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Algorithm to Use Increasing the Availability of Blood Components & Cost Effectiveness, Without Compromising Blood Safety

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Abstract – Risk Assessment and Management for Blood Safety and Availability ***There is a public expectation that blood and blood products are safe, and blood donation and transfusion process do not carry any risk; the public therefore also expects national health authorities to respond effectively to known risks and to anticipate and plan a response. Risks associated with ensuring safety, supply and accessibility to blood and blood products include adverse donor events during or after blood donation; threat to the existing VNRBD system, lack of timely accessibility to sufficient blood; adverse patient events and outcomes; and the risk of known transfusion-transmissible infections, other infections not currently screened for but with a proven or theoretical risk of transmission, and new/emerging infections.***

Keywords: Blood Safety, Blood Products, Supply and Accessibility to Blood and Blood Products

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INTRODUCTION

Risk Assessment and Management for Blood Safety and Availability There is a public expectation that blood and blood products will be safe, and blood donation and transfusion process do not carry any risk; the public therefore also expects national health authorities to respond effectively to known risks and to anticipate and plan a response. Risks associated with ensuring safety, supply and accessibility to blood and blood products include adverse donor events during or after blood donation; threat to the existing VNRBD system, lack of timely accessibility to sufficient blood; adverse patient events and outcomes; and the risk of known transfusion-transmissible infections, other infections not currently screened for but with a proven or theoretical risk of transmission, and new/emerging infections. Managing and minimizing risk throughout the transfusion chain from donor to recipient is an important part of the responsibilities of national health authorities, blood transfusion services, blood centres and hospitals. The appropriate management of risk ensures improved outcomes for donors and recipients, generates confidence in the system, and has a positive impact on public trust in the blood system. Establishing a risk management framework is a critical first step in determining appropriate mechanisms and interventions for risk reduction and response. Some risks, such as the residual risk of infection transmission after screening, may be well-characterized and quantified; there is less understanding of other equally important areas of risk, such as the risk of patient mortality or morbidity if blood is not available or the effects of repeat blood donation on donor iron stores. A comprehensive risk assessment should address all aspects of the transfusion chain, including donor, patient and staff safety, and not only blood safety and availability. Anticipating future risks should not be limited to the assessment of emerging infectious diseases but should also include a broader view of social, political, ethical, economic and environmental factors that might impact the blood system and blood availability for patient care. In the event of a local, regional or national emergency or disaster, a risk-based approach to contingency planning is required to ensure safety, availability and adequate continuity of services. Systems for the identification, prioritization and management of risk should be relevant to the local context. Identifying actual and potential risks requires the expertise of local technical and management staff as well as other relevant stakeholders. Risk matrices should be developed for all major processes to categorize key risks and identify suitable decision makers, actions and resources required.

REVIEW OF LITERATURE:

Elements of blood safety:

- **Safe donor**

Safe blood comes from an ‘altruistic’ voluntary donor who donates blood without any expectations. A

'repeat voluntary donor'[2] is one who donates blood at least once a year and is considered safer than occasional voluntary donors, as the blood bank is aware of his previous test results also. Friends and relatives of patients called 'replacement donors' constitute a significant chunk of blood donors in our country but are not really safe donors[3] as they are forced by family or friends to donate blood. Professional/paid donors may sometimes be passed off as replacement donors too. Some papers have shown that one time voluntary donors are no better than replacement donors[4]

- **Safe blood**

Blood banks have traditionally employed enzyme linked immunosorbent assay (ELISA) techniques for donor screening. Tests with greater sensitivity or those which take lesser time duration like chemiluminescence (CLIA)/enzyme-linked fluorescence assay (ELFA) are increasingly being used by blood banks.[5] Of late, expensive technologies like nucleic acid testing (NAT) have added to blood safety.[6-8] In addition to transfusion transmitted infections (TTI) testing, red cell antibodies screening being adopted by many blood banks and the newer gel/bead techniques have also added to blood safety. Blood processing techniques like leukoreduction,[9] Irradiation[10] and pathogen inactivation[11] are expected to play an increasingly important role in enhancing blood safety in future.[11]

- **Safe transfusion**

While there are some guidelines for safe donor selection and safe blood processing, there are no transfusion triggers or national guidelines for safe transfusion.

Ethical issues in safe blood transfusion:

Hospital based blood banks are compelled to practice replacement donations as they are denied permission to hold camps. Scientifically, directed donations are to be discouraged, but practically they are sought after by recipients and physicians, posing an ethical challenge to blood bankers. All blood bankers would like to use blood judiciously as blood components, however demand for whole blood leads to the contrary. The transfusion trigger for red cells was set at 10 g/dl at the turn of the 20th century as it left little room for anaesthetic errors. This has changed considerably over the years. However, some anaesthetists refuse to administer anaesthesia unless the haemoglobin is up to their expectation leading to unnecessary transfusions. A blood bank doing life-saving procedures like erythropheresis, plasma exchange, not mentioned in the D and C Act is scientifically and ethically correct, but may be legally incorrect. NBTC prescribes differential rates for different blood components, based on economic considerations, rather than ethical considerations. If the money is for processing only, then all components should be priced uniformly. Blood bankers are expected by community to provide the highest quality blood, free or at a low price, which maybe ethically right but economically unviable. Ethical practices need to be implemented by management and staff of blood banks. Conflict of interest involving management and staff of blood banks need to be avoided to ensure ethical practices especially with reference to manufacturers/suppliers of kits and reagents. Hierarchy of reporting should be clearly delineated with checks and balances to avoid bias and ensure that science and ethics play a more important part than commerce in the practice of transfusion medicine.

Absence of transfusion triggers poses an ethical challenge to blood bankers, as the treating physician who goes by his instinct is always right. The community perceives blood bankers as businessman selling blood to earn a livelihood. In reality blood, bankers are one of the poorly paid professionals compared to other clinical specialties. If blood bankers need minimum qualification to run a blood bank, so do drug inspectors. Drug inspectors must be trained for at least a year in the basics of blood banking, apheresis and molecular biology before inspecting blood banks. Inspection team should be drawn from a list of experts with blood banking experience lead by a technical expert and should include the drugs controller.

CONCLUSION:

Every blood transfusion service should establish an effective quality management system, based on appropriate national or international standards, to ensure a timely and sustainable supply of blood and blood products of appropriate and consistent quality, and in sufficient quantity. Quality systems should cover all BTS activities and hospital transfusion practices to ensure traceability, from the recruitment and selection of blood donors to the final fate of the donated unit, including its transfusion to patients and their follow up. They should reflect the structure, needs and capabilities of the blood transfusion service as well as the needs of the hospitals and patients that it serves.

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