group antigens
  2. Transfusion-associated graft-versus-host disease
    - This is caused by variable alloreactive T-lymphocytes contained in the blood components
    - In patients who are severely immunocompromised, transfused lymphocytes proliferate
    - This causes a syndrome characterised by fever, liver dysfunction, skin rash, diarrhoea and marrow hypoplasia
    - Develops in less than 30 days and is usually fatal

- Transfusion related immune modulation
  - Besides autoimmune response, some other immunomodulation effects of transfusion are there
  - These effects involve:
    - Alteration of graft survival
    - Increased susceptibility to recurrence of malignancy
    - Increased susceptibility to infection
    - Microchimerism
    - Following transfusion donor leucocytes briefly proliferate in recipient and disappear in 7-10 days

- Non-immunologic complications
  - Hypothermia
    - Due to transfusion of large volume of cold blood
  - Citrate toxicity
    - Whole blood is collected in citrate anticoagulant
    - Manifestation as hypocalcaemia with symptoms of muscle paraesthesias, twitching, anxiety and in severe cases seizures and cardiac arrhythmia
    - Citrate up to 1mg/kg/min is well tolerated
    - These rates are rarely encountered

Non-immunologic Complications of Transfusion

- Hypothermia
  - Due to transfusion of large volume of cold blood
- Citrate toxicity
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  - Manifestation as hypocalcaemia with symptoms of muscle paraesthesias, twitching, anxiety and in severe cases seizures and cardiac arrhythmia
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  - These rates are rarely encountered
Non-Immunologic Complications of Transfusion

- Bleeding tendency
  - In red cell suspension little plasma remains
  - Red cell suspension transfusion does not provide coagulation factor replacement
  - This occurs in massive transfusion and also involves depletion of platelets
- Electrolyte and acid-base imbalance
  - Potassium and ammonia may be elevated
- Circulatory overload

Non-Immunologic Complications of Transfusion

- Iron overload
  - Those who receive massive transfusion
  - Iatrogenic haemochromatosis may develop
- Embolism
  - With improved techniques and with modern equipment these complications are almost extinct
- Passive transfer of hypersensitivity
  - Delayed hypersensitivity in the form of positive skin test to tuberculin PPD can occur

Specialty wise Blood Need

- General Surgery: 7%
- Orthopaedic: 6%
- Paediatrics: 6%
- Neurosurgery: 5%
- Intensive Care: 3%
- Obs. Gynae: 3%
- Emergency: 2%
- Thoracic surgery: 31%
- Internal Medicine: 14%
- Oncology: 9%

Blood Requirements in Institutions

<table>
<thead>
<tr>
<th>Nature of Institution</th>
<th>No. of Beds</th>
<th>Blood Need</th>
<th>No. of Institutions</th>
<th>Total Blood</th>
<th>Total units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Superspeciality</td>
<td>100-500</td>
<td>30-100</td>
<td>30</td>
<td>2500-75000</td>
<td>750000-2250000</td>
</tr>
<tr>
<td>Special Teaching</td>
<td>500-1000</td>
<td>30-100</td>
<td>15</td>
<td>6000-250000</td>
<td>1800000-7500000</td>
</tr>
<tr>
<td>Non-Teaching</td>
<td>1000-2000</td>
<td>10-50</td>
<td>75</td>
<td>15000-75000</td>
<td>6750000-3750000</td>
</tr>
<tr>
<td>Dist Hospital</td>
<td>250-500</td>
<td>30-100</td>
<td>40</td>
<td>10000-50000</td>
<td>160000-800000</td>
</tr>
<tr>
<td>Charitable &amp; Pvt</td>
<td>100-250</td>
<td>10-100</td>
<td>10</td>
<td>8000-40000</td>
<td>80000-400000</td>
</tr>
<tr>
<td>Day care</td>
<td>10 units per patients per year x 30000 patients</td>
<td>300000</td>
<td>Total: 620000</td>
<td>62000000</td>
<td></td>
</tr>
</tbody>
</table>

Blood Collection Data in India

- The annual requirement of blood for the country is estimated at 12.8 million units of blood
- The calculation is based on the WHO norm of blood donation by 1% of population
- NACO supported blood banks have collected 63.85 Lakh units in 2015-16.
- 79% of this was through voluntary non remunerated blood donation.
- 69% of blood collected in NACO supported component separation units is separated into components.

Data of Blood Donation

<table>
<thead>
<tr>
<th>Financial Year</th>
<th>Total Collection in Millions</th>
<th>Collection in NACO supported BU</th>
<th>Blood Donation in NACO supported BU</th>
<th>Hb (%)</th>
<th>HbAg (%)</th>
<th>HCV (%)</th>
<th>HBV (%)</th>
<th>VL (%)</th>
<th>Component Separation in NACO supported BU</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012-13</td>
<td>6.6</td>
<td>3.48</td>
<td>0.0</td>
<td>0.2</td>
<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
<td>0.2</td>
<td>98.7%</td>
</tr>
<tr>
<td>2013-14</td>
<td>6.0</td>
<td>3.79</td>
<td>0.0</td>
<td>0.2</td>
<td>0.1</td>
<td>0.1</td>
<td>0.1</td>
<td>0.2</td>
<td>98.7%</td>
</tr>
<tr>
<td>2014-15</td>
<td>5.83</td>
<td>3.64</td>
<td>0.0</td>
<td>0.14</td>
<td>0.05</td>
<td>0.03</td>
<td>0.05</td>
<td>0.18</td>
<td>61.5%</td>
</tr>
<tr>
<td>2015-16</td>
<td>19.8</td>
<td>6.3</td>
<td>0.1</td>
<td>0.18</td>
<td>0.08</td>
<td>0.04</td>
<td>0.08</td>
<td>0.17</td>
<td>69%</td>
</tr>
<tr>
<td>2016-17</td>
<td>17.6</td>
<td>5.4</td>
<td>0.1</td>
<td>0.17</td>
<td>0.09</td>
<td>0.05</td>
<td>0.08</td>
<td>0.23</td>
<td>67.1%</td>
</tr>
</tbody>
</table>

21-09-2018
Blood Bank - Schedule of Space (D&C Rule 1945)

- Reception
- Waiting Room with accessible toilet
- Interview room
- Examination room for donors
- Bleeding room divided into cubicles (10 - 12 M² each). Air Conditioned
- Processing Area (20 M²)
- Preparation of blood component area (50 M²). Temp 20 to 25°C

Schedule of Space

- Centrifuge room (15 M²)
- Cold Storage cabinets (at 4°C)
- Laboratory
- Medical Officers Room
- Office space for documentation and records
- Recovery room for donors

Schedule of Space

- Refreshment room for donors (s)he should be kept under observation
- Administrators room
- Stores
- Cleaners’ room
- Minimum space required for blood bank: 100 M²
  - For components 50 M²
  - For apheresis 10 M²

Legal Provision

- The provision for procuring license, for manufacturing blood and blood products are laid down in
- The Drugs and Cosmetics Act 1940 and rules there under
- The Rule 122 F to 122 P read with schedule F part XII B & Schedule F part XII C of the Act deals with blood bank
- Every blood bank will need a license to operate
- All application for license to be made on Form 27 C

Space Need for a Blood Bank

<table>
<thead>
<tr>
<th>Facility</th>
<th>Space M²</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Reception, registration cum waiting room</td>
<td>14.00</td>
</tr>
<tr>
<td>2 Blood donation room</td>
<td>21.00</td>
</tr>
<tr>
<td>3 Donor recovery/rest &amp; refreshment room</td>
<td>10.50</td>
</tr>
<tr>
<td>4 Med exam or counseling room</td>
<td>10.50</td>
</tr>
<tr>
<td>5 Blood Bank Laboratory</td>
<td>14.00</td>
</tr>
<tr>
<td>6 Blood Storage Room</td>
<td>14.00</td>
</tr>
<tr>
<td>7 Blood Screening Laboratory</td>
<td>10.50</td>
</tr>
<tr>
<td>8 Washing/cleaning/autoclaving room</td>
<td>07.00</td>
</tr>
<tr>
<td>9 MO’s room</td>
<td>10.50</td>
</tr>
<tr>
<td>10 Records and Stores</td>
<td>07.00</td>
</tr>
<tr>
<td>11 Centrifugation, thawing and Blood Component Storage room</td>
<td>24.50</td>
</tr>
<tr>
<td>12 Plasma/compounds separation room</td>
<td>14.00</td>
</tr>
<tr>
<td>13 Office cum documentation cum change over room</td>
<td>10.50</td>
</tr>
<tr>
<td>14 Toilet (Common for Key No 2, 3, 4 &amp; 8)</td>
<td>2 x 03.50</td>
</tr>
</tbody>
</table>

Records

- Blood donor register
- Blood stock register
- Issue register
- Register for Diagnostic reagents
- Register for blood bags
- Cross match report
- Transfusion Adverse Reaction Records
- Records of purchase, use and stock in hand of disposable needles, syringes, infusion sets
Blood Transfusion Officer
- MBBS with one year experience in blood bank
- Or, MD in Pathology. No experience required

Blood Bank Technician
- DMLT with one year experience in blood grouping and serology work

Laboratory Assistant
- DMLT

Nurse
- RN, Experience not necessary

All blood banks are required to maintain good manufacturing practices
An SOP to be maintained. It should incorporate the following:
- For Selection/rejection of donor
- For Preparation for phlebotomy site
- For Blood collection procedure
- For investigating adverse reaction
- For storing blood and blood products
- For operation of equipment

For different tests to be done
- For issue of blood
- For handling of blood by the recipient
- For destruction of blood
- Regarding assessment of the technical staff

For blood donation camp
- For transporting blood
- For handling complaints/suggestion
- For quality assessment, improvement
- For handling labels, including safeguards to avoid labeling mix-up

Elisa Reader, Washer and Micropipettes
Refrigerator of 4-6 Degree Celcius (For tested blood)
Refrigerator of 4-6 degree Celcius (For untested blood)
Domestic refrigerator for reagents and empty bags
Autoclave/ Incinerator
Blood mixer
Sealer
Other lab equipment

Maximum Surgical Blood Ordering Schedule

- A Maximum Surgical Blood Ordering Schedule is a mechanism to maximise usage of blood and minimise wastage in elective surgery.
- A Maximum Surgical Blood Ordering Schedule can reduce the workload of unnecessary crossmatching and issuing of blood and optimise stock management.
- The MSBOS only applies to elective surgery and requires samples being in the Transfusion Laboratory at least twenty four hours prior to surgery.
This is a comprehensive activity implementing the principles of good manufacturing practices. Areas needing attention:

- GMP
- Clerical Procedures
- Specification for reagents, Techniques, equipment

Quality Assurance

- Quality control of technical performance
- Collection, Storage, Transportation of samples and blood
- Reporting system for errors and adverse reactions
- Education, Research and development
- Introduction of automation

Recommendations

- Central council/ Authority for transfusion medicine
- Regular courses in Transfusion Medicine (MD Transfusion Med, Bsc, Msc, PhD for Technologist)
- Regional blood transfusion centres
- Elimination of commercialization and accreditation of blood centres

- Involvement of Red cross for voluntary progm.
- Categorization and standardization for blood centre
- Disaster management
- Approval of NACO / Health Dept. for commercial Utilization
- ICMR for academic programme and research.
- Committee to evaluate implementation
Hemovigilance

- The word “hemovigilance” comes from the French hemovigilance.
- It is derived from the Greek haema meaning “blood” and Latin vigilance meaning “watchful.”
- It was coined in France in 1994 to function in the same way as the term “pharmacovigilance” does for the drugs.
- Several definitions exist for hemovigilance.

The international Hemovigilance Network (IHN) has formulated the following definition:

- A set of surveillance procedures covering the whole transfusion chain (from the collection of blood and its components to the follow-up of recipients), intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence.

Indian Pharmacopoeia Commission in collaboration with National Institute of Biologicals, Noida, Uttar Pradesh has launched a HvPI.

- The programme was launched on 10th December 2012 across the country.
- The programme is under Ministry of Health and Family Welfare, Government of India.
- Budgetary provision Rs 29.36 crore during 12th Five Year Plan (2012-2017) has been made.
- It is divided into three phases:
  - Initiation phase for financial year 2012-13,
  - expansion and consolidation phase for financial year 2013-15 and
  - expansion and maintenance phase for financial year 2015-17

Objectives

- Monitor Transfusion Reactions (Recipient Haemovigilance)
- Create awareness amongst healthcare professionals
- Generate evidence-based recommendations
- Advise CDSCO for safety related regulatory decisions
- Communicate findings to all key stakeholders
- Create National and International Linkages
Supreme court gave judgment in 1996
- After this, blood transfusion services got attention of the Govt.
- Professional donors almost eliminated
- Five mandatory tests were prescribed
- Transmissible diseases like HIV, Hepatitis B and Hepatitis C through blood transfusion sought to be controlled

Bibliography
5. NACO, MOHFW, G of I. National Blood Policy
6. NACO. Standards for Blood Bank and Blood Transfusion Services

Thank you