

The Status of Blood Safety in Islamabad, Pakistan

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Author's Contribution

^{1,3} study conceptualized, ¹data collection and analysis, ^{1,2}article drafting, ³supervision and review of manuscript

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ABSTRACT

Objective: To analyze Islamabad Blood Transfusion Authority data of 2015 and provide critical insights for policy formulation and advocacy.

Study Design: Multicentre retrospective study.

Place and Duration: The study was conducted by the Islamabad Blood Transfusion Authority in the Islamabad Capital Territory from Jan – Dec 2015.

Materials and Methods: The IBTA developed a pre-tested modified version of the WHO Global Database on Blood Safety (GDBS) questionnaire which was adapted to the local requirements. 19 licensed blood banks were contacted and data collection was 100%. Data analysis was done through SPSS statistics.

Results: In 2015, 65% of 65,376 blood donations were collected by just two out of the 19 licensed blood banks, of which only 8.23% were from non-remunerated volunteers, rest being family or replacement donors. Reactivity for transfusion transmissible infections was nearly 6%. The screening method was upgraded to at least ELISA (enzyme-linked immunosorbent assay) and donor/recipient haemovigilance system instituted for the first time. Licensed blood banks now prepare all three blood components (red cell concentrates, fresh frozen plasma, platelet concentrates). Whole blood collection is discouraged. Approximately 6% stocks were discarded due to transfusion transmitted infection (TTI) positivity or product expiry.

Conclusion: The analysis brought forth, previously unsuspected insights which can guide future policy making. It is apparent that many licensed blood banks do not have enough workload to justify their existence on turnover/cost-effectiveness basis. The Islamabad Regional Blood Centre to be constructed in 2017 will fulfill the needs of such small blood banks. Encouragement of voluntary blood donations, automation, and the institution of IT based, online, real-time data management stand out as the pressing needs of the sector. Measures are underway to harmonize IBTA policies and provincial blood transfusion regulations, with global norms and standards.

Keywords: Blood, Authority, Pakistan, Data

Introduction

The World Health Assembly has passed more than 25 resolutions on various aspects of blood safety since 1975.¹ The resolutions essentially urge the Member States to promote the development of national blood transfusion services based on voluntary non-remunerated blood donations and enact effective

legislation which should govern operations of the blood transfusion services. In Pakistan, the blood transfusion legislations were developed between the period 1997-2004 in the various provinces and regions² as shown in figure 1. Approval and enactment of the law requires a Blood Transfusion Authority to be established as a truly operational

regulatory authority. The regulatory authorities in the developed countries are either specific bodies or part of other health regulatory organization and include the European Blood Inspection System (EuBIS),³ Health Sciences Authority-Blood Services Group of Singapore,⁴ National Blood Authority of Australia,⁵ Medicines & Healthcare products Regulatory Agency of the UK,⁶ etc.

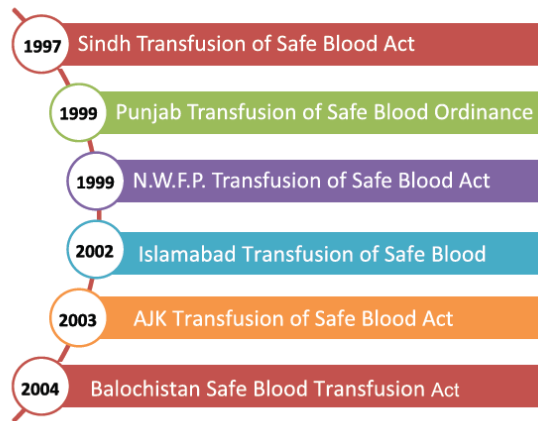


Fig. 1: Blood safety legislations in Pakistan

The federal capital Islamabad (1,165.5 km²) has an estimated population of 2 million. Compared to the other parts of the country, the Islamabad Capital Territory (ICT) has a better health care infrastructure. It has more than 25 public and private hospitals of variable size. The large tertiary care hospitals are modern amenities with quality health care, education, and research facilities. The blood regulatory body for Islamabad, the Islamabad Blood Transfusion Authority, was established in 2005, through the ICT Blood Safety Ordinance promulgated in 2002.⁷

Following the devolution of the health sector in June 2011 under the 18th constitutional amendment,⁸ the Authority was revived by the Ministry of National Health Services in 2013.⁹ Since then, the Ministry has taken the initiative to support the strengthening of the transfusion sector through regulation. This included the development of national blood policy, standards and guidelines and the operationalization of Blood Transfusion Authority in Islamabad. The functions of the Islamabad Blood Transfusion Authority include data collection, management, analysis and reporting for planning and evaluation of services. Accordingly, after its revival, the IBTA registered/licensed blood banks and data collection was streamlined through a standardized data collection tool. Data have been compiled for the year 2015.

This paper provides an overview on the general status of blood safety in the Islamabad Capital Territory based on the data of 2015. It will empower the policy makers to evaluate the situation and monitor its development in relation to other provinces and to regional trends in neighboring countries as

well as assisting them in the planning of research and in developing appropriate strategies to address the needs.

Materials and Methods

The Islamabad Blood Transfusion Authority is mandated to collect data from all the blood banks in its jurisdiction. The data were collected for the year 2015 and a pre-tested modified version of the WHO GDBS¹⁰ (Global Database on Blood Safety) questionnaire was used. This questionnaire was originally developed by the WHO Blood Safety Unit in 1998 in collaboration with regional offices and was based on the WHO Aide-Mémoire for National Health Programmes. The questionnaire was adapted to the local requirements and was further elaborated to allow a complete mapping of blood establishments in ICT.

The questionnaire was sent to all 19 licensed blood banks¹¹ in the ICT region through the IBTA Secretariat at the end of December 2015. The submission of data was timely and duly filled forms were returned by all the blood banks in January 2016. However, data errors and inconsistencies were common and corrected after follow-up. SPSS version 20 (IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.) was used to enter data and tables and graphs were prepared accordingly.

Results

Among the 19 IBTA licensed blood banks functioning in the Islamabad Capital Territory, eleven are in public sector and eight in the private sector. A total of 65,376 whole blood donations were collected in 2015. About 75% of the blood supply of the ICT is collected by three large blood banks, two of which are in the public sector. The contribution of the remaining 16 blood banks is only about 25%. The number of donations in these 16 blood banks range from 186 to 3,075 donations with a total blood collection of 18,335 (Table 1).

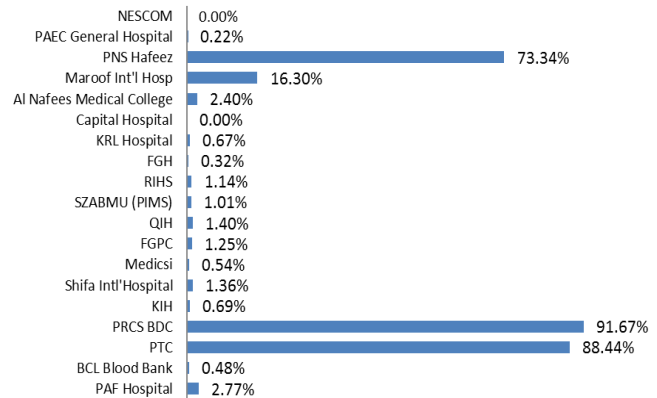
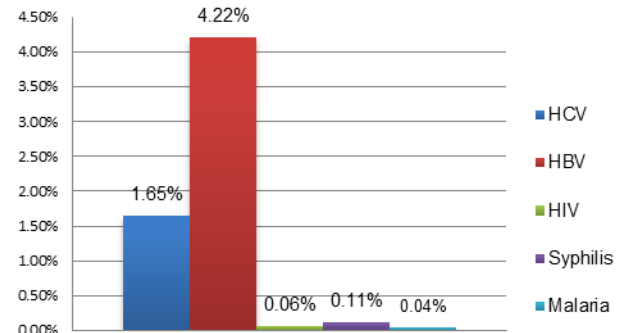
The number of replacement donations was 59,986 (91.75%) while 5,390 (8.25%) were voluntary non-remunerated blood donors (VNRBD). Breakdown of one-time voluntary donors and regular voluntary donors was not available. Blood from professional / paid donors was not collected by any blood bank. The voluntary blood donations in individual blood banks varied significantly. Pakistan Red Crescent Society (PRCS) Blood Donor Centre with 93.46% (n=2,857) has the largest share of voluntary donations from their total collections (n=3,057). PAF Hospital blood bank had 89.61% (n=500) voluntary donations and PNS Hafeez Hospital blood bank had 31.02 % (n=340) voluntary donations (Figure 2). However, the total voluntary donations of these three blood banks were 68.65% (3,697) of their total donations in the reporting period. Seven of the 19 blood banks did not have any voluntary donors. The total contribution of voluntary donations from the remaining nine blood banks was 31.35% (n=1,688). The range of voluntary blood donations in these nine blood banks was from 0.18% to 4.28%.

Table 1: List of donations in individual blood bank

Name of Blood Bank	Public / Private	Annual Donations	Percentage
PAF Hospital Blood Bank	Public	648	0.99%
BCL Blood Bank, Ali Medical Centre	Private	622	0.95%
Pakistan Red Crescent Society Blood Donor Centre	Public	3,075	4.70%
Kulsum International Hospital Blood Bank	Private	1,483	2.27%
Shifa International Hospital Blood Bank	Private	14,702	22.49%
Medicsi Hospital Blood Bank	Private	186	0.28%
Federal Govt. Polyclinic Hospital Blood Bank	Public	4,962	7.59%
Quaid-e-Azam Int'l Hospital Blood Bank	Private	1678	2.57%
SZAB Medical University (PIMS) Blood Bank	Public	27,377	41.88%
Rawal Institute of Health Sciences Blood Bank	Private	349	0.53%
Federal General Hospital Blood Bank	Public	930	1.42%
KRL Hospital Blood Bank	Public	2,210	3.38%
Capital Hospital Blood Bank	Public	1,050	1.61%
Al Nafees Medical College Hospital Blood Bank	Private	205	0.31%
Maroof International Hospital Blood Bank	Private	560	0.86%
PNS Hafeez Hospital Blood Bank	Public	604	0.92%
PAEC General Hospital Blood Bank	Public	2,275	3.48%
Islamabad Medical Complex NESCOM	Public	764	1.17%
PBM Thalassaemia Centre	Public	1,696	2.59%

A total of 59,443 (90.9%) blood collections were processed into three components, i.e. Red Cell Concentrates (RCC), Fresh Frozen Plasma (FFP) and Platelet Concentrates. Only 5,933 (9.1%) blood collections were used as whole blood, mostly for neonates or infants. All the 19 blood banks reported 100% (n=65,376) testing for HIV, Hepatitis B and C infections. 13 blood banks also screened for syphilis and malaria. A total of 24,849 (38.01%) donations were screened for syphilis and 30,069 (46.0%) for malaria. The percentage of donations reactive for these five TTI markers is shown in Fig 3. 68% of the donations, i.e. 44,538 were screened by CLIA (chemiluminescence immunoassay) technique. 10 % (n=6,524) were tested by ELISA (enzyme-linked immunosorbent immunoassay) technique. 21.47% were screened by NAT (nucleic acid test) technology and only 0.86% (n=560) were tested by the manual devices. Among the five TTIs tested, 2,765 (4.22%) were tested reactive for HBV, 1,083 (1.65%) were reactive for HCV while

HIV was detected in 45 (0.06%) donors (figure 3). Syphilis was positive in 71 donors (0.11%) and malaria in 24 donors (0.04%).

**Fig. 2: Voluntary donations in individual blood bank****Fig. 3: Donations reactive for TTIs**

Regarding the data management practices, 26.3% of the blood banks had a Management Information System (n=5) while 73.7% (n=14) have no MIS and use manual registers.

Establishment of Hospital Transfusion Committee (HTC) was a mandatory licensing requirement. Therefore every licensed blood bank had a functional HTC and through the HTCs, haemovigilance systems have been established in all the licensed blood banks. The donor haemovigilance data showed that out of a total of 65,376 blood donations in 2015, 750 donors experienced adverse events (Table 2). These adverse events included 1,262 signs and symptoms which were all mild in nature. The common adverse events included slow pulse (18.9%), low BP (18.9%), fainting (8.2%), nausea (7.9%), sweating (17.2%) and skin pallor (13.6%).

Table 2: Donor haemovigilance

Reaction	Number	Percentage
Slow pulse	206	18.9%
Low BP	205	18.9%
Sweating	187	17.2%
Fainting	89	8.2%
Pallor skin	115	13.6%
Nausea	86	7.9%

Drowsiness	15	1.4%
Vomiting	189	17.34%
Cold extremities	62	5.6%
Haematoma	5	0.5%
Multiple pricks	43	3.9%
Shortness of breath	25	2.3%
Vasovagal	5	0.5%
Headache	10	1.0%
Bruising	12	1.1%
Weakness	2	0.2%
Falling	6	0.6%

From January–December 2015, 173,168 transfusions took place in ICT including 2,170 whole blood, 61,004 RCC, 59,245 FFPs, 50,319 manual platelet concentrates and 430 aphaeresis platelet concentrates transfusion. 112 transfusion recipients suffered a total of 122 immediate transfusion reactions in the reporting period. 97 cases (49.7%) of allergic rashes, 23 cases (11.6%) of restlessness, 3 cases (1.5%) of headache, 2 cases (1.0%) of nausea, 2 cases (1.0%) of tachycardia, 11 cases (5.5%) of fever, 37 cases (18.7%) of shivering, 2 cases (1.0%) of shock, 1 case (0.5%) of hypertension, 1 case (0.5%) of dyspnea and 2 cases of respiratory distress (1.0%) classified as possible Transfusion-Related Acute Lung Injury (TRALI) were documented.

The wastage of blood was a significant finding in many small blood banks. Out of 65,376 blood collections, a total of 4,645 units were discarded. 3,281 (5.01%) blood units were discarded due to TTI positivity, 1.47% (n= 962) due to expiry date and other miscellaneous causes 0.61% (n=402).

Discussion

The objective of data collection in the blood transfusion services is to translate and interpret the information into actionable insights. The professional management of data and information lays the foundation for strengthening governance and leadership and development of an effective quality system. The main objective of IBTA to collect the detailed information of its licensed blood banks is to generate credible data to gain insight into the standard of practices of the blood banks and incorporate advancements in technology in the blood transfusion sector in Pakistan.

A very striking feature of the data collected in 2015 is that the distribution of the burden of work is very uneven. About 65% of the blood supply in ICT is generated from only two blood banks, one in the public sector and one in the private sector. The residual 35% of the total contribution is from the remaining 17 public and private blood banks. In other words, most of the blood banks functioning in the Federal Capital do not justify their existence as they do not have sufficient workload. In some of these 17 blood banks, less than one blood donation is collected per day for which expensive equipment is procured unnecessarily, technical manpower employed without enough work to keep them busy and automation which promotes blood safety cannot be practiced. This trend is equally prevalent in the public as well as the private sector. The existence of these small scale blood banks also means that these blood banks and their host hospitals remain dependent on the larger blood banks as

they cannot possibly ever have a sufficient inventory of the various blood components of all the blood groups. Currently, according to the prevalent blood safety legislations, blood banks cannot be closed down due to insufficient workload. But with the emergence of modern Regional Blood Centres in the country¹² and their reliance on regular voluntary blood donors, the unsustainable and unsafe smaller and medium sized blood banks dependent on the patients to provide blood donors would eventually fade out. For the interim period, the Authority has facilitated the smaller sized blood banks to develop linkages with larger sized blood banks to prevent the wastage of blood and components.

The situation in ICT regarding the source of blood supply is similar to the rest of the country. The 2015 data revealed that the predominant reliance remains on the patient's friends and relatives, the 'Replacement Donors'. This is despite the fact that Islamabad has the highest literacy rate¹³ in the country and also possibly the most sensitized populace. And in times of national crisis, droves of volunteers throng the blood banks for blood donations to save the lives of unknown recipients as witnessed in the 2005 earthquake disaster and many other natural and man-made calamities.^{14,15} This clearly implies that absence of voluntary blood donors for routine and regular emergencies is due to lack of a proper system to channelize the spirit of altruism in the society. Another main contributing factor for the shortage of voluntary blood donors and our reliance on the 'Replacement Donors' is the lack of a proper donor friendly infrastructure in our blood centres.

In Islamabad, except for one PRCS and Pakistan Bait ul Mal (PBM) Thalassaemia Centre, all the remaining blood banks are housed within the premises of large or medium-size hospitals. These hospital premises are invariably congested and overcrowded. And the blood banks functioning within these settings also have similar issues. The young and healthy people, the potential voluntary donors, are not inclined to visit such settings unless there is a family emergency. We thus have a situation where our potential voluntary donors usually present to the system as 'Replacement Donors'. As these blood banks, have basically evolved as 'blood manufacturing units' so due attention is not paid to the needs of the blood donors, the most important element of the transfusion chain. Therefore, in the absence of donor friendly environment and conditions, the experience of the individual donors is not very pleasant usually. Some ICT blood banks, however, do rely very significantly on VNRBDs, e.g. PRCS Blood Donor Centre, PNS Hafeez Naval Hospital Blood Bank and PBM Thalassaemia Centre but due to their low workload, the impact is negligible.

When IBTA initiated the regulation work in Islamabad in the last quarter of 2013, the situation regarding the component preparation was very unsatisfactory and only a few blood banks processed the collected whole blood into blood components. However, the situation has improved considerably since then due to the IBTA advocacy and capacity building of the management and technical leadership of the blood banks in addition to firm persuasion. Facilities for component production

and storage are now a mandatory requirement for licensing. In 2015, this figure is approximately 90%. There are however still a few blood banks which keep some percentage of their collections as whole blood. The reason is mainly the pressure from clinicians to issue whole blood or for use in neonates. The regular meetings of hospital transfusion committee are expected to improve this situation.

The blood screening for five TTI markers, i.e. HIV, HBV, HCV, Syphilis, and Malaria are mandatory under the clause 10, section (d) of the Islamabad Safe Blood Ordinance, 2002. However, the 2015 data indicate that 100% units are screened for HIV, HBV and HCV while 38% for malaria and 46% for syphilis. Last year only 25% of the donations were screened for syphilis and malaria. The management of the blood banks not screening for syphilis and malaria is being urged to initiate malaria and syphilis screening and they agree with the IBTA policy. But the resource constraints and administrative reluctance are cited as the main hurdle in the public sector. The screening data collected also provides information about the various serological screening techniques employed at the individual blood banks in the ICT. A large majority of the ICT blood banks are screening for HCV, HBV and HIV through the Chemiluminescence (CLIA) technology while rest of them through ELISA technology. During the course of 2015, one blood centre initiated the screening for these markers through Nucleic Acid Technology (NAT) also. The use of rapid devices for TTIs has declined due to IBTA advice in 2013-14, and they are now used in three centres only (for syphilis and malaria mainly) compared to 6 centres in 2014.¹⁶ The application of advanced technology and internationally certified kits for serological screening in blood centres in ICT augurs well for blood safety for the residents of Islamabad.

The TTIs statistics collected from the ICT blood banks reveal reactivity rate in Islamabad comparable to the national statistics¹⁷ with the exception of HBV which is on the higher side, almost 4%. This discrepancy is due to the screening of HBcAb in one of the larger blood bank in addition to the HBsAg testing. In all other blood banks, only HBsAg testing is conducted. The justification of doing HBcAb testing in a country like Pakistan is not clear or convincing. Although anti-HBcAb testing has a definite role in improving blood safety, the wastage of the blood units is a serious issue as up to 20% of the blood collections in Pakistani settings may have to be discarded on the basis of this testing.¹⁸ The subject blood bank has stopped this practice from August 2015, on the recommendations of the IBTA Advisory Board. The HBV figures for 2016 are therefore expected to be significantly reduced.

Prior to IBTA reactivation in 2013, due attention was not paid to documentation in the ICT blood banks. The data management methodology was mostly manual on registers. There is generally lack of a mechanism to facilitate the exchange of information and data between blood establishments and blood services on all aspects of blood supply management including processing, screening, storage, transportation, cold chain and

inventory management.¹⁹ The 2015 data reveals that 26.3% have now upgraded their data management practices to computer based MIS system.

The revived IBTA in late 2013 initiated awareness about the concept of haemovigilance among the ICT blood banks as the Authority strongly highlighted the significance of surveillance work. Training workshops organized for the capacity building of the blood banks comprehensively covered haemovigilance and guidance was provided to the blood bank management to initiate this practice in the blood banks and hospitals. A pre-condition of blood bank licensing was the establishment of a Hospital Transfusion Committee (HTC) with the representation of the senior management of the hospital and medical and surgical specialist as well as the nursing staff. The Authority made sure that the blood banks maintain records of adverse donor and transfusion reactions. During the inspections, it was observed that many blood banks did not have any record of transfusion reactions because according to them the blood supplied by them was so "safe" that no transfusion reaction occurred. As the transfusion reactions occur in even the best centres of the world so the Inspectors convinced the blood banks and ensured that records of adverse transfusion reactions are being maintained by the respective blood bank. The donor haemovigilance data of 2015 revealed that majority of the signs and symptoms reported were a slow pulse, low BP, vomiting, and fainting. These events are often avoidable, provided trained, vigilant and committed staff is available. Such vigilance systems allow monitoring of donor safety and assessment of the success of interventions designed to further improve donor safety.²⁰ The patient haemovigilance data showed the very low number of immediate adverse events if compared with anecdotal evidence from other developing countries.^{21,22} No haemolytic transfusion reaction and delayed transfusion reaction took place during the reporting period in ICT. The majority of the reactions were febrile, urticarial and allergic reactions. This is probably due to underreporting because of fear of reprisal or lack of awareness about recognition of the signs and symptoms of transfusion reactions. The figure may rise with more stringent follow-up from individual blood banks with the wards.

A significant amount of the blood collected is being discarded (6%) due to TTI reactivity. This figure can be reduced by strengthening the behavioral and physical screening step of the screening process. The percentage of blood being discarded due to expiry is also very high in some small-sized blood banks for obvious reasons. Wastage of the scarce blood resource is inexcusable and can be avoided by centralization and better coordination with large blood centres.

Conclusion

The Authority has demonstrated remarkable progress since 2013 with very limited resources. The roadmap IBTA followed was very structured and systematic and had a huge impact on the quality of blood transfusion services in the federal capital. The IBTA has also made plans to generate real time data on the

IBTA website as the pressing need of the sector. All the licensed blood banks will be provided a link through which they can update their blood inventory status online on the IBTA website. The IBTA is continuously coordinating with the provincial BTAs to build their capacity to eventually have uniform standards of regulation throughout the country. Collaboration between IBTA and the provincial BTAs will go a long way in improving the standard of blood safety in Pakistan.

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