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Framework of Indian Blood Transfusion Services

Ravi Ranjan Kumar

Research Scholar

Abstract – Over the past 2 decades the pendulum of blood safety policy has swung wide and hit hard. Intense criticism of delayed responses to the early clues of the transfusion AIDS epidemic and of tolerance to the long standing problem of post-transfusion hepatitis has had enormous repercussions. Blood collection systems in a number of countries have been completely restructured. Policy makers and physicians have gone to jail. Over the past five years the working paradigm has shifted toward "the precautionary principle" and the elusive mirage of a "zero risk" blood supply. However, recent commentary on the precautionary principle suggests that even this conservative approach must not seek zero risk or involve disproportionate responses, but rather should incorporate scientific data, consistency with comparable situations, and cost-benefit analyses into precautionary decision making. In this issue of Transfusion, a number of papers on Nucleic Acid Amplification Testing (NAT) for infectious agents, illustrate some of the very different drivers that have influenced the formulation of blood safety policy: perception, science, ethics, international politics and economics.

Keywords: Blood System, Blood Transfusion, Conservative Approach

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INTRODUCTION

Blood System Strengthening for Universal Access Provision of safe blood and blood products for patients requiring transfusion is a vital component of universal health coverage. All health care system should strive for universal access to blood transfusion services (BTS) as this will lead to equity, social justice and an end to geographical or financial exclusion from access to safe blood and blood products. Protecting, promoting and maintaining the health of the population (for patients and blood donors, in the case of access to safe blood and blood products) is a core responsibility of governments. In exercising this stewardship role, governments should develop, implement and enforce policies that are evidence-based, ethical and effective in strengthening blood transfusion services as an integral part of health systems together with efficient service delivery model, proper financing systems and mechanisms to ensure the availability of adequate resources. Current blood system challenges include inadequate community education and mobilization on need for voluntary, non-remunerated blood donation, inadequate infrastructures for the provision of quality blood transfusion services, inadequate financing or inappropriate financing systems, poor organization and management of blood transfusion services, unnecessary use of blood, shortages of health workers with the required skill mixes, mismatches between service requirements, and the education provided by health training institutions, poor procurement and supply management systems, limited information systems and lack of good governance. All these contribute to inadequate supply and inequitable access to quality blood transfusion services by patients requiring transfusion. While reforms in blood system are required for safer blood and blood products, more efficient and cost-effective blood service delivery, they should be supported by wider policy, leadership and stewardship reforms which should be considered as synergistic and tackled concurrently

REVIEW OF LITERATURE:

Despite some successes, self-sufficiency in safe blood and blood products is not yet a reality and many countries with inadequate supplies of blood from voluntary non-remunerated blood donors remain dependent on systems of family/replacement donation and payment to blood and plasma donors to fill the gaps between supply and demand; even systems of family/replacement donation often involve "hidden" payment systems. Increasing global needs for blood and blood products, the complex nature of systems to supply these products and the inability of many national health systems to meet these urgent needs have resulted in a rapid expansion of international commercial activities in relation to blood and blood products, as shown by increasing global markets in commercial plasma collection. Such policies and practices seriously compromise the safety of blood and blood products. In 2010, the World Health Assembly deliberated on challenges to the availability, safety and quality of blood products and defined self-sufficiency in the supply of safe blood components based on voluntary

non-remunerated blood donation (VNRBD), and the security of that supply, as important national goals to prevent blood shortages and meet the transfusion requirements of the patient population. Resolution WHA63.12 urged Member States "to take all necessary steps to establish, implement and support nationally-coordinated, efficiently-managed and sustainable blood and plasma programmes according to the availability of resources, with the aim of achieving self-sufficiency". Countries that have already established policies and systems to achieve self-sufficiency can serve as models by demonstrating the effectiveness of policies, strategies and mechanisms that should be supported and implemented.

Framework of indian blood transfusion services [6]:

National blood policy

The National Blood Policy[1] (NBP) was published by the Government of India in 2002. The NBP reiterates government commitment to safe blood and blood components and has well documented strategies, for making available adequate resources, technology and training for improving transfusion services. It also outlines methods for donor motivation and appropriate clinical use of blood by clinicians. It has also taken steps for R and D in transfusion medicine. Further, it is also entrusted with the job of ensuring legislation and education to eliminate profiteering in blood banks

Role of National Aids Control Organization

Many improvements seen in our country over the last decade and a half has been the result of licensing which laid down minimum requirements in terms of space, staff and equipment and also National Aids Control Organization (NACO) support for blood safety.[2] While the drugs controller is the regulatory authority, NACO/NBTC has been the main technical body to frame guidelines for the practice of transfusion medicine. The NBP is an offshoot of the National Aids Control Program.[3] NACO together with NBTC has played a pivotal role in improving blood safety by infrastructure development, setting up component separation units, promoting voluntary blood donation, training staff and has also laid down standards for blood banks in India.[4]

Organogram of Indian Blood Transfusion Service [6]

- **Licensing of blood banks by drugs controller**

The procedure for licensing of blood banks is written in the D and C Act 1940 and Drugs and Cosmetics Rules, 1945. Basic licensing standards for blood banks have remained unchanged over the past decades.[5] The D and C act has only seen minor changes such as rising the age of donation from 60 to 65 years and recognition of transfusion medicine as a specialty. Perhaps the only major amendment has been the guidelines for setting up blood storage centres.

- **Who can operate a blood bank**

Any individual or institution can apply for opening of a blood bank. Following an application to the drugs controller, a joint inspection is conducted by drug control authorities from state and centre which make a recommendation to the Central Licensing Approving Authority (CLAA), which is the ultimate authority for grant of license. This drug controller inspection is preceded by an inspection by the SBTC, the advisory body, which gives its consent to the drugs controller.

- **Space requirements**

Minimum standards for space, equipment and staff have to be met with by all blood banks, and these are inspected at the time of grant/renewal of the license. An area of 100 sqm for whole blood and an additional 50 sqm for blood components and 10 sqm for aphaeresis is needed for operating a blood bank in India.

- **Staff requirements**

The medical officer may be a person with MD in Transfusion Medicine or Pathology, Diploma in Pathology with 6 months experience or MBBS qualified with 1-year experience in blood banking. Technicians with BSc (MLT) or DMLT and staff nurses are additional requirements

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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