

Critical Control Points in donor lab

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► **OFFICE MEMO:**

All members of staff - please note that due to recession, there will only be one drink per person at this year's Annual Party.

And please bring your own cup!

Regards,

Management

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And see what happened at the annual party.....



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- ▶ *The specifications were missing in the memo (size of cup).*


Moral of the story:

Be very specific in your daily life including project work.

Give specific specifications

Introduction & Definition

- ▶ Blood transfusion services is a vital part of Health care system, but transfusion of blood and blood components is not risk free, so should only be prescribed when it is in the patients' best interest to do so.
- ▶ Processes are therefore focused on producing quality components that are efficacious and safe, which is dependent on the quality & reliability of blood donation.
- ▶ The process steps, that have the highest potential for error and are most likely to have an impact on quality or safety if they are not controlled adequately are called "**CRITICAL CONTROL POINTS**"

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- **“CRITICAL CONTROL POINTS”** for the blood donation process includes-
- (A) Selection of Blood Donor
 - (B) Collection of blood
 - (C) Handling & storage of the unit
 - (D) Transportation of blood units to the component preparation area.
 - (E) Emergency equipments/items- check expiry of drugs

(A) Selection of blood donor

- ▶ **Staff training-** selection criteria, counselling, various processes & donor adverse reaction
- ▶ **Guideline-** recent (Drugs & Cosmetics (Second Amendment) Rules, 2020 **published in Gazette on 11/03/2020**)
 - reviewed regularly to determine what changes should be made and how urgently.
- **Donor questionnaire** - use of a standard donor questionnaire (in understandable language) based on recent guideline which donors are required to complete and sign.
- **Initial screening-** Weight, Blood Pressure,
Hb-Method (validated) , Precautions, QC Approved
CBC & S. Protein
- ▶ **Equipment** - Calibration & ?????

(B) Collection of blood:-

► Critical Control Points during collection of blood includes-

- (1) Selection of bag
- (2) Venepuncture process
- (3) Mixing and weighing the bag
- (4) Striping.
- (5) Emergency equipments/items - as per requirement
 - Check for expiry of drugs

(1) Selection of bag-

- * Sterility check- each new lot**
- * Weight of donor- 350/450**
- * Components preparation- S/D/T/Q etc.**
- * Inspection of bag**



(2) Venepuncture process

► Biggest risk of bacterial contamination-

- * Use standard & validated method of disinfection of venepuncture site.
- * Use of disinfectant that has been validated to demonstrate efficacy.(QC check)

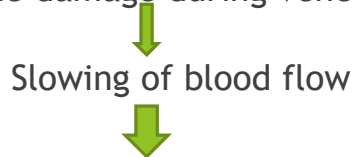
Precautions- Donor should never be left unattended.

- Excessive probing with the needle should be avoided.
- Avoid palpation of vein once phlebotomy site is prepared.

Recommendation- preferably use bag with diversion pouch

► Correctly carrying out venepuncture-

Localized tissue damage during venepuncture (occurs when veins are difficult to locate)



Reduction in available platelets & labile coagulation factor.

Recommendation- use vein locator device/vein finder device/vein visualization system

(3) Mixing and weighing the bag

- ▶ It is important to maintain ratio of blood to anticoagulant (+ 10% variation is acceptable) as well as regular mixing of blood with anticoagulant.
- ▶ Use automated blood mixer - advantages
 - * mixing of blood during collection
 - * sounds an alarm when the blood flow slows
 - * collection of targeted volume.
 - * time duration of donation.

(4) Sealing & Striping

- ▶ Seal the tube immediately near the needle end to prevent bacterial contamination.
- ▶ Striping at the end of donation process to prevent clotting in the line- twice
- ▶ Post Donation Care----

Blood Bank, Sir Takhtasinhji General Hospital, Bhavnagar <small>Ph./ Fax: 0278 -2520091, E-mail : sirth_bb@yahoo.com</small>	
Instruction to Donors after blood Donation	
Do's	Don'ts
Drink at least 10-12 Glasses of water in 24 hour following blood donation	Do not lift heavy weight today from the arm from which blood been collected.
Please ensure that you have taken enough food and fluids.	Do not lift heavy weight today from the arm from which blood has been collected.
Remove the bandage after 24 hours of donation.	Do not chew tobacco or Smoke for 3 hours after blood donation.
if you feel giddiness or headache, lie down with your legs raised. If symptoms are not relieved contact nearest doctor immediately	Do not drive a vehicle for one hour after donation or drive carefully for untoward reaction.

(C) Handling and storage of the blood bag

- ▶ Critical Control Points include-
 - (a) temperature at which units are stored & transported
 - (b) duration between collection & processing.
- ▶ Units should be stored either **2-6° C** or **20-24° C** depending on components that are to be prepared.
- ▶ Recommendation- preferably use mobile blood bank refrigerators or use validated storage containers, packing materials and coolants.

(D) Transportation of blood units to the processing area

- ▶ Mainly applicable in out door blood donation camps with significant distances.
- ▶ Storage containers need to be robust, capable of withstanding normal wear & tear sustained during transport and maintain internal temperature within required ranges no matter how cold or hot the external conditions are. (Validated)
- ▶ Continuous temperature monitoring & recording during transportation
- ▶ Recommendation- Utilization of “Cooling plates”,
 - Mobile blood bank refrigerators,
 - Storage containers with data-logger

(E) Emergency equipments/items

- ▶ As per requirement.
- ▶ Check expiry of drugs.
- ▶ Policy of replacing expired drugs.
- ▶ Oxygen cylinder/ Oxygen line



Take home message

- ▶ Use standard donor questionnaire based on recent guideline issued by regulatory authority.
- ▶ Use calibrated equipment & do performance check on each day of use.
- ▶ Use only validated method & QC approved reagent/solution
- ▶ Prepare and implement SOP.

