WORKING OF BLOOD BANKS

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“First Transfusion” Myth

In 1492, Pope Innocent VIII is said to have received a transfusion of the blood of three ten year old boys, each of whom was paid and all of whom died. Probably the blood was drawn, but was intended to be taken orally. Indeed, there is no reliable evidence that the sickly pope accepted the blood at all.

This story has been told and retold

Andreas Libavius, 1615

He was the first person to advocate transfusion, though he is not known to have actually attempted to perform a transfusion.

“Let there be a young man, robust, and also an old man, thin, his strength exhausted, hardly able to retain his soul. Let the performer of the operation have two silver tubes fitting into each other. Let him open the artery of the young man, and put it into one of the tubes, fastening it in.
Let him immediately after open the artery of the old man, and put the female tube into it, and then the two tubes being joined together, the hot and spirituous blood of the young man will pour into the old one as it were from a fountain of life, and all of his weakness will be dispelled.”

Circulation

Understanding the concept of circulation was critical to developing the reality of blood transfusion.

Ancient Greeks believed that blood was formed in the heart, then consumed as it flowed out to the body in veins, while air was passed from the lungs to the body in arteries.

Erasistratos (~270 BC) envisioned the heart as a pump.

Galen (131-201 AD) proved that arteries contain blood, but thought that blood was formed in the liver, not suspecting that arteries and veins are attached.

Circulation

Andrea Cesalpino (1519-1603) used the term ‘circulation’ and believed that the veins and arteries were connected by a fine vascular network.

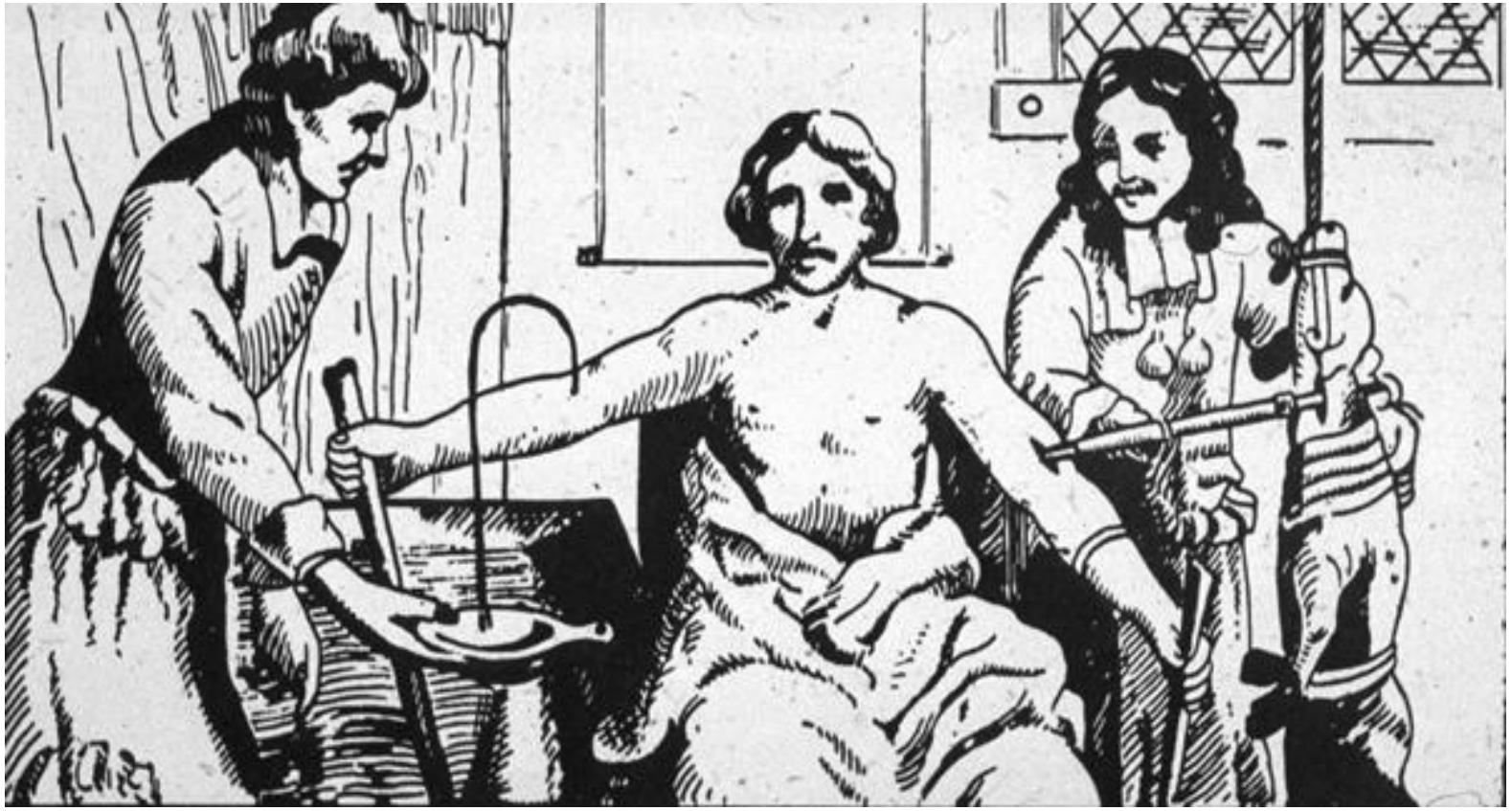
William Harvey is generally credited with the discovery in 1616 (published in 1628) of the circulation of blood as we know it today.

Jean Baptiste Denis

Denis and Emmerez performed transfusion of lamb blood into the carotid artery of a young woman in 1667.

Denis reported that the woman passed urine as black as soot following the transfusion, a finding indicative of a hemolytic transfusion reaction, but she survived.

Animal to Human Transfusion



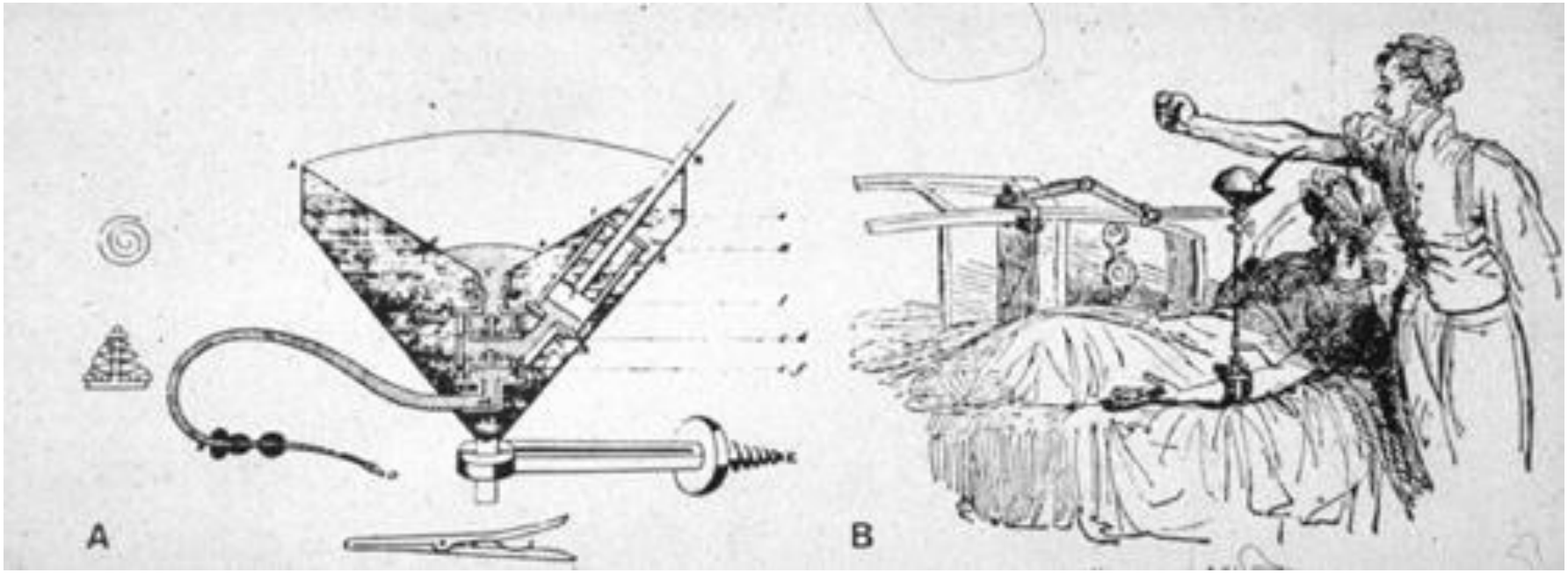
Early lamb blood transfusion

James Blundell

In 1818, James Blundell attempted human-to human transfusion of a man suffering from gastric carcinoma.

“What is to be done in such an emergency? A dog might come when you whistled, but the animal is small; a calf might have appeared better suited for the purpose, but then it has not been taught to walk properly up the stairs.”

James Blundell

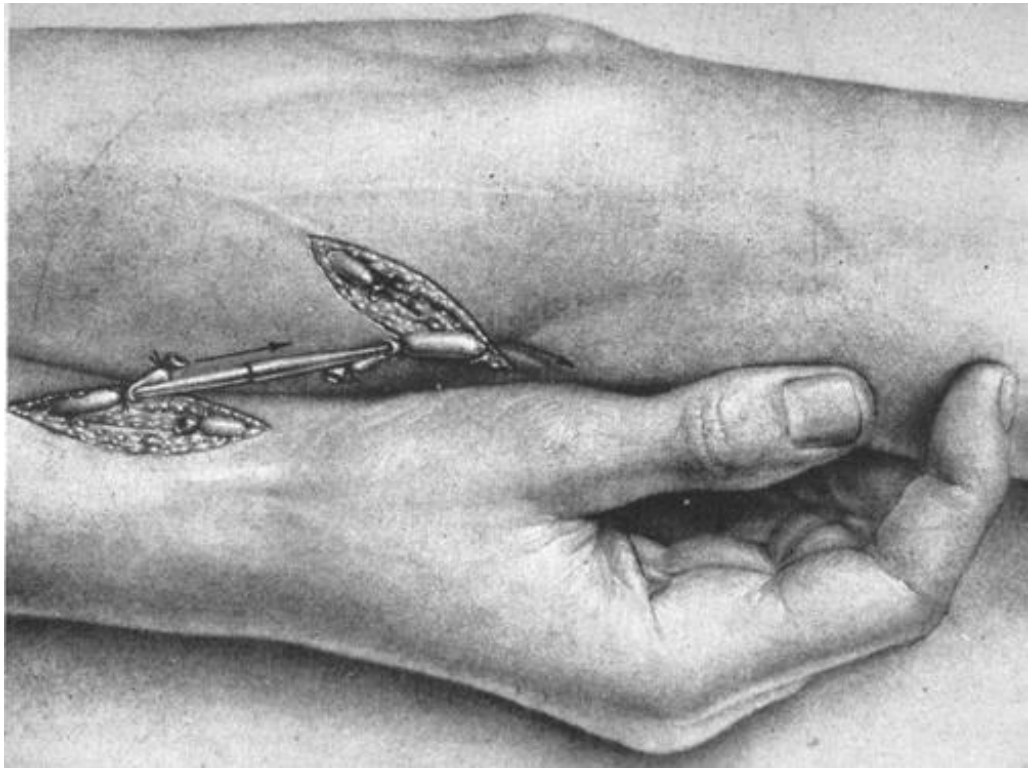


Blundell's transfusion devices included the impellor (A), which consisted of a cup, tube , and syringe; and the gravitator (B), consisting of a receptacle held high above the patient with an attached tube through which the blood was injected into the patient.

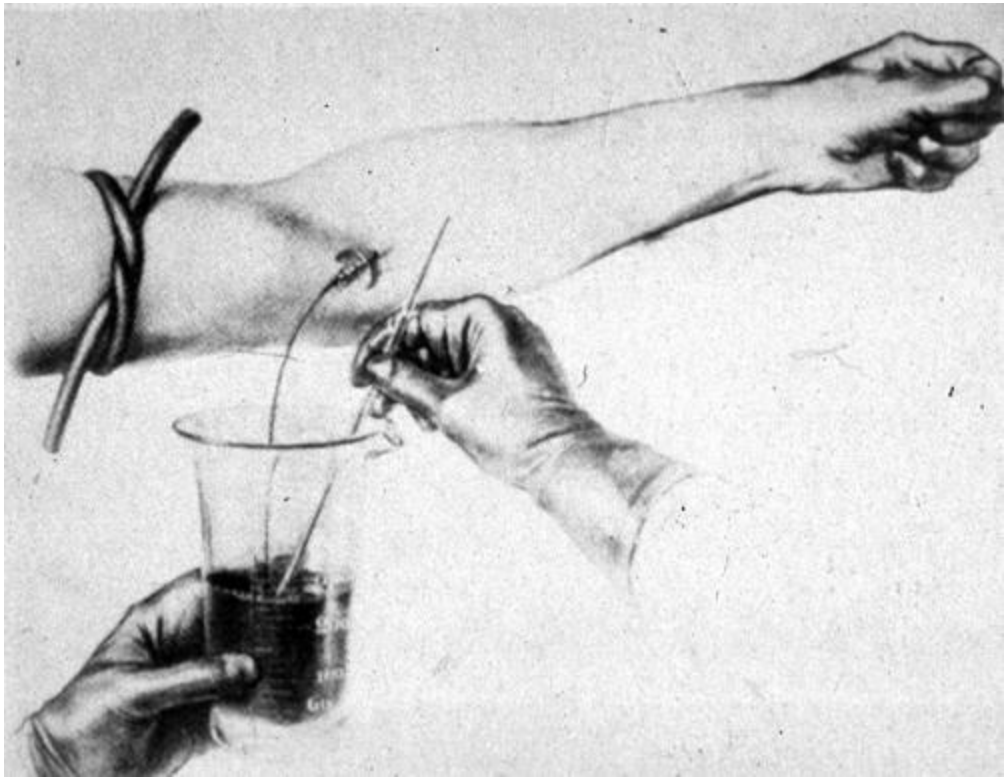
Anti-coagulation

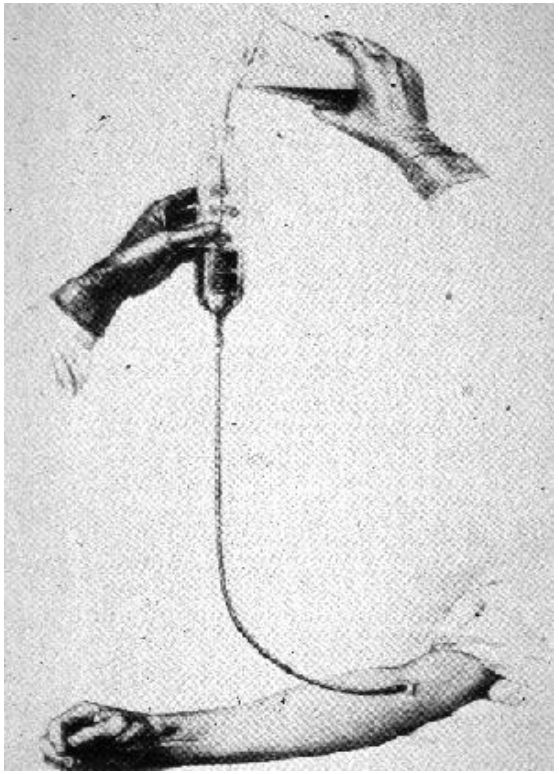
Blundell had observed the need for rapid transfusion in order to prevent coagulation.

Direct transfusion (artery to vein for speed) was advocated.

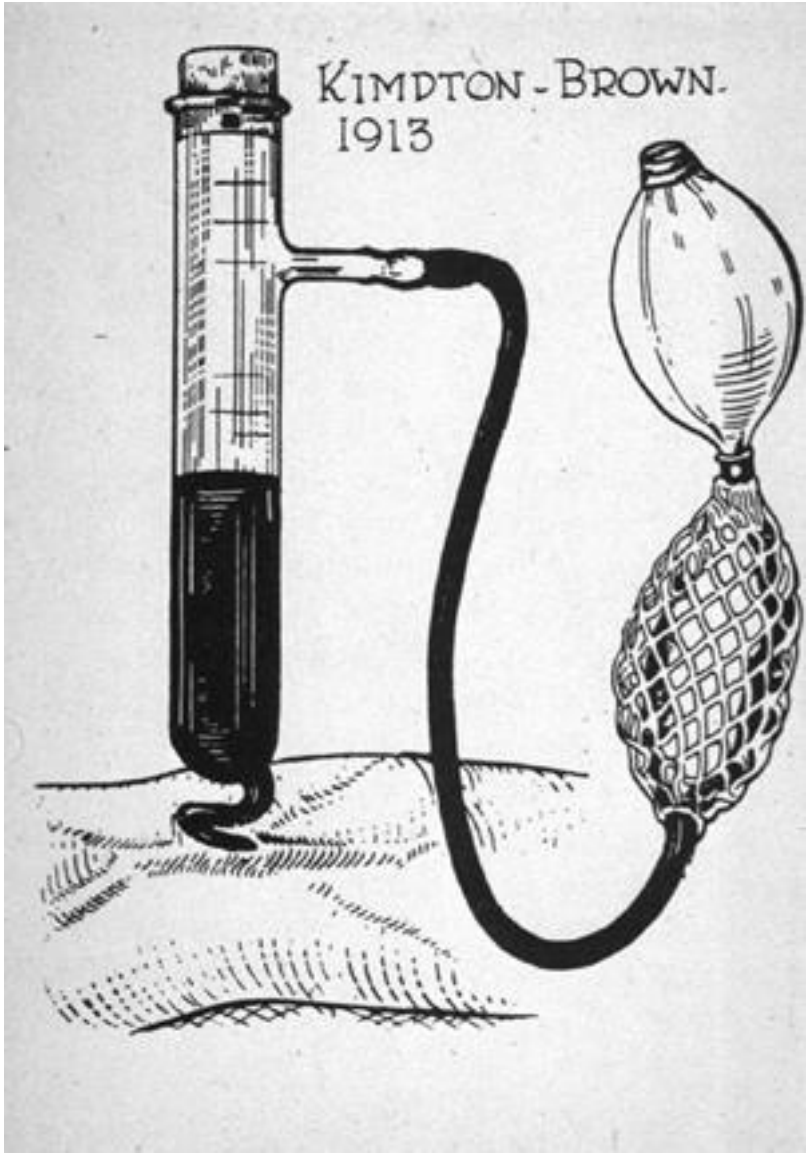


Lewisohn's Method of Transfusion





Blood is collected in a citrated flask…….and immediately transfused.



The Kimpton-Brown transfusion apparatus was commonly used before citration. It consisted of a paraffin-coated gradient glass cylinder with a horizontal side tube for suction. It was in use until approximately 1918.

The Nineteenth Century

Transfusions in the 1800s were plagued by the complications of transfusion reactions.

Panum and Landois showed that same species transfusions were more efficacious than interspecies transfusions.

Landois noted that in interspecies transfusion red blood cells were hemolyzed and white blood cells would cease their amoeboid motion and die.

However, animal to human transfusions were performed as late as 1890.

- Many patients have died and it was not until 1901, when the Karl Landsteiner discovered human blood groups, that blood transfusions became safer.

Karl Landsteiner

1930 Nobel Prize Laureate

In 1900, Landsteiner showed that serum from some individuals could agglutinate or hemolyze the red blood cells of certain, but not all, other individuals. The serum of the latter would likewise agglutinate the red blood cells of the former. Still other individuals' red cells were unaffected by the serum from either of these. He named these three different types A, B, and C. Today these are types A, B, and O.

Blood Typing

Sturli and DeCastello described the fourth blood group, AB, in 1902.

Levine and Stetson, in 1939, describe a severe reaction in a Type O woman given a transfusion of her husband's Type O blood following a stillbirth. Her serum agglutinated 80% of Type O blood.

Landsteiner and Wiener, in 1940, describe Rh typing. This leads to dramatic decrease in the incidence of hemolytic disease of the newborn.

Over 400 different antigens categorized into 23 major discrete systems are now known.

Quote

- “Talent will take you to the high position, But good character helps you to maintain high position” Be always genuine and win the hearts.

Major Innovations in the 20th Century

Compatibility testing
Anticoagulant solutions
Preservative solutions
Refrigeration
Blood Banks
Venous access
Plastic blood bags
Component administration
Infectious disease testing
High-risk donor screening

Blood Groups, Blood Typing and Blood Transfusions

- Mixing blood from two individuals can lead to blood clumping or agglutination.
- The clumped red cells can crack and cause toxic reactions.
- This can have fatal consequences.
- Karl Landsteiner discovered that blood clumping was an immunological reaction which occurs when the receiver of a blood transfusion has antibodies against the donor blood cells.

- Karl Landsteiner's work made it possible to determine blood groups and thus paved the way for blood transfusions to be carried out safely.
- For this discovery he was awarded the Nobel Prize in Physiology or Medicine in 1930.

What is blood made up of?

- An adult human has about 4–6 liters of blood circulating in the body. Among other things, blood transports oxygen to various parts of the body.
- Blood consists of several types of cells floating around in a fluid called plasma.

- **The red blood cells** contain hemoglobin, a protein that binds oxygen. Red blood cells transport oxygen to, and remove carbon dioxide from, the body tissues.

  The white blood cells fight infection.

  The platelets help the blood to clot, if you get a wound for example.

  The plasma contains salts and various kinds of proteins.

What are the different blood groups?

- The differences in human blood are due to the presence or absence of certain protein molecules called antigens and antibodies.
- The antigens are located on the surface of the red blood cells and the antibodies are in the blood plasma.
- Individuals have different types and combinations of these molecules.
- The blood group you belong to depends on what you have inherited from your parents.

- There are more than 26 genetically determined blood group systems known today, but the AB0 and Rh systems are the most important ones used for blood transfusions.
- Not all blood groups are compatible with each other.
- Mixing incompatible blood groups leads to blood clumping or agglutination, which is dangerous for individuals.

AB0 blood grouping system

- According to the AB0 blood group system there are 4 different kinds of blood groups: A, B, AB or 0

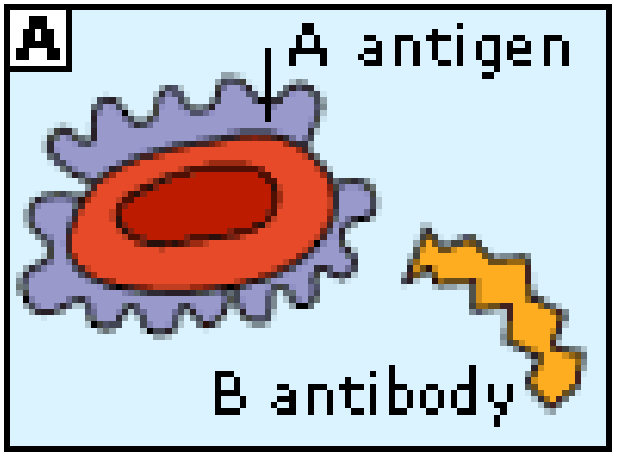
Bombay Phenotype (Oh)

- Lack of A, B and H antigens
- Reciprocal antibodies Anti A, Anti B and Anti H

- Both Rh (D) +ve and -ve

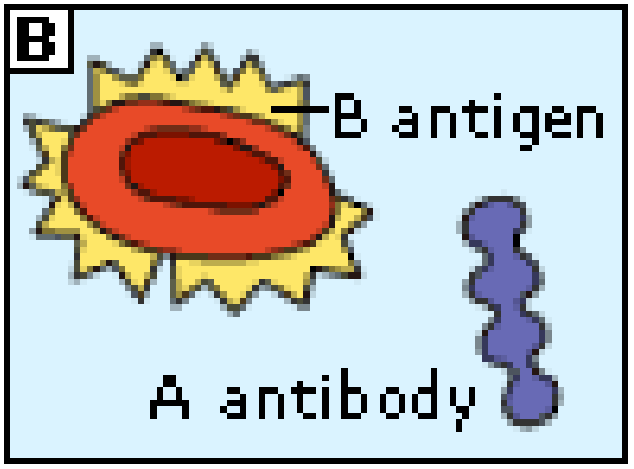
Blood group A

- If you belong to the blood group A, you have A antigens on the surface of your red blood cells and B antibodies in your blood plasma.



Blood group B

- If you belong to the blood group B, you have B antigens on the surface of your red blood cells and A antibodies in your blood plasma.



Quote

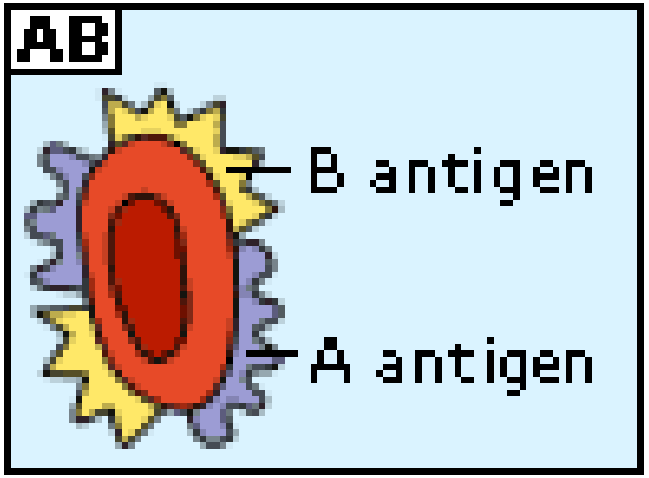
- Truth is always like oil in water. No matter how much water you add, oil always floats on Top.

Quote

- “You cannot change your future but you can change your habits and sure your habits will change your future”

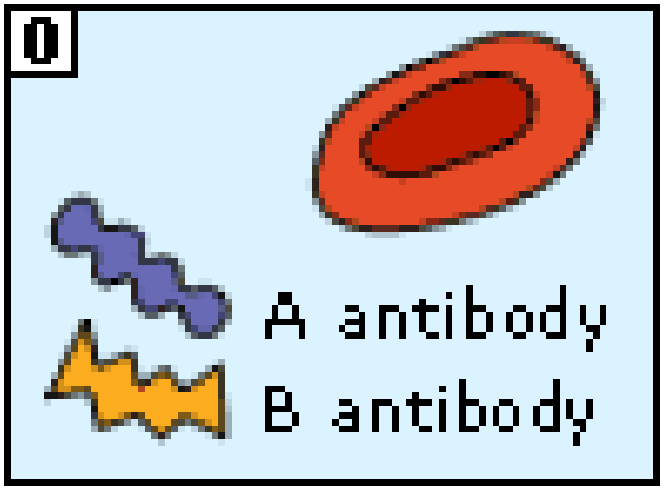
Blood group AB

- If you belong to the blood group AB, you have both A and B antigens on the surface of your red blood cells and no A or B antibodies at all in your blood plasma.



Blood group 0

- If you belong to the blood group 0 (null), you have neither A or B antigens on the surface of your red blood cells but you have both A and B antibodies in your blood plasma.

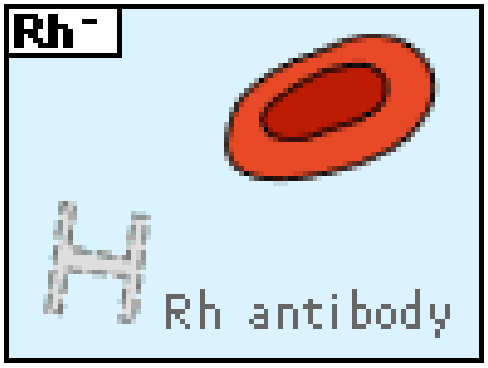


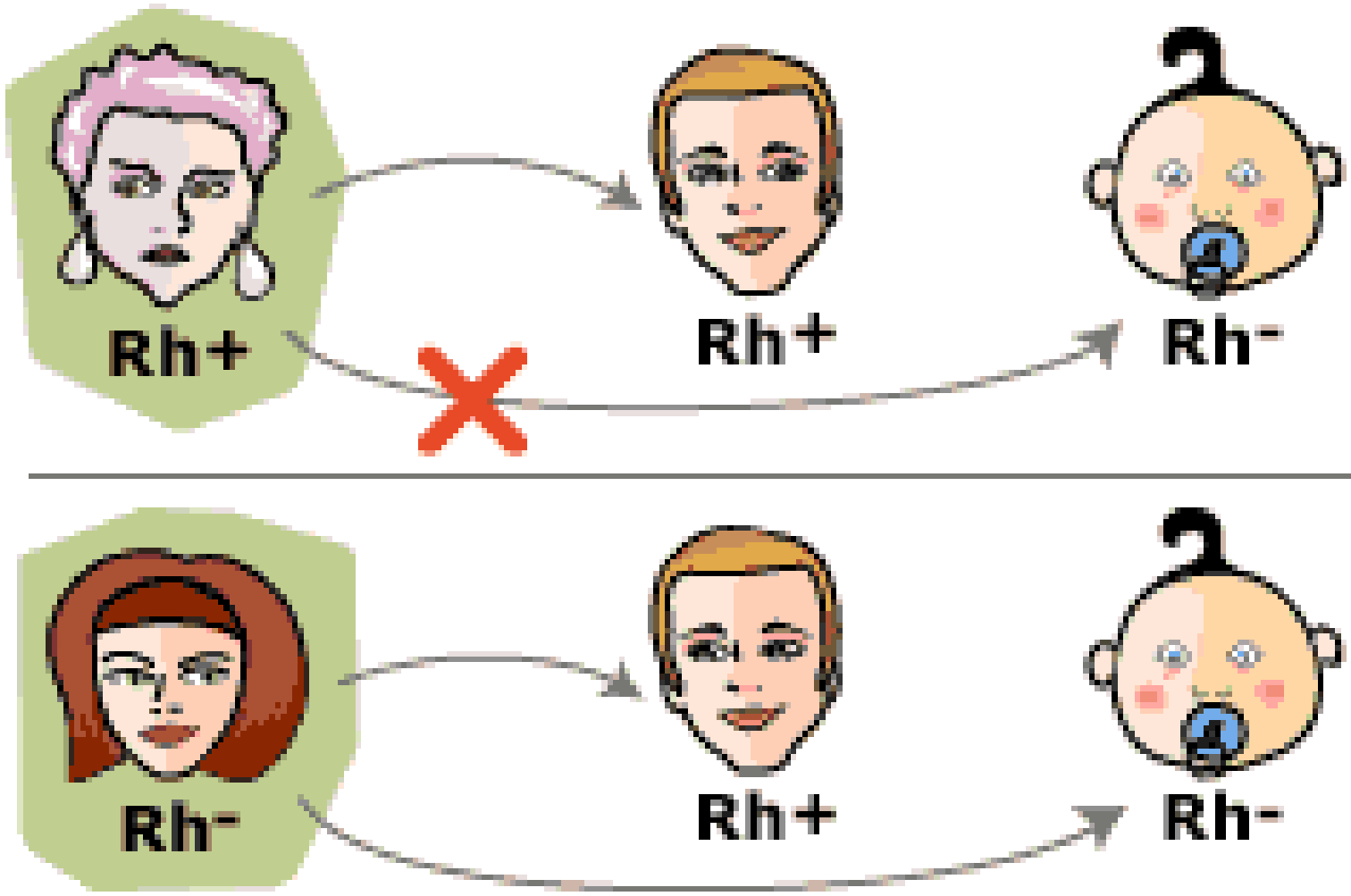
Rh factor blood grouping system

- Many people also have a so called Rh factor on the red blood cell's surface.
- This is also an antigen and those who have it are called Rh+.
- Those who haven't are called Rh-.
- A person with Rh- blood does not have Rh antibodies naturally in the blood plasma (as one can have A or B antibodies, for instance).

Cont.

- But a person with Rh- blood can *develop* Rh antibodies in the blood plasma if he or she receives blood from a person with Rh+ blood, whose Rh antigens can trigger the production of Rh antibodies.
- A person with Rh+ blood can receive blood from a person with Rh- blood without any problems.




Rh+
Rh+
Rh-
Rh-
Rh+
Rh-

Blood group notation

- According to above blood grouping systems, you can belong to either of following 8 blood groups:
- Rh+B (B+) Rh-B (B-)
- Rh+AB (AB+) Rh-AB (AB-)
- Rh+0 (O+) Rh-0 (O-)
- Rh+A (A+) Rh-A (A-)

Blood typing – how do you find out to which blood group someone belongs?

- **1.**
  You mix the blood with three different reagents including either of the three different antibodies, A, B or Rh(D) antibodies.

- **2.**
  Then you take a look at what has happened. In which mixtures has agglutination occurred? The agglutination indicates that the blood has reacted with a certain antibody and therefore is not compatible with blood containing that kind of antibody. If the blood does not agglutinate, it indicates that the blood does not have the antigens binding the special antibody in the reagent.

- **3.**
  If you know which antigens are in the person's blood, it's easy to figure out which blood group he or she belongs to!

What happens when blood clumps or agglutinates?

- For a blood transfusion to be successful, AB0 and Rh blood groups must be compatible between the donor blood and the patient blood.
- If they are not, the red blood cells from the donated blood will clump or agglutinate.
- The agglutinated red cells can clog blood vessels and stop the circulation of the blood to various parts of the body.
- The agglutinated red blood cells also crack and its contents leak out in the body.
- The red blood cells contain hemoglobin which becomes toxic when outside the cell.
- This can have fatal consequences for the patient.

- The A antigen and the A antibodies can bind to each other in the same way that the B antigens can bind to the B antibodies.
- This is what would happen if, for instance, a B blood person receives blood from an A blood person.
- The red blood cells will be linked together, like bunches of grapes, by the antibodies.
- As mentioned earlier, this clumping could lead to death.

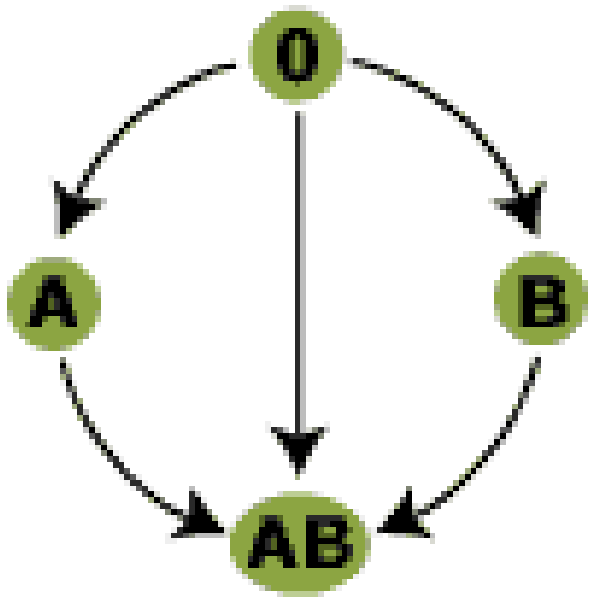
Blood transfusions – who can receive blood from whom?

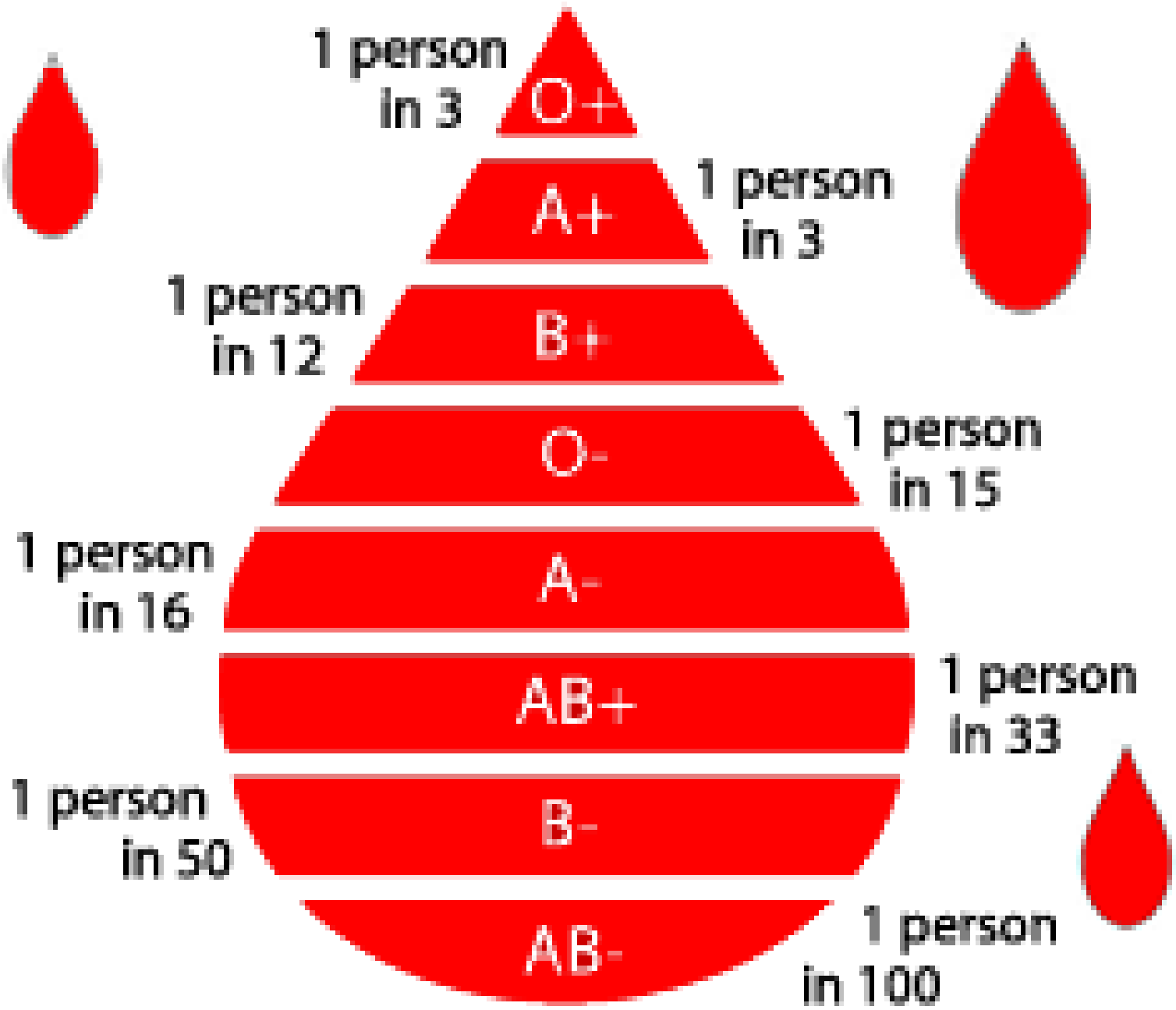
- Of course you can always give A blood to persons with blood group A,
- B blood to a person with blood group B and so on.
- But in some cases you can receive blood with another type of blood group, or donate blood to a person with another kind of blood group.

Cont.

- The transfusion will work if a person who is going to receive blood has a blood group that doesn't have any *antibodies against the donor blood's antigens.*
- But if a person who is going to receive blood has antibodies matching the donor blood's antigens, the red blood cells in the *donated blood* will clump.

Cont.




1 person in 3
O+
A+
1 person in 3
1 person in 12
B+
O-
1 person in 15
1 person in 16
A-
AB+
1 person in 33
1 person in 50
B-
AB-
1 person in 100

Quote

- No matter how good our intentions are, the WORLD judges our presentations. No matter our presentation is GOD judges our intentions

If You Have	*You Can Receive*			
O+	O+	O–		
O–	O–			
A+	A+	A–	O+	O–
A–	A–	O–		
B+	B+	B–	O+	O–
B–	B–	O–		
AB+	AB+	AB–	O+	O–
	A+	A–	B+	B–
AB–	AB–	O–	A–	B–

Possible Blood Groups for Children

	OO	AA/AO	BB/BO	AB
OO	O	A or O	B or O	A or B or AB
AA/AO	A or O	A or O	A or B or O or AB	A or B or AB
BB/BO	B or O	Guess-?	B or O	A or B or AB
AB	A or B or AB	A or B or AB	A or B or AB	Guess - ?

Random Donor Platelets and Cryo

- NO BLOOD GROUP AND Rh IS REQUIRED FOR THIS PRODUCTS

FFP/Plasma (Rh is NOT REQUIRED)

o	o	A	B	AB
A	A	AB		
B	B	AB		
AB	AB			

- Almost all healthy individuals above 3-6 months of age have “Naturally occurring Ab’s” to the ABO Ags that they lack
- This Ab’s termed naturally occurring because they arise without antigen stimulation

SDP

- Rh is not required but it should be group specific
- If same group is not available then we can issue with volume reduction (150 ml or less)

Rh Blood Group System

Rh Blood Group System

History of the Rh System

Levine and Stetson described a hemolytic transfusion reaction in an obstetric patient following delivery of stillborn infant. The women required transfusion. Her husband, who had the same ABO type, was selected as her donor, after transfusion the recipient, demonstrated the classic symptoms of acute hemo]ytic transfusion reaction.

Rh Blood Group System

- Subsequently an antibody was isolated from the mother's serum that react both at 37° C and 20 °C with the father's red cells. It was postulated that the fetus and the father possessed a common factor that the mother lacked.

- While the mother carry the fetus, the mother was exposed to this factor and subsequently built up an antibody that reacted against the transfused red cells from the father and resulted in hemolytic transfusion reaction.

Rh Blood Group System

- Landsteiner and Wiener reported on an antibody by guinea pigs and rabbits when they were transfused with rhesus monkey red cells.

- This antibody which agglutinated 85% of human red cells was named Rh.

- The name Rh was retained for the human produced antibody.

Rh Antigens

- Rh antigens are highly immunogenic, the D antigen is most potent
- D ➢ c ➢ E ➢ C ➢ e

  Highly ⟶ Rarely

  Immunogenic

❖ Exposure to less than 1 ml of Rh positive red cells can stimulate Ab production in an Rh negative person.

Determination of D Status

- Is essential when test donor blood sample.
- Blood considered Rh positive if either the D or D^u test is positive
- If any donor blood sample that types Rh_o(D) negative by either slide or rapid method must be tested further by indirect anti-globulin test (IDAT).
- If both test results are negative, the donor sample is considered Rh negative.

Blood Screening

- TTI – Transfusion Transmitted Infection
- TTD – Transfusion Transmitted Disease
- Blood Screening

Quote

- A strong and positive attitude creates more miracles than any other thing because life is 10% how you make it and 90 % how you take it.

Blood Screening

- HIV
- HBsAg
- HCV
- VDRL
- MP
- HBc (Total) – Optional
- Anti HBs – Optional
- LFT – Optional

Types of Screening equipments

1. Manual ELISA system
2. Semi Automated
3. Fully Automated

Manual & Semi Automated ELISA Systems

- Run Controls with every batch of samples
- Calculate CO value after every run
- Run Low +ve samples along with every batch
- Decontamination of equipment as per the defined protocol
- Calibration of equipment as per the manufacture Instructions
- With and without barcodes
- Always batch processing
- Data can be manipulated
- Skilled staff is required

Automated ELISA systems

- Daily known +ve and –ve controls
- No need to calculate the CO value
- Mostly barcoded samples but manual enter is also availabe
- Calibration as per manufacturer instructions
- Mostly Random Access
- Cannot manipulate the data
- Regular maintanance like (Daily, weekly, monthly and as and when required)

Component Preparation
&
Quality Control of Components

Different types of Components Prepared in Blood Bank

- RBC or Packed RBC or Packed Cells
- RBC with Additives Solutions (SAGM/Adsol)
- Saline Washed RBC
- Leucocyte Reduced RBC
- Fresh Frozen Plasma
- Frozen Plasma
- Cryoprecipitate or AHF
- Random Donor Platelets
- Single Donor Platelets
- Granulocyte Concentrate

Products prepared through Fractionation

- Factor VIII
- Factor IX
- Factor XI
- Factior XIII

Prothrombin complex concentrate
(PCC, Factors II, VII, IX, X)

- Fibrin glue
- Intramuscular IG (IMIG)
- Intravenous IG (IVIG)
- Hyperimmune IGs
- Albumin
- Naturally occurring inhibitors (e.g. antithrombin)

Blood Component Preparation

Terms used in whole blood centrifugation

"**light spin**" – short time, low RPM - 2000 X g for 3 mts

"**heavy spin**" – longer spin, high RPM - 5000 X g for 5 to 7 mts

CALCULATIONS

$$RCF = 28.38 \times R \times (RPM/1000)^2$$

$$RPM = \sqrt{[RCF/(28.38 \times R)]} \times 1000$$

RCF = RELATIVE CENTRIFUGAL FORCE (X g)
R = RADIUS IN INCHES
RPM = REVOLUTIONS PER MINUTE

			RPM REQUIRED FOR		
CENTRIFUGE	**ROTOR**	**RADIUS**	**1615 X g**	**1248 X g**	**3000 X g**
SORVALL RC-3BFOR RC-3C	HG-4L	9.09 inches	2500	2200	3410
	H4000	9.09 inches	2500	2200	3410
	H6000A	10.25 inches	2356	2070	3211

Q.A.

Quality Assurance
in a Blood Transfusion service
is intended to ensure supply of
Safe and effective
blood and blood components

Preparation of RBC & FFP

- Centrifuge Whole Blood 5000 X g for 5 to 7 mts with temp. setting of 4^0C

$$RPM = \sqrt{[RCF/(28.38 \times R)]} \times 1000$$

5000/(28.38 * 9.09) = 5000/258 = 19.37

Square of 19.37 = 4.4

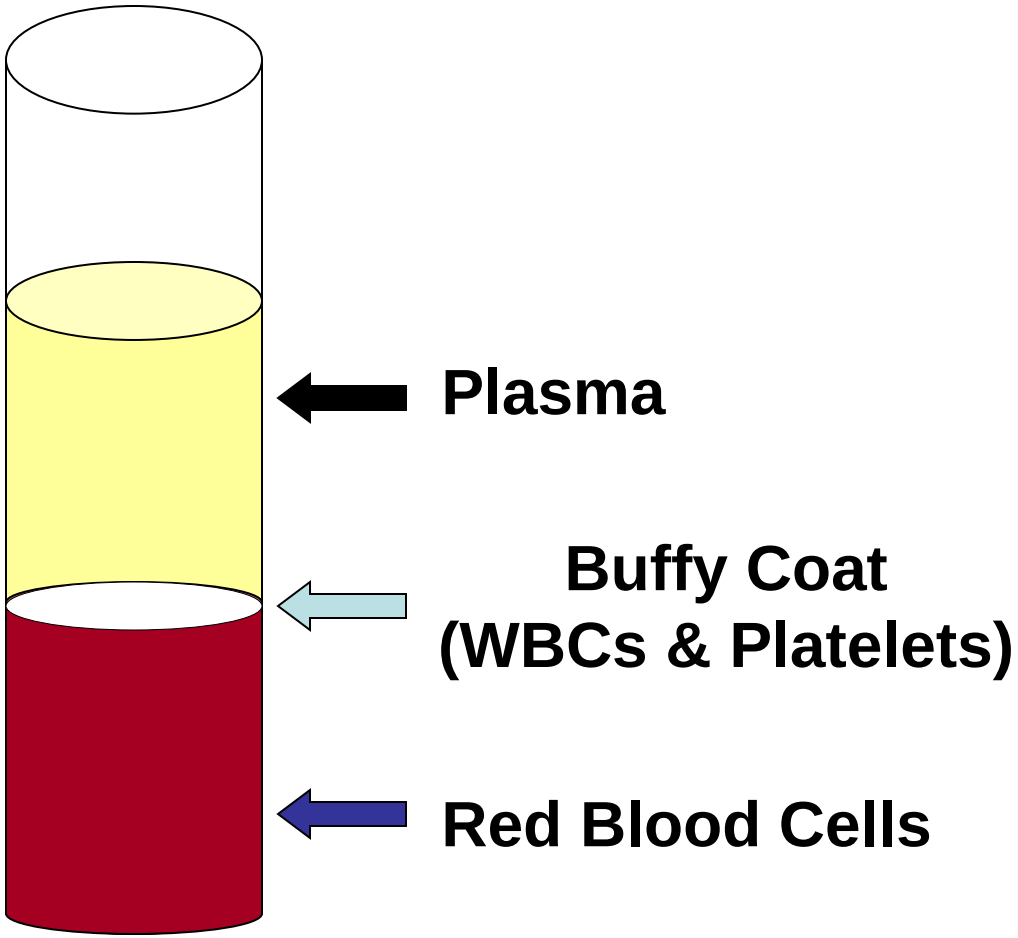
4.4 *1000 = 4400 RPM

Preparation of RBC & FFP

- After centrifugation - Place the bag on plasma expresser and transfer the plasma in to transfer bag
- After sealing disconnect the FFP bag write Blood group and expiry date then keep it at -30^0 C for 1 yr

- <u>Primary or Main Bag</u>
- If we remove plasma completely then the bag has to be issued with in 24 hrs.
- If we keep 50 ml of plasma then the bag can be stored for 35 day
- If any additive solution is added to packed cells we can store for 42 days.

Centrifuged blood



Preparation of Random Donor Platelets

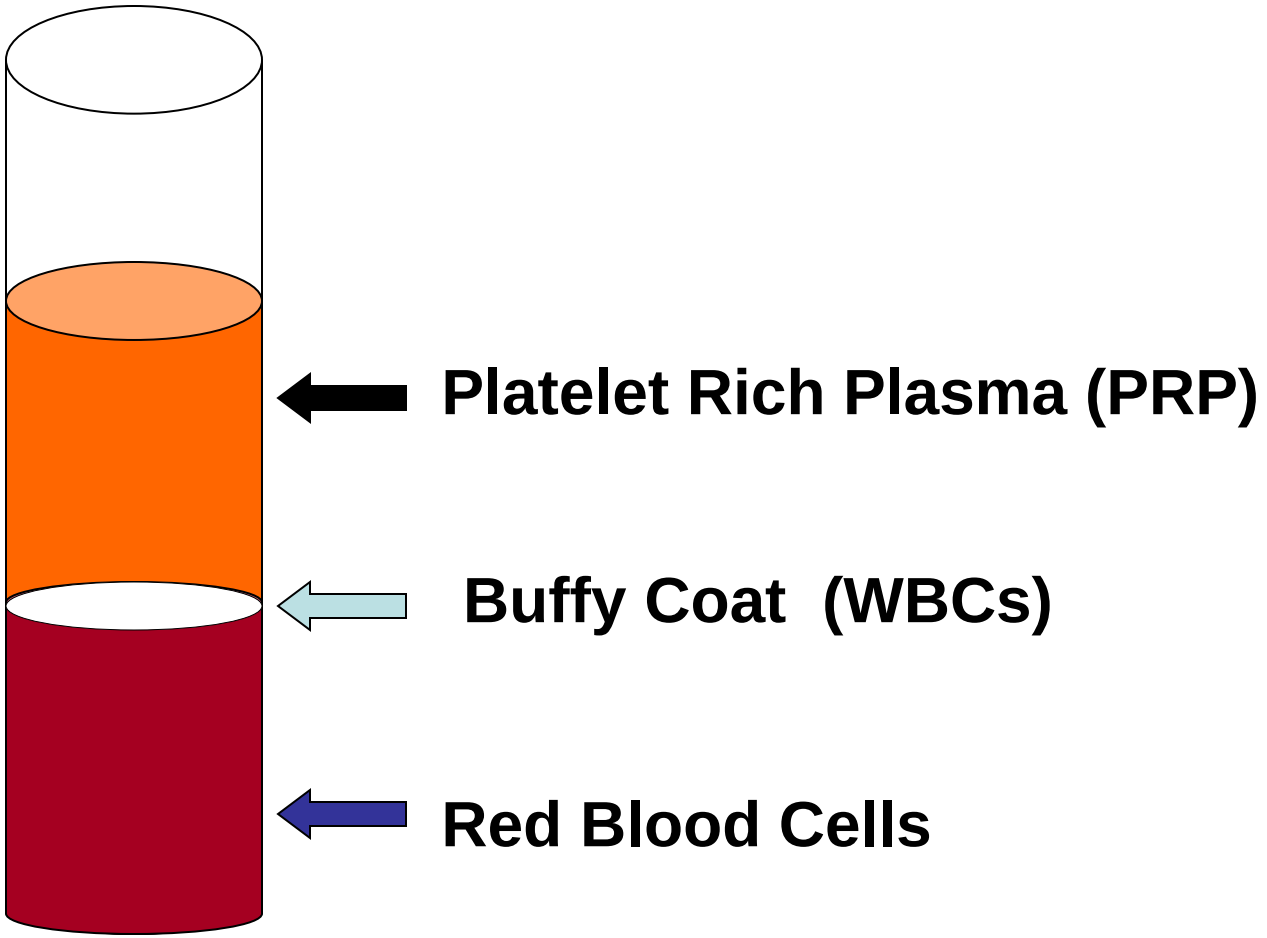
Centrifuge the Blood Bag at 2000 X g for 3mts with temperature setting at 22^0 C

2000/(28.38 * 9.09) = 2000/258 = 7.75

Square of 7.75 = 2.74

2.74 *1000 = 2740 RPM

Centrifuged blood



Preparation of RDP

- Place bag on plasma expresser and transfer the PRP in to transfer bag
- Add additive solution or keep 50 ml of plasma to main bag and store it as per the PC storage procedure
- Centrifuge the PRP bag with heavy spin and keep the temp. setting at 22^0 C

Preparation of RDP's From PRP

- Centrifuge PRP at 5000 X g for 5 to 7 mts <u>with temp. setting of 22^0C</u>

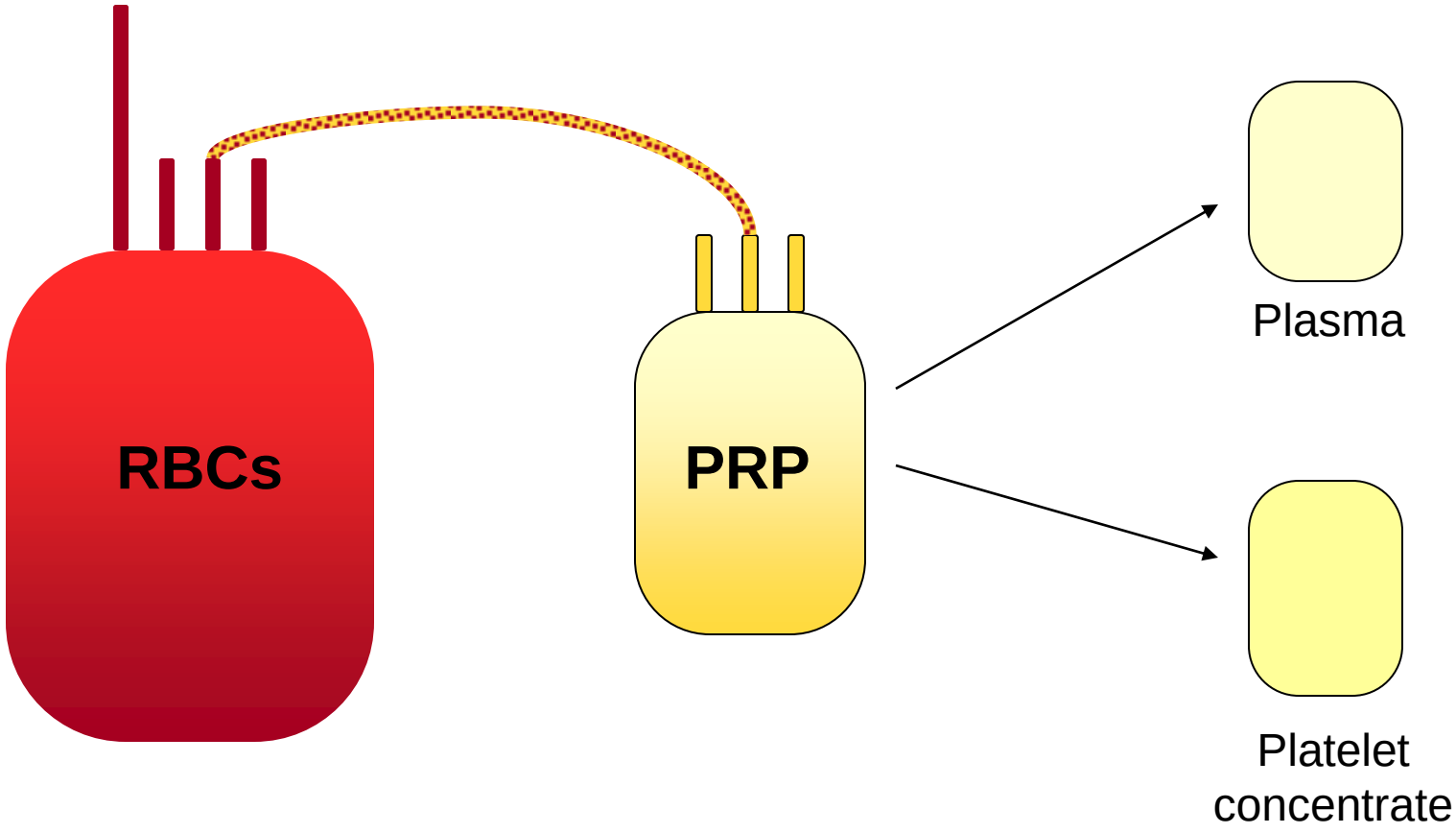
$$RPM = \sqrt{[RCF/(28.38 \times R)]} \times 1000$$

5000/(28.38 * 9.09) = 5000/258 = 19.37

Square of 19.37 = 4.4

4.4 *1000 = 4400 RPM

RDP & FFP are separated



Preparation of Washed RBC's

- Add equal quantity or more volume of Normal Saline to Packed Red Cells with sterile infusion set
- Centrifuge the bags at 3000 RPM for 8 mts with temp. setting at 4^0 C
- After Centrifuge remove the supernatant and discard
- Repeat the process for 3 times
- After final wash add 50 ml NS and issue as early as possible (or < 24 hrs)
- During entire process all sterile precaution to be taken care

Preparation of Cryoprecipitate

- Keep the FFP at 2^0 – 6^0 C for 8 to 12 hrs
- After 12 hrs centrifuge the bags at heavy spin for 7 mts
- Place the plasma bag in a plasma expresser and transfer the supernatant plasma into transfer bag
- Remaining 20 to 30 ml cryoprecipitate crystals are leftout in main bag
- Cryo poor plasma/plasma can be stored for 5 yrs from the date of collection
- Store the Cryoprecipitate immediately below

  -30^0 C for <u>up to 12 months from the date of Blood Collection.</u>

Cryoprecipitate may be prepared from FFP at any time within 12 months of collection.

Preparation of Single Donor Platelets(SDP) or Platelet Concentrate

- Cell separators are used to prepare SDP's
- Interrupted procedure and one arm procedure

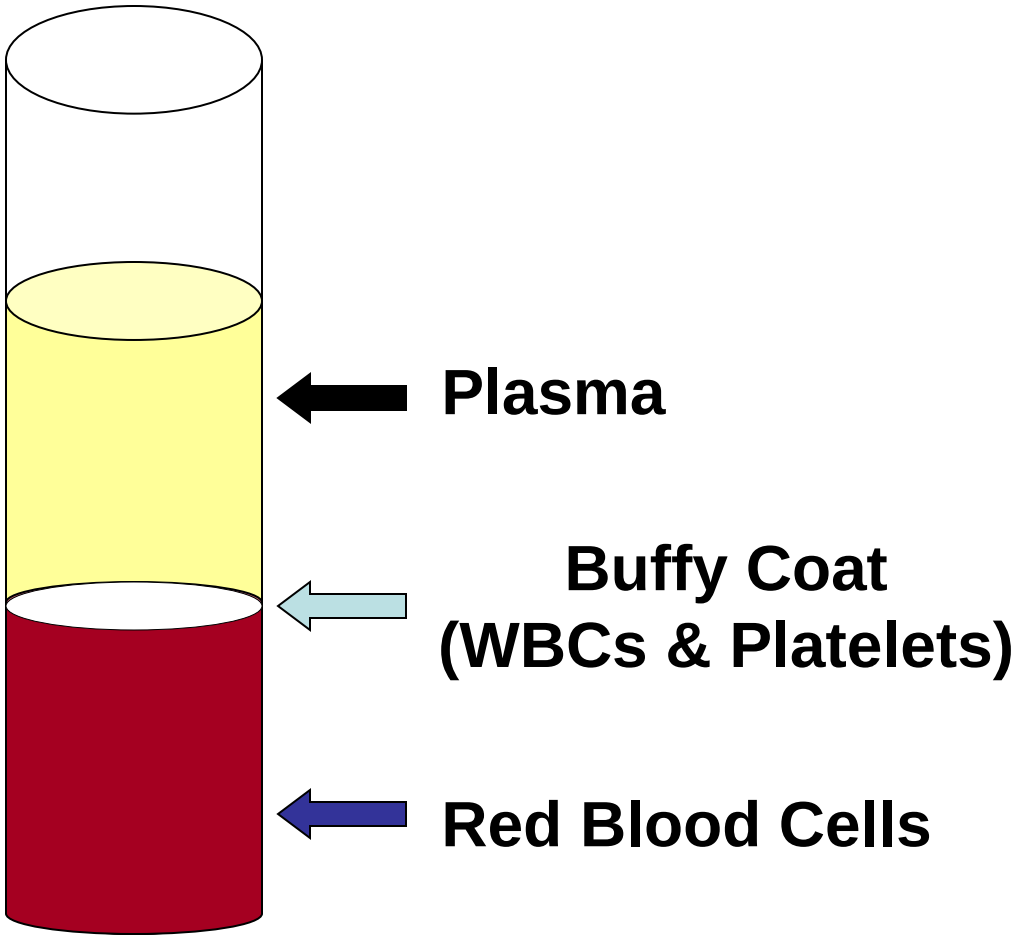
Preparation of Single Donor Platelets(SDP) or Platelet Concentrate

- Continuous process one arm or two arm procedure

Q.C.

- **Quality control is an integral part of Quality Assurance**
- **provides the means to measure and monitor the quality of all functions**
- **As per standard specified limits.**

Centrifuged blood



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- Frozen Plasma
- Cryoprecipitate or AHF
- Random Donor Platelets
- Single Donor Platelets
- Granulocyte Concentrate

(Cont.)

- **Collection, storage and transportation of blood and component units and blood samples**
- **Guidelines for administration of blood**
- **Reporting system for errors and transfusion reactions**
- **Q.C. for Automation**

Quality Control of Blood and Blood Components

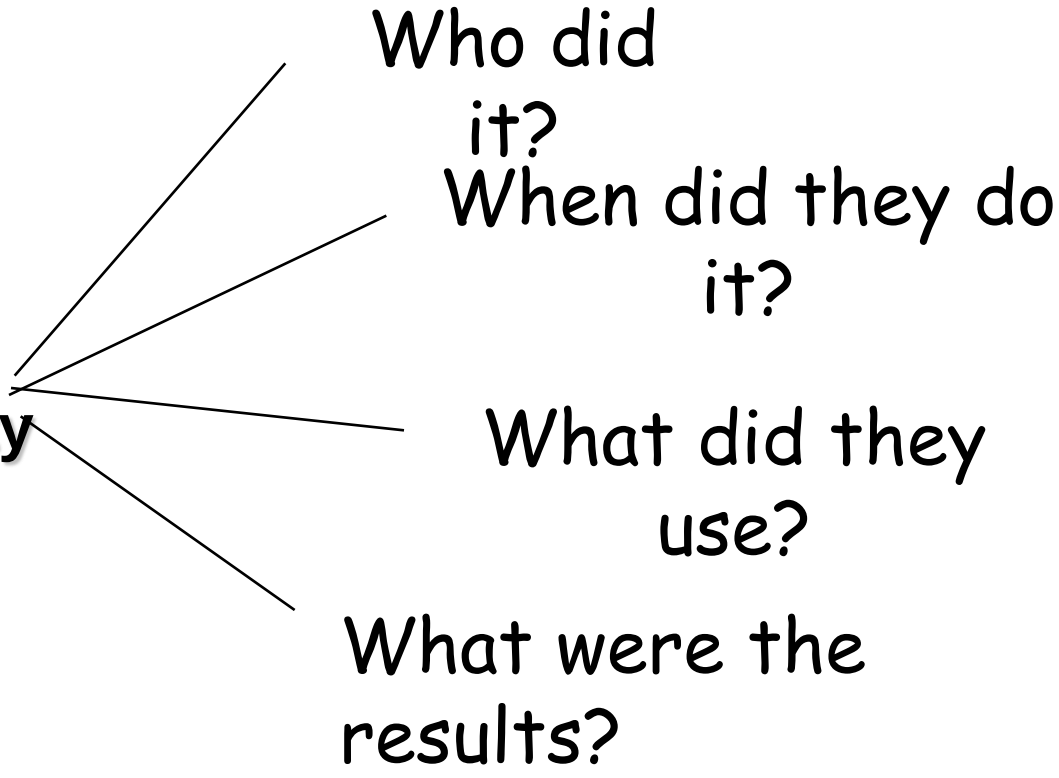
- Donor Selection – No Aspirin
- Donor phlebotomy area should be cleaned properly
- Exact volume is collected acceptable limit is ± 10 ml
- Continuous mixing of blood with anticoagulant

Quality Documentation in Laboratories

- **Why Document?**

To ensure:

- **consistency**
- **reproducibility**
- **traceability**
- **efficiency**



Staff

- **well-trained and meticulous**
- **Periodic assessment of all staff members should be carried out to judge their competence, skill & reliability.**
- **Continuing education is necessary for the staff**

Quality Control of Equipments

- **The function of all the equipments must be checked on receipt, after repairs and periodically during use.**

- **Good thermometers are necessary for checking temperature. General guidelines for quality control and maintenance of equipments.**

Q.C. of Blood Bank Equipment

- **Blood Bank Refrigerators:**

- **Required temperature 2°C - 6°C.Check the temperature for several days before putting the refrigerators in use and then check temperature daily.**
- **Check uniformity of temperature in upper and lower shelves.**
- **Put date, time and signature of technical staff, responsible for recording the temperature.**
- **Ensure continuous power supply**
- **Periodically check alarm system for temperature fluctuations,**
- **Keep the refrigerator clean.**

- **Note : If any variation in the required temperature for storage of blood / components in the Blood Bank Refrigerator or Freezer is noted , immediately shift the products to the back-up storage equipment. Intimate concern personnel to check and rectify the problem . After repairs observe if the temperature is being maintained for 48hrs before shifting the respective storage equipment.**

Water Bath

Change the water every day.

Record temperature daily.

Maintain uniform temperature using a stirrer

Keep the water clean.

Take extra care of water baths used for thawing FFP & Cryo

a) Add thymol to the water bath.

b) Put the bags in a plastic cover when thawing

c) Use sterile water.

FREEZER

Quality control same as blood bank refrigerator.

Check the temperature of the digital system by using an external thermometer kept inside the cabinet periodically.

Cold Centrifuge

- Keep a thermometer in between the bags and check the temperature after the bags are centrifuged.
- Check accuracy of timer using a stopwatch.
- Maintain regular asepsis in between the procedures.
- The Bio Medical engineer should periodically check the speed using tachometer.

Equipment Calibration Schedule

S.No	Equipment Name	Company Name	Calibration Required
1	Blood Bank Refrigerator	Forma Scientific	6 months
2	Blood Bank Refrigerator	Forma Scientific	6 months
3	Blood Storage Cabinet	Remi	6 months
4	Blood Storage Cabinet	Remi	6 months
5	(-)30 Freezer	Forma Scientific	6 months
6	(-)35 Vertical Freezer	Remi	6 months
7	(-) 35 Vertical Freezer	Remi	6 months
8	(-) 70 Freezer	Remi	6 months
9	Platelet Incubator	Remi	6 months
10	Platelet Incubator	KELVIN INSTR	6 months
11	Platelet Agitator		6 months
12	Plasma Thawing Bath	Remi	6 months
13	Cold Centrifuge	Beckmann	6 months
14	Cold Centrifuge	Kendro	6 months
15	Laminar Flow	Klenzaida	1 year
16	Haemocontrol	EKF diagnostics	6 months
17	Hb201	hemocue	6 months
18	Automated Sample/Reagent Dispenser & Processor	Ortho Diagnostics	6 months
19	Axsym MEIA	Abbott	6 months
		Ortho	

20	Chemiluminescence Automated Elisa System	Ortho Diagnostics	6 months
21	VDRL Rotator	-	6 months
22	ID centrifuge 12-SII	Diamed-ID	6 months
23	ID Incubator	Diamed-ID	6 months
24	Blood Cllection Monitor	Terumo penpol	6 months
25	Blood Cllection Monitor	Terumo penpol	6 months
26	Blood Cllection Monitor	Terumo penpol	6 months
27	Blood Cllection Monitor	Terumo penpol	6 months
28	Central Temperature Control Monitor	Udayam Shree	6 months
29	Cell Separator MCS 3P	Haemonetics	6 months
30	Cell Separator MCS PLUS	Haemonetics	6 months
31	Cell Separator AMICUS	Baxter	6 months
32	Table Top Centrifuge	Remi	6 months
33	Table Top Centrifuge	Remi	6 months
34	Table Top Centrifuge	Remi	6 months
35	Binocular Microscope	Nikon	Regular cleaning maintanance
36	Incubator	-	6 months
37	Hot Air Oven	-	6 months
38	Digital Weighing Machine	Alto	6 months
39	Digital Weighing Machine	Alto	6 months
40			6 months
41	Domestic Refrigerators		6 months
42	Micropippettes		6 months

Q.C. for Blood Collection

1% Of all collected blood undergo quality check

1. Donor Hb :EDTA samples form donors who are donating blood are sent to the Hematology lab

2. Sterlility check of donor phlebotomy site

swabs from the phlebotomy site of the donors are sent for sterility check every month to the dept of microbiology

Sterility Checking

Blood Bags from a new lot is sent for sterility checking to the microbiology department for aerobic and anaerobic cultures

Packed cells

Once a month the contents of 4 blood units (blood segments) stored approximately for 10 days are sent for aerobic and anaerobic bacteriological cultures

Random platelets :

Once a month after expiry of platelets 6 units are sent for sterility check for aerobic and anaerobic cultures to the microbiology department

Sterility check of the antecubital fossa of the donor

Swabs from the antecubital fossae of 4 blood donors are taken every 15 days after routine asepsis and sent for microbiological analysis

Q.C. 0f Components

RANDOM PLATELETS : A sample from a batch of random platelets a minimum of two once every 15 days is sent for platelet count to the Hematology Department.

There must be atleast 5.5 x 10^{10} platelets per bag tested.

The volume should be 40-60 ml.

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Platelet bags must be inspected for grossly visible platelet aggregates before issuing. Instructions should be given to use immediately.

Cont.

Single Donor Platelets

A sample from a concentrate bag is sent for platelet count and pH every 15 days. The count should be above $3.5x10^{11}$ pH must be > 6

Cryoprecipitate :

A sample from every batch of Cryos at the time of preparation is sent for Factor VIII estimation to the Hematology Department. The result should be above 90%.

Cont.

Packed Cells :

- **Samples from two bags are sent to Haematology Department for estimating haematocrit value every week.**
- **The value should be 70% and below for the blood collected in 350 ml bags without SAGM and < 55 % for 350/450 ml blood which are collected in SAGM**
- **This ensures maximal viability during storage and ensures adequate glucose for red cell metabolism and enough citrate to maintain pH levels during storage upto 35 days.**

Transportation of Blood

Transported within the hospital or from centre to centre. The blood units should be checked for:

Leakage

Change in colour of plasma or cells

Clots or abnormal mass

Fuzzy interface

- **Blood must always be transported in**

Temperature proof containers

- **Use ice packs**
- **There should be no direct contact with ice packs**
- **Temperature must be 2^0 to 6^0 C**
- **Must be transported as quickly as possible**

Transportation of components

Frozen blood components

Preferable to transport in frozen condition either with ice packs or dry ice

Pack each bag in cardboard box to prevent from getting frozen on the surface of other bags

Once thawed it should be used within 4 hours and should not be refrozen

Transportation of Platelets

Platelets are to be maintained at room temperature @ 20^0 to24^0C

Well insulated container

Coolant pouches may be used and not ice packs

Discard of Blood Bags

The reasons for Discard of Blood/Components

1. Sero positive
2. Broken Bags
3. Returned Bags from wards
4. Expired bags

Disposal of waste

All Blood Bags should be Autoclaved and send it for incinerator

Types of Blood Donors

- Voluntary Donors
- Replacement Donors
- Directed Donations
- Paid Donors (banned)
- Autologous (Patient - Donor)

Types of Blood Banks

- Voluntary Blood Banks – Run by the Charitable organizations
- Hospital Attached Blood Banks
  - Private and Govt.
- Private Blood Bank – for Commercial purpose.

What is New in Blood Banks

- Leucocyte removal filter for RBC/WB
- Leucocyte removal filter for Platelets
- Leucocyte depleted Blood Products
- Irradiation of Blood and Blood Products
- NAT
- Viral Inactivation
- Integral filter
- Multiple component preparation

Role of Drug Inspector in Blood Bank

Role of Drug Inspectors in Blood Bank

- Drug Inspector plays very important role in inspecting the premises and checking whether all requirements are followed as per the Drug Act.

Role of Drug Inspectors in Blood Bank

- SBTC approval
- Licence and its validity
- Space as per the approved plan
- No. Rooms as approved in Licence
- Equipments
- Manpower
- Reagents & kits
- Calibration status of all the equipments

- Backup generator and/or UPS supply for all the critical equipments
- SOP
- All records
- Contents of all the records as per the Drug Act.
- QC results
- Test results

REQUIREMENTS FOR THE FUNCTIONING AND OPERATION OF A BLOOD BANK

- 1. Space
- 2. Manpower
- 3. Equipments
- 4. Records

Space

- 100 sq mts for only Whole Blood
- 50 sq. mts for Components
- 10 sq. mts for Apheresis

Mandatory rooms for WB

- Registration and Medical Examination
- Phlebotomy (Blood Collection) - AC
- Refreshments and Recovery - AC
- Lab 1 – Red cell serology (Grouping and compatibility testing) - AC
- Lab 2 (Screening/ TTI lab) AC
- Records and Stores
- Washing and Autoclave room

Components - AC

- Additional 50 sq.mts
- Component Preparation
- Component storage

Apheresis - AC

- 10 sq mts for Apheresis

Manpower

- Medical Officer, -
  - MD pathology/Transfusion Medicine
  - MBBS DCP/DTM with adequate knowledge in blood bank
  - MBBS with 1 year Blood Bank Experience

- Technical supervisor (where blood components are manufactured), possessing-

- (i) Degree in Medical Laboratory Technology (M.L.T) with six month's experience in the preparation of blood components; or

  (ii) Diploma in Medical Laboratory Technology (M.L.T) with one year's experience in the preparation of blood components the degree or diploma being from a University / Institution recognized by the Central Government or State Government.

Manpower

- Blood Bank Technician(s) possessing –

  (i) Degree in Medical Laboratory Technology (M.L.T) with six months experience in the testing of blood and/or its components; or

(ii) Diploma in Medical Laboratory Technology (M.L.T) with one year's experience in the testing of blood and / or its components. the degree or diploma being from a University / Institution recognized by the Central Government or State Government.

Registered Nurse(s);

Equipments

- Temperature monitoring of all the equipments with graphs or with CMS
- Calibration of equipments with know standards approved by ETDC (Electronic Test & Development center).
- Regular maintenance like daily, weekly, monthly and as when required
- Scheduled Preventative maintenance

EQUIPMENT

(i) Air Conditioner;
(ii) Laminar air flow bench;
(iii) Suitable refrigerated centrifuge;
(iv) Plasma expresser;
(v) Clipper and clips and or dielectric sealer;
(vi) Weighing device;
(vii) Dry rubber balancing material;
(viii) Artery forceps, scissors;
(ix) Refrigerator maintaining a temperature between 2 degree centigrade to 6 degree centigrade, a digital dial thermometer with recording thermograph and alarm device, with provision for continuous power supply;
(x) Platelet agitator with incubator (wherever necessary)
(xi) Deep freezers maintaining a temperature between minus 30 degree centigrade to minus 40 degree centigrade and minus 75 degree centigrade to minus 80 degree centigrade;
(xii) Refrigerated Water bath for Plasma Thawing
(xiii) Insulated blood bag containers with provisions for storing at appropriate temperature for transport purposes;

Equipment

- Automated Equipments company will give the calibration certificates
- Some equipments have self calibration
- We cannot bypass the maintenance of equipment in automated equipment and there will be a reminders.

Blood Donor Card

Blood Donor Card with consent

Records

- (1) *Blood donor record*
- Master records for blood and its components:
- (3) Issue register:
- (4) Records of components supplied:
- (5) Records of A.C.D./C.P.D/CPD-A/SAGM bags giving details of manufacturer, batch

  number, date of supply and results of testing

CRITERIA FOR BLOOD DONATION:

General – No person shall donate blood and no blood bank shall draw blood from a

person, more than once in three months. The donor shall be in good health, mentally alert and

physically fit and shall not be inmates of jail, persons having multiple sex partners and drug addicts.

The donors shall fulfill the following requirements, namely

(a) the donor shall be in the age group of 18 to 60 years.
(b) the donor shall not be less than 45 kilograms;
(c) temperature and pulse of the donor shall be normal;
(d) the systolic and diastolic blood pressure and are within normal limits without medication;
(e) haemoglobin which shall not less than 12.5 grams;
(f) the donor shall be free from acute respiratory diseases;
(g) the donor shall be free from any skin diseases at the site of phlebotomy;
(h) the donor shall be free from any disease transmissible by blood transfusion, insofar as can be determined by history and examination.
(i) the arms and forearms of the donor shall be free from skin punctures or scars indicative of professional blood donors or addiction of self injected narcotics.

(a) Abortions 6 months
(b) History of Blood transfusion 6 months
(c) Surgery 12 months
(d) Typhoid 12 months after recovery
(e) History of Malaria and duly treated 3 months (endemic)
3 years (non endemic area)
(f) Tattoo 6 months
(h) Breast feeding 12 months after delivery
(i) Immunization (Cholera,Typhoid, Diphtheria, Tetanus,
Plague, Gammaglobulin) - 15 days
(j) Rabies vaccination 1 year after vaccination
(k) History of Hepatitis in family or close contact. 12 months
(l) Immunoglobulin 12 months

- a. Cancer
- b. Heart disease
- c. Abnormal bleeding tendencies
- d. Unexplained weight loss
- e. Diabetes -controlled on insulin
- (f) Hepatitis infection]
- (g) Chronic nephritis
- (h) Signs and symptoms, suggestive of AIDS
- (i) Liver diseases
- (j) Tuberculosis
- (k) Polycythemia Vera.
- (l) Asthma
- (m) Epilepsy
- (n)Leprosy
- (p)Endocrine disorders

Donor Record

- *Blood donor record* : It shall indicate serial number, date of bleeding, name, address and signature of donor with other particulars of age, weight, hemoglobin, blood grouping, blood pressure, medical examination, bag number and patient's detail for whom donated in case of replacement donation, category of donation (voluntary / replacement) and deferral records and signature of Medical Officer In charge.

Master Records for Blood and its components

bag serial number, date
of collection, date of expiry, quantity in ml. ABO/Rh Group, results for testing of
HIV I and HIV II antibodies, Malaria, V.D.R.L. Hepatitis B surface antigen and
Hepatitis C Virus antibody and irregular antibodies, name and address of
the donor with particulars, utilization issue number, components prepared or
discarded and signature of the Medical Officer in charge.

(3) Issue register: Serial number, date and time of issue, bag serial
number, ABO/Rh Group, total quantity in ml, name and address of the recipient,
group of recipient, unit/institution, details of cross-matching report, indication for
transfusion.

(5) Records of A.C.D./C.P.D/CPD-A/SAGM bags giving details of manufacturer, batch number, date of supply and results of testing .

(6) Register for diagnostic kits and reagents used: name of the kits/reagents, details of batch number, date of expiry and date of use.

(7) Blood bank must issue the cross matching report of the blood to the patient together with the blood unit.

(8) Transfusion adverse reaction records.
(9) Records of purchase, use and stock in hand of disposable needles, syringes, blood bags, shall be maintained.

NOTE : The above records shall be kept by the licensee for a period of five years.

LABLES

(1) The proper name of the product in a prominent place and in bold letters on the bag.

(2) Name and address of the blood bank

(3) Licence number

(4) Serial number

(5) The date on which the blood is drawn and the date of expiry as prescribed under

(6) A colored label shall be put on every bag containing blood. The following color

scheme for the said labels shall be used for different groups of blood:

Blood Group Color of the label

O Blue

A Yellow

B Pink

AB White

(7) The results of the tests for HIV, HBsAg, HCV, VDRL and MP
(8) The Rh. Group
(9) Total volume of blood, the preparation of blood, nature and percentage of anticoagulant.

10. The label shall indicate the appropriate donor classification like “Voluntary Donor”
or “Replacement Donor” in no less prominence than the proper name.

BLOOD DONATION CAMPS.

A blood donation camp may be organized by

(a) a licensed designated Regional Blood Transfusion Centre ; or

(b) a licensed Government blood bank; or

(c) the Indian Red Cross society; or

(d) a licensed blood bank run by registered voluntary or charitable organizations

Additions

- 1. Space
- 2. Social worker
- 3. Blood Bank Technicians
- 4. B. Sc – Transfusion Medicine
- 5. PG Diploma – Transfusion Medicine
- 6. Central Blood Banking system
- 7. Storage centers
- 8. Central Screening system

Additions

- Interfacing of equipments
- Software
- Encouragement of Voluntary Donors

Thank You

Questions ?????

Questions are guaranteed in Life
but Ans’r Doesn't