

8. SUMMARY AND CONCLUSION

Blood transfusion is a highly critical aspect of many realms of healthcare. Its advantages encompass saving lives, improving life expectancy, improving quality of life, etc. A well structured and maintained BTS is a prime element of any health care service system(134,135). So much so that it is of paramount importance for every country to have in place a strict and efficient hemovigilance system.

It is a paradox that while transfusion-related adverse events have been extensively studied by transfusion medicine professionals, there have not been significant strategical changes to reduce the frequency of transfusion errors in developing countries, most of which are preventable. Underreporting of adverse events, possibly due to the lack of a strong system, is one of the major obstacles towards the implementation of a better hemovigilance policy, as it masks the true scale of the issue at hand. To counter the effect of limited resources in developing countries on the implementation of a system, it is better to have a stepwise implementation that starts at the grassroots level, recognize the shortcomings and slowly building on it.

Recognizing the need to support countries in establishing National Hemovigilance systems, WHO has launched certain initiatives to facilitate the same such as:

- Training material, recommendations, such as “FRAME” : Toolkit for evaluation of NBP”
- Global Database on Blood Safety
- Blood Safety Indicators
- Global Consultation on Universal Access to Safe Blood Transfusion was arranged in 2007
- Establishing a Global Hemovigilance Network

The study was aimed at comparing hemovigilance programmes of BRICS countries with that of USFDA and EMA, and thereby to shed light on the making of what could be a plausible successful Hemovigilance Programme of India. Such a programme should be able to detect, collect and analyze adverse effects associated with transfusion of blood and also blood donation. Further, this information should be used in policy-making and the formulation of transfusion and donation guidelines, whose implementation and efficiency should further be analyzed and improved upon.

The Ministry of Health (MoH) should be the apex to facilitate the development of such a national blood system and its integration with the healthcare system. While the structure of the former will always be closely linked to the organization of the latter, it is imperative that all the prime activities of a national blood system are co-ordinated nationally to maximize the efficiency and the output of such a system.

A national blood system should ideally include the following:

- A unit within the MoH which serves as the apex for the coordination of all the activities and programmes of the system throughout the country
- An advisory body which serves to assist in policy-making and advising on key issues
- Blood Transfusion Services involve all activities from donor recruitment to proper distribution of blood products to healthcare facilities . Service delivery models may be single service provider or multiple service provider.
- Committees at the levels of healthcare facilities to be provided to monitor the safe and timely provision and use of blood and blood products(135)

NBTC/SBTC and NACO/ AIDS control society in the state level are the systems in place to monitor the blood safety programmes of India(136,137).The following suggestions can hence be put forth regarding a proper HvPI which will not only aim at increasing the quality and safety profile of blood transfusions, but also facilitate timely and accurate reporting of possible adverse reactions, and policy-making through proper channels for their prevention.

Ideal Strategy for India to develop successful haemovigilance system

1. Good coordination between various Govt sectors like NIB, NACO, NBTC, DGHS, DCG(I), State AIDS Control societies, SBTCs State Drugs Control wing etc are required to promote HVPI in each and every licensed blood bank of the country.
2. Imparting training for all categories of stakeholders, generating data standards
3. TTIs to be included in the form for reporting Transfusion reactions
4. Accreditation of blood banks, establishing regional blood testing centres to improve blood safety and cost of testing can thus be reduced
5. Establishing fully functional HTC
6. Mandatory adverse reaction reporting
7. Reducing or minimising human errors in collection, screening, storage, transportation and transfusion
8. Imparting awareness to clinicians that reporting adverse incidences is also a part of treatment
9. Improving reporting capability
10. Continuous and guaranteed budgeting and finance facility
11. Strengthening the Centre evaluation set up at NIB and transfusion departments in hospitals
12. Clarity on commonly agreed definitions by IHN to ensure identifying and categorising the events accurately
13. Standardised reporting protocol to be followed and timely up gradation
14. TTIs related to virus is to be specifically included in the form for reporting Transfusion reactions
15. TTI screening should ideally be done for a period up to 3 months after transfusion as a follow-up measure. Before transfusion also the TTI screening should be done to assess whether the TTI is received from transfusion or not
16. Screening for HTLC should be made mandatory
17. NAT test should be made mandatory for viral infections
18. Centralised testing facilities should be established so as to reduce the cost of testing
19. Development of rapid alert or early warning system
20. Culture of professionalism to be inducted
21. Introducing preventive and corrective procedures for blood safety
22. Creating better international co-operation

23. Guidelines on roles of blood centres, Industry and clinical segment are to be implemented and should be followed
24. Competent authorities to play role in legislation, inspection and budget designing
25. GMP and GLP to be strictly followed by the blood banks and Industry.
26. Guidelines on donor selection and donor deferral(133) should be followed strictly
27. Proper Implementation of Regulations and guidelines to be placed for managing and review of BTS
28. NACO and NBTC should have a proactive role in licensing aspects.
29. Procedures licensing system is to be simplified
30. Ensure enrolment of all blood banks in the HvPI by the Drugs Control Authorities
31. Better National Blood Policy and Safety initiative – The existing national Blood Policy was framed in 2002. Such policies should be updated along with existing definitions of terminologies, as changing with the times is of paramount importance to maintain efficiency of any problem
32. Amendments should be done under the drugs and Cosmetics act to include therapeutic procedures like erythropheresis and all the components prepared through different technologies like Pooled platelet concentrate,in detail.
33. Steps to be taken to prevent profiteering in blood banks as well as their proliferation by regulatory control
34. Policy decisions like 100% component separation and Universal Leucoreduction should be made
35. Ensure appropriate clinical usage of blood and blood
36. HvPI should be popular among Healthcare Team and Public
37. Awareness programmes related to donors, education, motivation, recruitments and retaining for ensuring the adequate availability of safe blood should be effectively conducted.
38. Pricing should be uniform and should be controlled by the regulatory authorities
39. Proper planning to conduct blood donation camps at a suitable time can be scheduled based on climate and prevalence of diseases
40. There should be a system of getting the reports from the hospitals to stand alone blood banks, from where the blood units are procured
41. Proper guidelines are to be framed for the reporting of Blood storage centre
42. At least one officer in each state should be designated to ensure the implementation of Haemovigilance in the blood banks and blood storage centres their area.

Setting up an efficient and effective HvPI in accordance with the above recommendations can go a long way in improving blood safety, availability, and thereby has a huge positive impact on the overall health scenario of the nation.

9.FUTURE SCOPE

Blood transfusion practices and hemovigilance has been a relatively under-researched field in the Indian backdrop. This project aims at shedding light on some of the areas that we can improve on, with respect to the implementation of the Hemovigilance project on India. Future studies can be conducted with respect to better bedside transfusion practices, adoption of latest transfusion techniques to reduce errors and improve quality, as well as the development of better understanding of use of blood and blood products by clinicians. More research can also be directed at improving the scope of usage of autologous blood in transfusion practices, considering its obvious benefits. These types of study also helps to outline some of the better hemovigilance practices in other countries across the world, and frame guidelines for their implementation in an Indian setting, as the Hemovigilance is always a never ending process.

The surveys conducted in this study covered the blood banks of Kerala state. It can be extended to other states as well as across the country.