Assuring Quality

in

Blood and Blood Products

Dr. Gajendra Gupta
Head of Department
Department of Pathology and Transfusion Medicine
Santokba Durlabhji Memorial Hospital,
Cum Medical Research Institute,
Bhawani Singh Marg, Jaipur

Quality Assurance

This describes all the steps taken both in and outside the Blood Bank to achieve safest possible blood for the recipient.

Steps of Transfusion

- Decision to transfuse the patient with blood/component
- Sending the requisition form and blood sample of patient to the blood bank
- Processing the request by the blood bank according to the requisition and in accordance with its own SOP's and standard policies of the hospital transfusion committee
- Preparing Blood / Blood component testing and storing

Cont….

- Collection of the product from the blood bank maintaining the cold chain and delivery to the clinical area
- Storage in the ward/theatre and in blood bank till transfusion is given.
- Pre-transfusion checks
- Actual transfusion and monitoring of transfusion
- Recording the transfusion

Objectives of Quality Assurance in Blood Bank

- Is to ensure availability of a sufficient supply of blood, blood components of high quality with maximum efficacy and minimum risk to both donors and patients.
- To ensure maximum safety of blood
- To determine problems in the whole transfusion chain and solve it to achieve the goal .

Risk to the Patient from Blood Transfusion

Even with highest level of standards, working sophistication, best of equipments and trained personnel there are inherent risks in blood transfusion. Some are preventable and on some there is no control

How can Low / Minimize risk be achieved ??

Implementing Quality Control

QC is a technique used to detect and correct errors before they result in defective product or service.

Type of Quality Control

- Internal Quality Control
- External Quality Control

Internal Quality Control

- The internal quality control can be maintained by going through a complete checklist of items or test **Daily** to make sure that all systems are being monitored and in control.
- Immediate decisions can be taken to accept or reject results / products on daily basis.

External Quality Control

- External quality control is a way to compare the performance of a laboratory of Blood Bank with reference to other Blood Bank.
- External Quality Assurance also know as ‘proficiency testing’ or External Quality control

Accuracy

- The closeness of measurement to the true value is indicative of the ‘accuracy’ of the assay
- External Quality Assessment is used mainly to monitor accuracy the test in ordered to provide accurate results.

Precision

- The degree of fluctuation in the measurements is indicative of the “precision” of the assay.

- Internal Quality Control is used to monitor the precision of the assay in order to provide reproducibility of results.

Quality Control in Blood Bank Laboratories

- Serology Laboratory
- Transfusion transmitted disease
- Component preparation Lab

Indian Scenario

Drug & Cosmetic Act - 1945

with its Amendments

Quality Control In Serology Lab (Reagents)

The primary objective of a reagent quality control is to ensure that reagent is functioning as expected.

Frequency of Quality Control of Reagent

Reagents	Frequency of testing along with Controls
Anti human serum	Each day of use
Blood grouping serum	Each day of use
Antibody screening and reverse grouping cells	Each day of use
Enzymes	Each run
Normal saline (LISS and BPS)	Each day of use
Bovine albumin	Each day of use

Quality Control of ABO Reagent (Anti-A, Anti-B, and Anti-AB)

Parameters	Quality Requirement	Frequency of Control
Appearance	No turbidity, precipitate, particles or gel formation by visual inspection	Each day
Specificity	Positive reaction with red cells having corresponding antigen(s); and no reaction with negative control	Daily and of each new lot/batch
Avidity	Macroscopic agglutination with 50% red cells suspension in homologous serum/normal saline using the slide test; 10 seconds for anti-A, anti-B and anti-AB with A_1 and/or B cells at R.T; 20 seconds with A_2 and A_2B cells.	Daily and of each new lot/batch
Reactivity	No immune haemolysis, rouleaux formation or Prozone	Each new lot/batch.
Potency	Undiluted serum should give +++reactions in saline tube test using a 3% red cells suspensions at R.T., titre should be 256 for anti-A, anti-B, and anti-AB with A_1 and/or B cells, 64 with A_2 and A_2B cells.	Each new lot/batch.

Quality Control for Reagents

Requirements

- All reagents should be clearly labeled with batch number, expiry date and storage temp;
- Instructions for use should be in-form of SOP's with training.
- All reagents and kit should be used according to the manufacturer's instructions.
- FIFO shall be maintained

Quality Control for Reagents

- Use of positive & negative controls should be done with each batch to show that reagents are potent and specific.
- All reagents must be carefully stored at recommended temp.
- Reagents to be kept at 4-6^{o}C should never be frozen and are stored according to manufacturer's instructions only
- Supply, storage and transportation of kits and reagents should be strictly standardized & manufacturer's instructions should be followed with ensured continuous power supply and periodic temperature monitoring.

Transfusion Transmitted Disease Done in Blood Bank

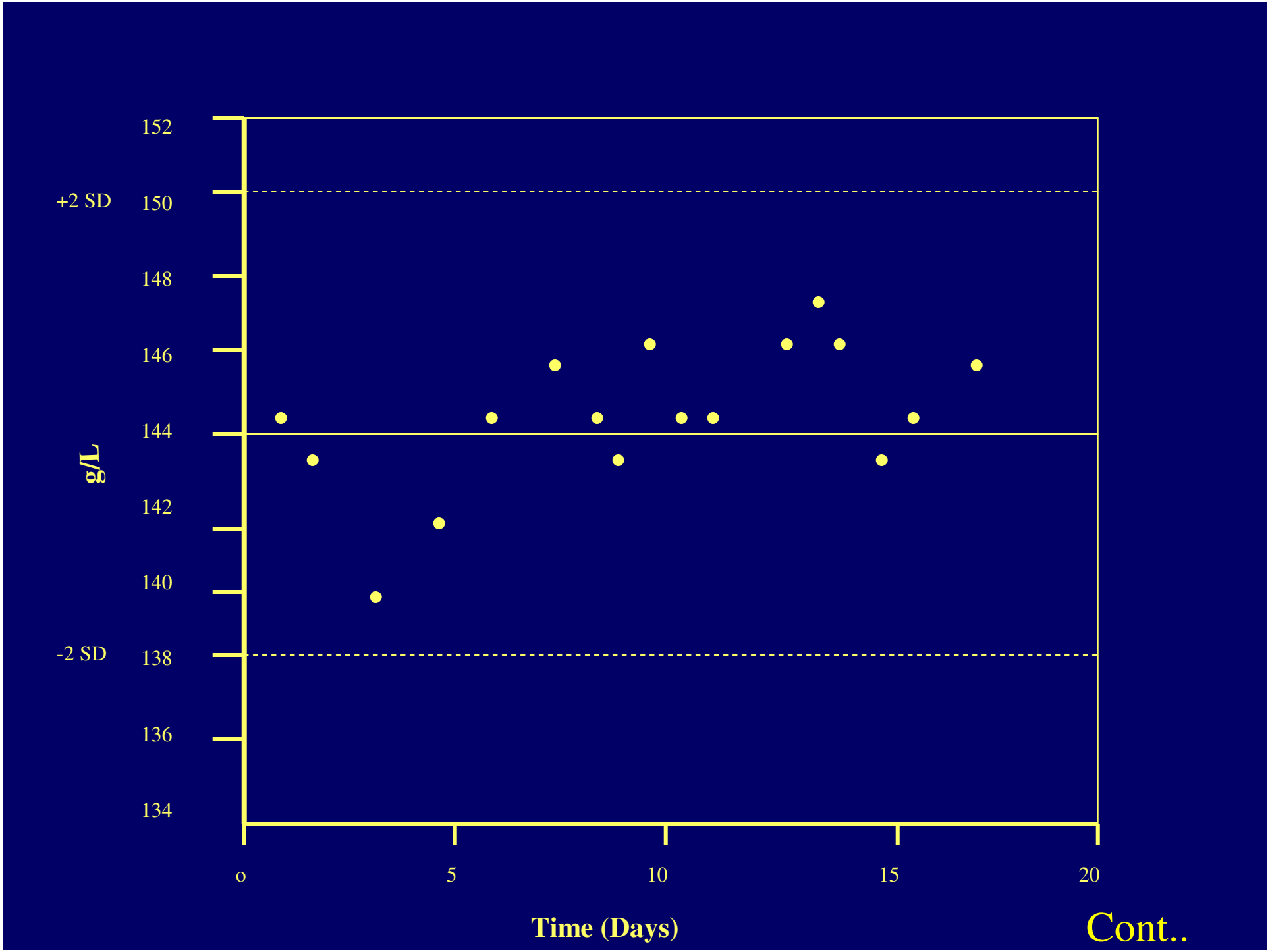
- HBs Ag
- HIV 1 & 2
- HCV
- Syphilis
- Malaria Parasite

Frequency of Transfusion Transmitted disease

Reagents	Frequency of testing along with controls
Hepatitis B Antigen	Each run
HIV 1 & 2 Antibody	Each run
Hepatitis C Virus	Each run
Syphilis serology reagents	Each run
Malaria Test	Each run

Comparison Between Each Run
(Internal Quality Control of ELISA)

- Collect optical density (OD) values for Controls for each assay run.
- Collect cutoff (CO) value for each run.
- Calculate ratio of OD to CO (OD/CO) for each
- Use these ratio values to calculate the Mean, SD and CV%


152
+2 SD
150
148
146
144
g/L
142
140
-2 SD
138
136
134
o
5
10
15
20
Time (Days)

Cont..

Rules to Follow for Accepting/Rejecting Quality Control Values

When 2 level QC Material are used

- Any QC value is outside 3 SD (1_3S)
- Both QC value are outside 2 SD on the same side but within 3 SD (2_3S)
- Difference between both QC values is >4 SD (R_4S)
- Ten consecutive values of same level are on one side of mean (10X)
- Five consecutive values of one level and five consecutive value of other level QC are on same side of mean but within 2 SD(10X)

Quality Control in Blood/ Blood Products

Frequency of Testing

1% of component shall be tested for Quality Control out of which 75% shall match the acceptable ranges.

QC of blood/blood component preparation

1. Whole blood:

- Frequency of control: 1% of all units with minimum of 4 units per month
- Storage :- 2ºC to 6 ºC, for CPDA-1 the storage time is 35 days, CPD & CD2D – 22days.

Parameter	Quantity Requirement	Frequency of Control
Volume	350/450 ml ± 10%	1% of all units
Anticoagulants	49/63 ml	All units
PCV (Hct)	30 to 40%	4 units per month
HBsAg	Negative by ELISA	All units
Anti-HCV	Negative by ELISA	All units
Anti-HIV ½	Negative by ELISA	All units
Syphilis	Negative by Screening test	All units
Sterility	By culture	Periodically (1% of all units)

2. Red cell concentrates

- Perform the same assay as for Whole blood
- Storage : 2º-6º C, for 35 days if prepared from WB collected in CPDA-1

The Quality Control of red cell concentrate (Prepared from 450 ml Blood)

Parameter	Quantity Requirement	Frequency of Control
Volume	280 ± 40 ml	1% of all units
PCV (Hct)	70%± 5%	Periodically (1% of all units)

The Quality Control of red cell in preservative sol. (ADSOL/SAGM)

Parameter	Quantity Requirement	Frequency of Control
Volume	350 ± 20 ml	1% of all units
PCV (Hct)	55-65%	Periodically (1% of all units)

3. Platelet concentrates

- Prepared within 6 hours of blood collection
- Must evaluate at least 1% of platelets monthly for platelet count, pH and plasma volume
- Platelets should be selected from each centrifuge in use
- Storage : 20°-24°C

Parameter Quality	Requirements	Frequency of control
Volume	50-70 ml	All units
Platelets count	$\geq 5.5 \times 10^{10}$	4 units per month/ 1% of all units (whichever is more)
pH	>6.0	4 units per month/ 1% of all units (whichever is more)
RBC contamination	0.5 ml	4 units per month/ 1% of all units (whichever is more)
WBC contamination	$5.5 \times 10^7 - 5 \times 10^8$	4 units per month/ 1% of all units (whichever is more)

4. Quality of Platelet concentrate by Apheresis

Parameter	Quality requirement
Volume	>200 ml
Platelets count	$\geq$ 3.0 – 7.0 x 10^{11}
pH	> 6.0 (at the end of permissible storage period)
Residual leucocytes	< 5.0 x 10^{6}
Red cells	Traces to 0.5 ml

5. Fresh Frozen Plasma

- frozen within 6 hours of blood collection using –80°C deep freezers or blast freezers
- Stored at –30°C
- Date of expiry one year

Parameter	Quality control	Frequency of control
Volume	200–220 Plasma	4 units per month/ 1% of all units (whichever is more)
Factor VIII	0.7 units/ml	4 units per month
Fibrinogen	200–400 mg	4 units per month

6. Cryoprecipitate

Parameter	Quality control	Frequency of control
Volume	10–20 ml	1% of all units
Factor VIII	80–120 units	1% of all units
Fibrinogen	150–250 mg	1% of all units

Quality Control

Internal Quality Control:

- Monitors quality of single Blood Bank
- Necessary for daily monitoring of precision and accuracy

External Quality Control:

- Comparison of performance of many Blood Bank
- Long term accuracy & performance of the analytical method

Both are complementary activity

Objective of External Quality Assurance

- Monitor Blood Bank performance and evaluate QC measures.
- Establish inter-Blood Bank comparability.
- Ensure credibility of Blood Bank.
- Stimulate performance improvement and promote high standards of practice.
- Encourage use of standard reagents/methodology
- Identify common errors.

Parameters / Test Covered Under EQA

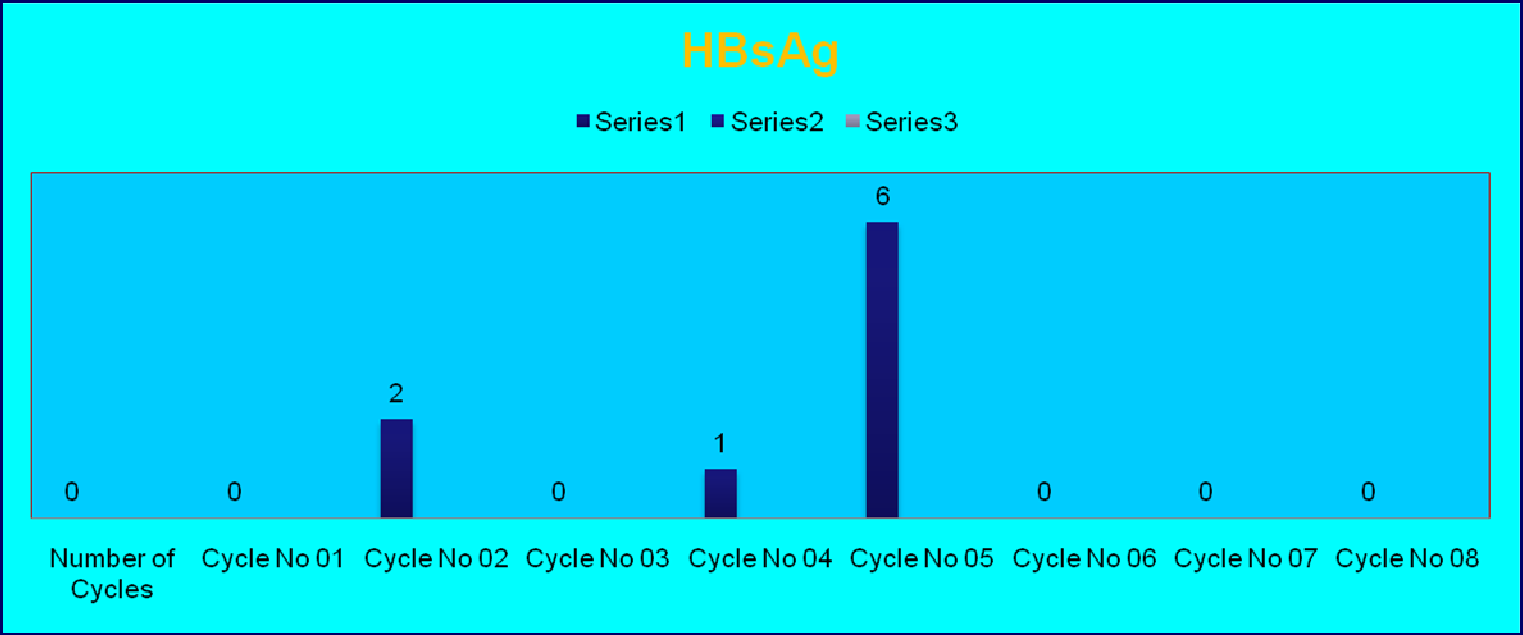
1. HBsAg
2. Anti- HIV 1&2
3. Anti- HCV
4. Syphilis (VDRL)
5. Malarial Parasite
6. NAT (HBV/ HCV/ HIV-1, HIV-2, HIV-O & HIV-M)
7. Haemoglobin
8. Blood Group
9. Cross-match
10. Antibody Screening & Identification
11. Factor VIII
12. Fibrinogen
13. Sterility Testing
14. APTT

Benefit of EQA

Benefit the participating laboratories:

- Identify and evaluate the capabilities of Blood Bank
- Guide Blood Bank in corrective action and improvement
- Provide continuing education to Blood Bank staff on standard diagnostic methods.
- Raise awareness of the successes and challenges in Blood Bank practice
- Provide information for advocacy

BEQAS Partcipating Distribution List in India



Parameter	Cycle No	% of Errors	Possible Reasons
HBsAg	02	2.8%	Possible Root causes: 1.Technical error 2.Inscriptional error 3.Kit is not validate for specificity and sensitivity
	04	1.1%	
	05	6%	

Thanks