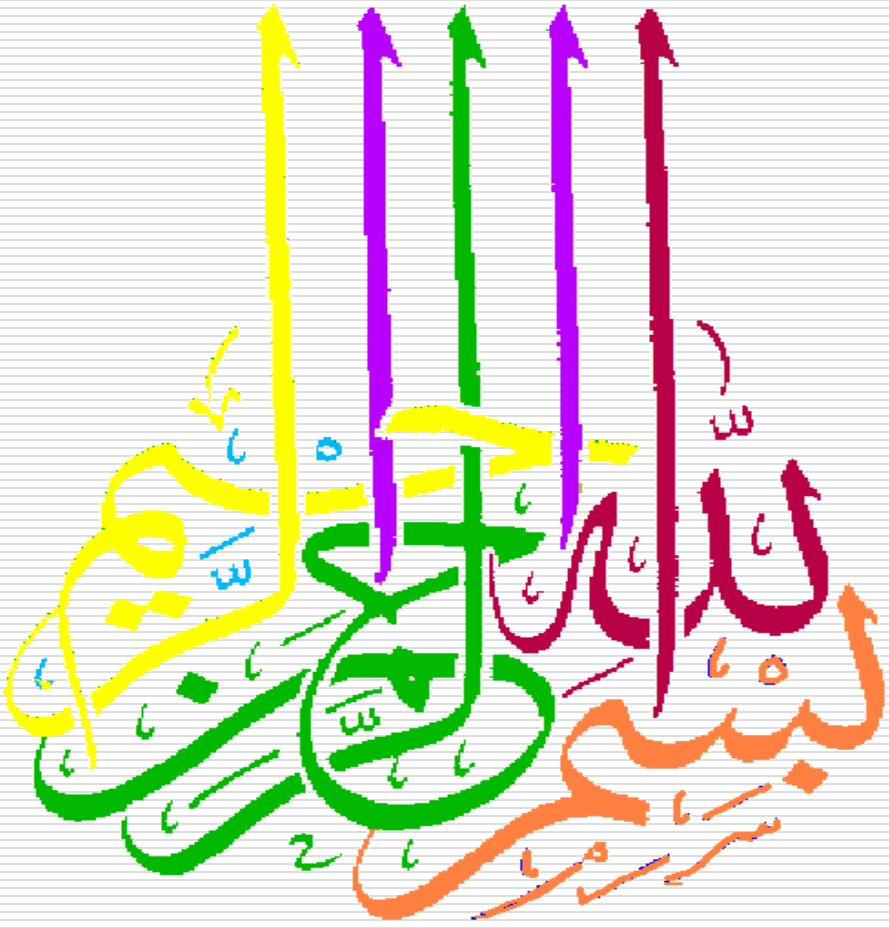
بسم الله الرحمن الرحيم

Blood Safety

Screening of Blood & Blood Products

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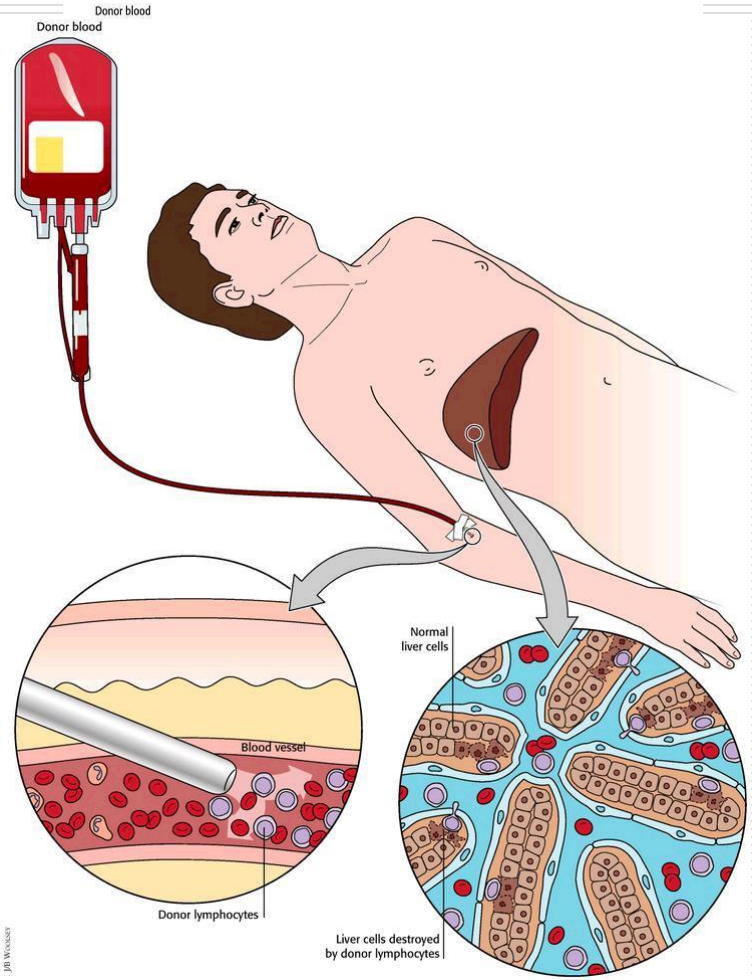

Aim and objectives of presentation

- To promote use of safe blood (screened against HBsAg, HCV, HIV, Syphilis & Malaria).
- Rational use of blood and blood products
- Sensitization with the risk involved in blood transfusion
- Awareness of some of the guiding principle of safe blood transfusion
- Update and refreshment of the knowledge of bed side blood transfusion practices

Safe Blood

Safe blood is blood that does not contain any viruses, Parasites, drugs, alcohol, chemical substances, or other extraneous Factors that might cause harm, danger or disease to the recipient.

Various Steps

Vein to Vein multistep process

There are various steps taken to ensure optimum safety of blood. These consist of

- **Proper selection of blood donor, proper collection, storage, issue .**
- **Pretransfusion testing procedures, ABO & incompatibility**
- **Laboratory screening testing for HIV, HBV, HCV ,Syphilis & Malaria (BACK BONE)**
- **Appropriate use of Blood & Blood components**
- **Infectious control practices – Waste Disposal & Health care workers safety.**
- **Transportation of blood & blood products.**
- **Good bedside practices**

Transfusion Transmitted Infections

- Microbial agents of importance to blood transfusion services are the ones which are transmissible by blood or Blood component transfusion and can cause morbidity and mortality in recipients

TTI Screening

- It is the responsibility of the government to assure a safe and sufficient supply of blood and blood products for all patients requiring transfusion

- It involves a number of processes
  - Selection of blood donors
  - Collection processing
  - Testing of blood donations

TTI Screening

- Effective screening for evidence of the presence of the most common and dangerous TTIs can reduce the risk of transmission to very low levels.
- Blood transfusion services should therefore establish efficient systems to ensure that all donated blood is correctly screened for specificTTIs and that only non reactive blood and blood components are released for clinical and manufacturing use

Characteristics of TTI

To be transmitted by blood, the infectious agent or infection usually has the following characteristics

1. Presence in the blood for long periods (sometimes in high titers)
2. Stability in blood stored at 40c or lower
3. Long incubation period before the appearance of clinical signs
4. Asymptomatic / mild symptomatic phase in the affected person (blood donor) hence not identifiable during the blood donor selection process

Identification Time

- The various markers of infection appear at different times after infection
- Window Period
- Each TTI has one or more window periods, ranging from few days to months
- During this period, the particular screening marker is not yet detectable in a recently infected individual, even though the individual may be infectious

Screening Assays

- Various types of assays have been developed for use in blood screening over the past three decades

- Designed to detect
  - antibodies,
  - antigens or the
  - nucleic acid of the infectious agent

- Not all assays are suitable in all situations and each assays has its limitations

Enzyme immunoassays (EIAs) and Chemiluminescent immunoassays (CLIAs)

- Currently the most commonly used assays for screening donated blood for TTIs
- Differ in the mode of detection of immune complexes formed
  - Colour generation in EIAs
  - Measuring light produced by a chemical reaction in CLIAs
- Suitable for a large numbers of samples and require a range of specific equipment
- May be performed either manually or automated assay processing system

Rapid / Simple ingle-use assays (Rapid tests)

- Discrete, individual, disposable assays

  They are used once and discarded

  Not suitable for screening large numbers of blood samples
- Many tests are based on a form of immunochromatography in which the added sample flows down an inert strip and reacts with previously immobilized reagents.
- Samples – Serum / Plasma / Whole blood
- Positive reaction is visualized as a dot or a band appearing on the device strip.

- Includes a control dot or band that is used to validate the results of each individual device

Nucleic acid Amplification Technology assays (NAT)

- Detects the presence of viral nucleic acid, DNA or RNA in donation samples
- A specific RNA/DNA segment of the virus is targeted and amplified in-vitro
- The amplification enables the detection of virus in the original sample (in low levels) by increasing the amount present to a level (of specific target) that is easily detectable
- The presence of specific nucleic acid indicates the presence of the virus itself and that the donation is likely to be infectious
- Can be performed on individual donations(ID) or on mini-pools (MP) to detect the nucleic acid of the infectious agent

BLOOD AND NATIONAL NEEDS

- Approximately 2.6 million blood units are needed every year
- Available blood is estimated as 1.2-1.5 million units per year
- Exchange blood donors 80-83%
- Voluntary donors 05-07%
- Commercial blood donors 10-13%

DONOR SELECTION

- **Voluntary Donors:- 0.25 % risk**
  They give blood out of his/her own free will and accord

- **Exchange Donors:- 5-7 % risk**
  Relative or friend of the patient gives replacement of the blood

- **Professional Donors:- High risk**
  These are donors who make their livelihood or part of their livelihood by donating blood . They are potential carriers of diseases

Safe Blood: not to spread the disease

A total no. of 20% blood banks in NGO sector are lacking either of five screening markers: HIV, HBsAg, HCV, malaria and syphilis.

A total of 32% blood banks in public sector are lacking either of HIV, HBV, and HCV screening kits (Supply System)

Safe Blood: Do not spread the disease

A total of 86% blood bank reported draining the infected blood in the common sewerage line and discarding the empty bag at community waste site.
A total of 11% facilities were bleeding paid donors in their facilities

Safe Blood –High prevalance spread the disease

patients	Hepatitis B	Hepatitis C	HIV
Thalassaemia Major patients (multi-transfused)	22%	51%	0%
Hemo- dialyses Patients	27%	46%	0%

Reference E- tel JPMA

Prevalence of Hep B/HCV/HIV Blood Donors (Husaini Blood Bank)

YEAR (2016-2017) Total Donors Bled N=132,231

Tests conducted on Chemiluminescence technology

Infection	Total reactive cases.	Prevalence
HCV	4363	3.3%
HBV	3834	2.9%
HIV	11	.001%

Blood transfusion is a dangerous clinical medication

High risk of:

- **Sensitization (To antigen negative blood sub groups)**
- **Transfusion Reactions**
- **Blood transmitted infection**
- **Bone marrow suppression (Eg; GVHD)**

Blood Safety-Challenges

- High prevalence of HCV & HBV
- Low percentage of volunteer donors
- Lack of Standardization of screening procedures
- Fragmented blood transfusion services

Pre-requisites for Blood Predonation safety

- Safe blood donors
- Through repeat voluntary donations and thorough donor screening
- Safe blood transfusion practices – better screening
- Appropriate Rational use of Blood & Blood Product

Screening of donor blood

- Verbal Screening
  - **Selection**
  - **Pre-donation counseling**
  - **Physical examination**
  - **Questionnaire (cross examination)**

OUT COME: Rejection rate approx. 10 %)

- Laboratory Screening

LABORATORY TEST (Mandatory)

- HBV (HBsAg)
- HCV (Anti HCV)
- HIV (Anti HIV 1&2)
- Malaria (Mostly Antigen & Rarely Antibody)
- Syphilis (Mostly antibody)

Comparison of assay results screening kits

Calculation of sensitivity

specivity predictive values

- **Sensitivity=a/(a+c)**

Positive predictive value =a(a+b)

- **Specificity =d (b+d)**

Negative predictive value=d(c+d)

Result of assay	**a True positive**	**b False positive**	**a+b**
Under evaluation	**c False negative**	**d True positive**	**c+d**
	a+c	**b+d**	

MALARIA & SYPHILIS

- **Malaria**
  - **Microscopy**
  - **ICT (Immuno chromatography)**
- **Syphilis**
  - **RPR (Rapid Plasma Reagin) detects antibodies (Specific / Non Specific antibodies)**
  - **TPHA (Treponema Pallidium Hemagglutination Assay) Confirmatory Test**

Rapid tests (For HBV / HCV / HIV)

- **Advantages**
  - – Ease of use
  - – No capital equipment
  - - Bed Side Test
  - – Use in Remote areas
  - – Quick Results

- **Disadvantages**
  - - Sensitivity and specificity is a great concern
  - - Improper Kits Storage Facility
  - – Subjective visual results, qualitative only

ELISA Methods (For HBV/HCV/ HIV)

Advantages

- 96 tests format
- Objective results
- Automatable
- Appreciable sensitivity & Specificity

Disadvantages

- Needs to test in batches
- Decade old method
- Demands skill sets
- Detection capability surpassed by newer methods
- Narrower detection window

Chemiluminescence's Methods

- **Advantages**
  - Lasting luminescence
  - More Sensitive
  - High precision when automated
  - Wider detection limits

- **Limitations**
  - Limited suppliers
  - Capital equipment

Nucleic Acid Tests (NAT)

- General Characteristics

  - Confirmatory Tool
    - Sample preparation, including viral concentration and extraction of DNA or RNA
    - Amplification target viral of the DNA or RNA
    - Detection of the amplified product

NAT methods

- **Advantages**

  – Direct detection of viruses
  – High skill sets
  – Closure of window period of detection
  - Pool upto 16 samples

- **Limitations**

  – Infra-structure
  – Sample processing step yet to be automated
  – Higher sensitivity than ELISA
  – Room for error
  – Cost of single NAT: 10X ELISA

conclusion

Think Twice,before decide the blood transfusion.

- What are the benefits involved in the blood transfusion
- What are the risks involved in the blood transfusion.
- Do benefits outweigh the risk?

Always arrange screened blood & blood products for your patients to prevent TTI's from a registered licensed standard blood bank

Thank You