Legislative reforms of the blood transfusion system in Pakistan

Dear Sir,

The member states of the World Health Organization have committed to promote blood safety in their respective countries through a number of World Health Assembly resolutions passed since 1975 (WHA, 1975). The implementation of this commitment is a major challenge for many developing countries. A major constraint in this regard is often the absence of national policies, poor healthcare service delivery structures and governance issues. As the legal and regulatory framework is the cornerstone of blood safety, without comprehensive blood safety legislation, improvements in access and quality of services will remain a testing challenge. As a result, the blood programmes in the developing countries strive to achieve the objective of universal blood safety through systems reform involving development or review and revision of the existing legal and regulatory frameworks.

With a population of 180 million, Pakistan is the world’s sixth most populated country. Healthcare coverage is not comprehensive and plagued with financial and management constraints. The public sector healthcare system operates through a three-tier delivery structure and a variety of public health interventions. The role of private sector is growing and according to one estimate, its share has reached 75% (Nishtar, 2006). Weaknesses in the overall healthcare system include lack of adequate regulatory framework in addition to weak implementation. The public health system is deficient in terms of human and physical infrastructure to match the needs of the growing population and the challenges faced by natural and man-made disasters occurring with increasing frequency in the recent past. In addition, as a result of the introduction of the long delayed constitutional amendments, the subject of health has been devolved to the provinces where there is limited capacity to cope with the technical and administrative issues of the transition phase.

Currently, the blood transfusion services in Pakistan are fragmented with insufficient regulatory oversight. As a result, there exist suboptimal standards for donor selection, inadequate practices for manufacturing, laboratory testing, storage, transport and transfusion and compromise the donor and patient safety. There is limited interaction among the more than 1830 service providers functioning in the public, private and NGO sector in the country (Zaheer et al., 2012). The heterogeneous state of affairs makes provision of quality service to the large population a very challenging task. Cognizant of these ground realities, the Government of Pakistan has since 2008 taken concrete measures to reform the blood transfusion system in Pakistan. The reforms include the formulation of a National Blood Policy and Strategic Framework (2008–2012), establishment of Blood Transfusion Programmes at the National and Provincial levels and the creation of a new infrastructure which will, in the first phase, develop 13 Regional Blood Centres as ‘production units’ and 78 Hospital Blood Banks as ‘consumption units’ (Fig. 1).

The proposed centralized coordinated model will ensure quality practices at every step of the vein to vein transfusion chain. The reform process is led from the platform of the Safe Blood Transfusion Programme in which the detailed operational activities and implementation is the responsibility of the federal, state and provincial health departments.

The Blood Transfusion Programme is supported through a grant from the Government of the Federal Republic of Germany through Technical and Financial Cooperation components. The Technical Cooperation (TC) component is funded by GIZ [German Agency for International Cooperation] and is part of the GIZ Health Sector Support Programme. The TC component works to improve access to safe blood and blood products by providing advisory services concerning organization and governance of the system including Management Information System, Voluntary Non-Renumerative Blood Donations, Clinical Use of Blood, Legal and Regulatory Framework, Quality Management and Capacity Development. The outputs of the TC component over the last 4 years have strengthened the national blood safety system reforms process. The Financial Cooperation (FC) component of the project, funded by KfW [German cooperative bank], is responsible for the development of the new infrastructure, which consists of constructing and equipping a network of Regional Blood Centres, and renovation and refurbishment of the existing Hospital Blood Banks.

With the initiation of implementation of the reforms process, it was imperative to review and, if necessary, revise the existing blood safety legislations so that the new system being introduced functions under the umbrella of a proper regulatory framework. The review has also been necessitated due to rapid advances in the field of Transfusion Medicine as the existing legislations were drafted about 15 years ago.

During the period 1997 to 2004, various provinces passed their respective legislations on blood safety. The first blood law approved and implemented was from the province of Sindh in 1997, followed by similar legislations passed by the provinces of Punjab and Khyber Pakhutkhwa in 1999. The Islamabad Blood Safety Ordinance for the federal capital and federally administered tribal and northern areas (FATA, FANA) was enacted in 2002, whereas Baluchistan approved its law in 2004.

Correspondence: Prof. Hasan A. Zaheer, PhD, Safe Blood Transfusion Programme, Government of Pakistan
Islamabad, Pakistan.
Tel.: 0092 51 926 32 36; fax: 0092 51 926 32 38;
e-mail: hazaheer@gmail.com
Letter to the Editor

Regional blood centres
Hospital blood banks

Fig. 1. Regional distribution of 13 blood centres and linked 78 hospital blood banks across Pakistan.

(SBTP, 2012). These blood safety legislations have never been fully or properly implemented for various reasons including lack of a proper service delivery structure, insufficient political commitment, etc.

In 2012, the Safe Blood Transfusion Programme conducted an exercise to review all existing legislations on blood safety and prepared a synoptical summary that allowed a comparison of 23 key concepts in these documents. The summary highlights a considerable degree of diversity between the legislations and the current EU directives. The key findings about the limitations of the current legislations are omission of haemovigilance, quality management, sector diversity, hospital interface, functional separation and considerable latitude in the financial penalties and physical imprisonment.

The new proposed law, drafted in December 2012 and endorsed by all the partners, is based on the 2005 EU directive and formulated with the objective to introduce more cohesion and uniformity in the regulation of quality standards for blood and blood products across the different federating units, which would then be more tuned with the envisaged national safe blood transfusion system. The proposed new legislation is consistent with the modern concepts and trends in transfusion medicine and expected to bring a paradigm shift in the entire system. Unlike the existing law, the new law template contains a comprehensive list of definitions and outlines the roles and responsibilities of the Blood Transfusion Authorities. It also separates the functions of the ‘blood banks’ into production (Regional Blood Centres) and utilisation (Hospital Blood Banks) activities, an organizational arrangement comprising the core of the system reform in Pakistan. In addition, the concepts of haemovigilance (including Hospital Transfusion Committees), record keeping, data protection, confidentiality and traceability have been introduced in the new template. The section on the penalties for contraventions is under scrutiny by all the federating units, with similar views that penalties should be specified in terms of imprisonment and/or monetary fine. The first-phase of the project will be completed in 2014, and in subsequent phases, coverage will be extended until universal coverage is achieved in about 20 years. The new legislation must therefore allow for transition period during which the existing fragmented system and the new system will function in parallel. The SBTP also intends to record the enactment process of the new legislation and its implementation and intends to do a follow-up study to see the impact of the intervention.
and how far it has contributed to achieve the goal of blood safety.

In the current post-devolution institutional environment (Nishtar and Mehboob, 2011), the Programme is facilitating the passage and subsequent enactment of this law through a series of interventions. Advocacy sessions are directed at health authorities, legislators, policy makers and other important partners in order to create a new momentum for the enactment of blood safety legislations. In addition to adopting the new legislations, attention also needs to be paid to ensure appointment of appropriate committed leadership to improve the local governance and implementation structures at administrative and operational levels through allocation of adequate resources and development of trained technical workforce.

ACKNOWLEDGMENTS

U. W. conceived the study. H. A. Z. designed the project. U. W. and H. A. Z. wrote the manuscript.

CONFLICT OF INTEREST

The authors have no competing interests.

H. A. Zaheer & U. Waheed
Safe Blood Transfusion Programme, Government of Pakistan

REFERENCES


