Role of Regulation in Protecting Blood Safety

A Panel Discussion

Regulation

- Regulation is prescribed rules
- Rules and regulations ensure blood safety guided by basic principles of ethics
- Necessary to establish and maintain an appropriate and effective system for the inspection and licensing

Blood defined as Drug

- Human blood is covered under definition of "DRUG" under section 3 (b) of Drugs and Cosmetics Act, 1940 and rules (1945) there under
- Drug controller is the regulatory authority
- It is imperative that Blood Banks are regulated under its provision
- Manufacturing License for operating BB is mandatory & is the first step towards Quality

Legislation

- Collective laws
- ML issues are important determinants of quality & safety of blood supply
- It is necessary to enact effective legislation to take action to protect and promote health of donors and recipients
- WHO recommends legislation of NBPolicy

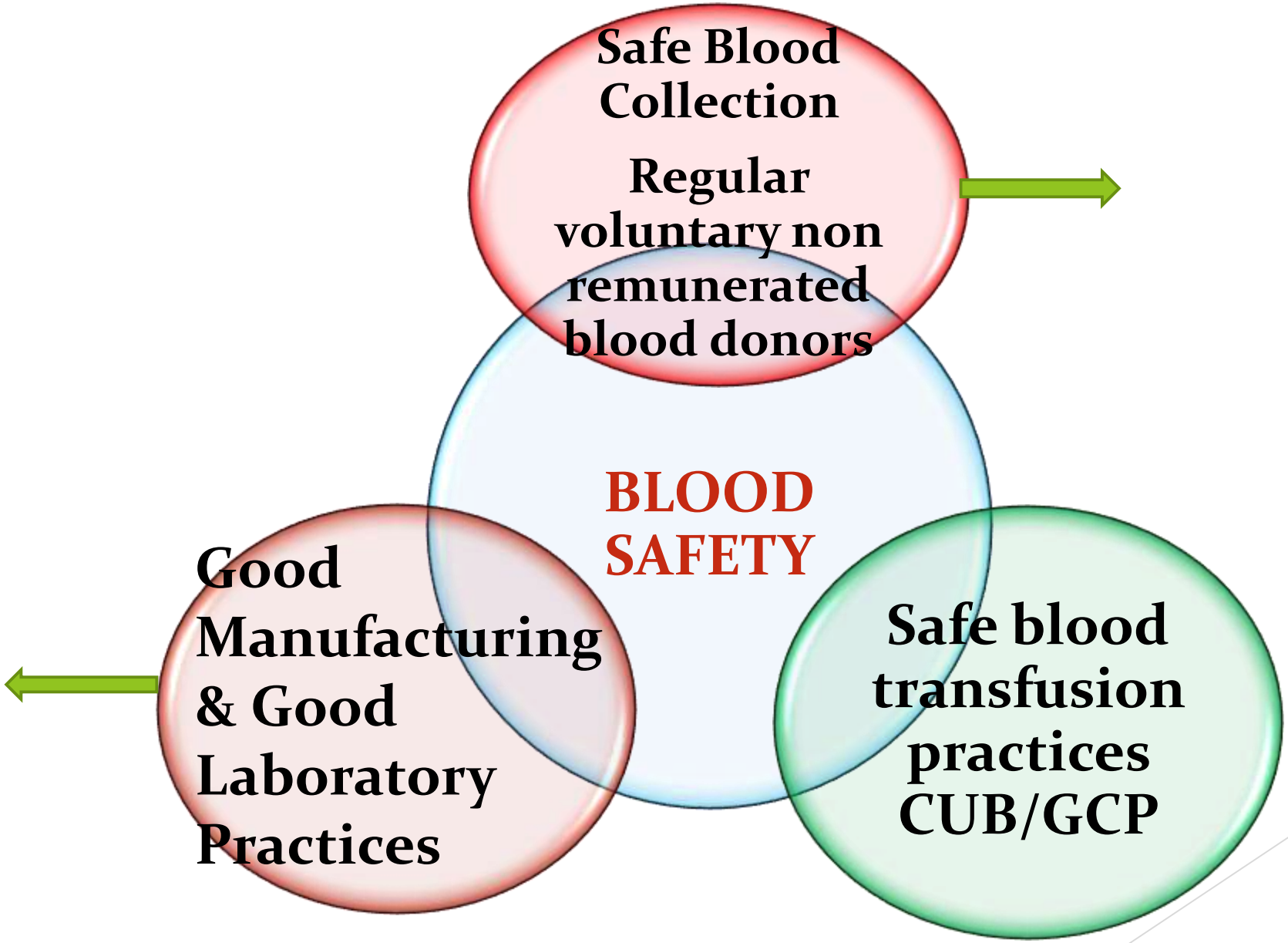
Role of Legislation in Blood Transfusion

- Legislation gives expression to public policy and provides support and authority to those who are charged with governance and responsibility to implement the policy

- Whatever its merit, without law no public policy could be clearly formulated, effectively implemented, and sustained

- Appropriate blood transfusion legislation and adequate regulation is a public health priority to ensure safety and availability of blood and blood components

Achieving Blood Safety



- **As seen in the earlier slide there is no regulatory control over the clinical use of blood. Is it therefore necessary to have a separate legislation and regulation for the BTS – A vein to vein approach**

Increasing advancement in the field of Transfusion Technology has necessitated to enforce stricter control over the quality of Blood and its products

Do you think drug rules take care of this?

- **As I understand Blood Rules do not keep pace with science & technology – some modified products and some which are not yet in IP are necessary for patients**

  Could you please throw light on this issue

Change of term Blood Bank to Blood Center

- **Is there a need to curb the no. of BBs?**

- **Will it be useful to have Director NBTC on Drug Technical Advisory Board**

- License and renewals of many BBs are delayed What is your opinion. Is the Criteria used uniform in all states?
- Does it hinder the work in SBTC
- What is the reason for the delays in licensing

  and renewals of the blood banks
- Are the outdoor camps esp the massive ones visited by drug inspectors?

- **Is the NOC for starting a new BB given by SBTC in all states?**

- Delays due to unavailability of inspection team
- Involvement of SBTC/State FDA/ CDSCO zonal office/experts
- Dual authority involves formalities of reporting by state FDA and approval or authorisation by DCGI
- Central as well as state bodies – inspecting staff needs to be increased
- Continuous training of inspectors needed
- Vigilance cell in all states necessary

- Need to review the procedures

- **Many circulars have been received by the BBs under the signature of Secretary NACO –**

  e.g. transfer of blood, storage center

BBs are confused whether they need to wait for a GR

- Inspections often take place much beyond office hours; many a times start at 4 pm and go on till 10 p.m.
- TM expert on inspection team
- BB may be informed a wk in advance
- Need to train inspectors

- Often it is seen that the regulations required for a pharmaceutical industry are applied to Blood Banks by the inspection teams. Besides air lock entries to processing room instructions for changing ceramic wash basins with stainless steels ones, removing all wooden doors and furniture, replacing them with glass and aluminum (GMP style furniture) need to be clarified.

- **Is there a need for window AC to be fixed in TTI Lab where the central AC is fixed by the hospital?**

- **What is the need of a separate generator for a hospital based blood bank which is covered under the hospital generator?**

- Is MO required at night if blood collection is stopped in the evening?
- The technician's qualifications is DMLT. Why is there insistence on B.Sc. DMLT?
- Is there a need for a separate BBO and nurse for apheresis
- Is HIV testing of staff required? It may undermine confidentiality. AIDS law does not permit this
- Is there a need to appoint a MSW for recruiting donors?
- Counseling a must- Is there a counsellor in all BBs?
- Staff requirement based on no. of collections should be in guidance document

- **Therapeutic apheresis procedures By TM specialists should be permitted in the BBs**
- **Blood Banks /companies are not permitted to provide blood bags to any department without a license. The need for blood bags in the OT for autologous transfusions/cell saving procedures has to be specified to obviate violation of rules.**

- **There has been a request for UDBT from rural surgeons – Can this be permitted? What is your opinion**

- The procedures are mentioned but products not being in IP the license is not given
- Products with Q stds to be described and licensed

1. RDP /Pooled Plts / SDP /PAS suspended
2. Granulocytes – pooled buffy coats or apheresis prod
3. PBSC
4. Plasma – cryo/pooled cryo
5. Therapeutic plasmapheresis /cytapheresis

- It is necessary to decide calibration frequency
- How do we calibrate thermograph?
- Temper proof sharp containers with disinfectant & not needle burners
- Need for CMS or data loggers
- There is no need to do titration of ABO reagents daily. This is required only when new batch is procured
- Analysis & QC Certificate of empty blood Bags issued by the manufacturer may be sufficient rather than every Blood Bank carrying out raw material analysis of the blood bags
- Monitoring Biosafety, waste mgt
- Advances in technical procedures in testing, processing and cold chain maintenance

- There is a need for specifying the minimum SOPs as per the products & procedures carried out by the blood Bank. The site inspection criteria are available but the SOP is not required.
- As far as the Documentation is complete with traceability it should be acceptable.
- Computerisation of records may obviate the need for manual entries.
- Use of IT / softcopies for records

- To eliminate profiteering in BB
- Imposing on price control - DPCO ? /FDA ?
- Variable in states
- The charges are for processing cost – no MRP

THANK YOU