CORRESPONDENCE

Consumables Quality: Is It Critical for Transfusion Services?

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Dear Editor,

Quality management system for transfusion services have few critical essentials like materials supply and management of non-conforming events [1]. There should be an acceptance and rejection policy for purchasing of qualified material in blood banks. The non-conforming events in blood bank have direct effects on the donor and recipients, so it should be reported properly and managed by corrective and preventive actions. As per International Organization for Standardization (ISO) 3826-1 [2] blood bags should have appropriate resistance to breakage and deterioration as these defects after blood collection lead to wastage of blood as well as its resources.

Here, we are reporting few events of defects in blood bags after whole blood collection that resulted in wastage of blood. Figure 1a, b shows a broken closure seal that has moved into the mother bag hence rendering the blood bag unfit for use. Figure 1c depicts the transfer of whole blood from mother bag to satellite bag before breaking the closure seal. Closure seal prevents the movement of

blood from one bag to another bag but in our case it was broken or not in its place at the time of manufacturing or transport. Beckman et al. [3] in National blood services (NBS) of United Kingdom report showed that 326/2719 defects were due to broken or damaged parts in blood bags from the manufacturer site. Figure 1d, e shows detachment of collection tube and needle from their respective hubs without applying any force. As per ISO [2] blood bags should be able to bear pressure equivalent to 50 kPa at $(23 \pm 5)^\circ\text{C}$ for 10 min. NBS [3] also reported 91/2719 moulding defect and 59/2719 needle defect in blood bags. Figure 1f shows a kink in the collection tube of blood bag towards the proximal end, which led to obstruction, and ultimately under-collection of blood. As per American Association of Blood Bank (AABB) blood bag should be flexible, and kink resistant [4]. NBS [3] had also reported > 200 kinks per million packs in collection tubes of blood bags made by a particular manufacturer.

The plastic materials and manufacturing process of blood bags and its accessories like collection tube, closure seals etc. should qualify the International standards. Defects in blood bags although is a minor reason for discard of blood units but proper investigation and preventive measures in view of these faults leads to an improved user confidence. NBS [3] report described the defects in blood bags which led to blood pack fault which was significantly decreased after corrective action by the manufacturers.

Although the corrective actions on manufacturing defects will not always be immediate but regular reporting will definitely help in sensitization of such concerns and future quality improvement. In India there is a need of a national reporting agency where these kinds of defects in

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Fig. 1 Defects in means of closure (seal) and collection tube attachments in mother bag

consumables can be reported to improve the quality of blood transfusion services.

References

1. Motschman LT, Jett WB, Wilkinson LS (2014) Technical manual AABB. 18 ed 810. AABB, Bethesda, p 38
2. International Organization for standardization ISO G, Switzerland (2013) Plastics collapsible containers for human blood and blood

components—Part 1: conventional containers. International Organization for standardization (ISO), Switzerland, p 23

3. Beckman N, Nicholson G, Ashford M, Hambleton R (2004) Blood pack fault monitoring. *Vox Sang* 87(4):272–279
4. Fung MK, Grossman BJ, Hillyer CD, Westhoff CM (2015) Standards for blood banks and transfusion services, 18th edn. AABB, Bethesda

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