ORIGINAL ARTICLE

Evolution of Blood Banks of Islamabad in Ten Years (2006 -2016)

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Author`s Contribution

[1]Lead & Corresponding Author, Study theme, Field work & 2016 Data collection
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ABSTRACT

Objectives: To assess the evolution of screening and associated practices in blood banks of Pakistan between 2006 & 2016 through a study in Islamabad. To identify shortcomings that still remain and discuss their fallouts on TTIs while suggesting practical improvements.

Methodology: Data was collected twice, once in 2006 and then 10 years later, using structured questionnaires and specifically prepared checklists. Both public and private sector Blood banks of Islamabad were included in our survey.

Results: Overall, practices were observed to have improved considerably with time. It was observed that 65% blood banks in Islamabad were screening samples for all five viral diseases i.e. HIV (Human immunodeficiency virus), Hepatitis B virus (HBV) and Hepatitis C virus (HCV), Malaria and Syphilis in 2016; reflecting significant improvement in TTI coverage as compared to 2006 when only 22 % blood banks were found screening for all five markers. Though variations in the parameters being screened, techniques being employed, procedures being followed and care being exercised by different blood banks still existed, improvement in these aspects was also evident.

Conclusion: The study revealed that screening & associated practices in vein - vein transmission chain have improved considerably in 10 years. Although both public and private sector blood banks were still found to have some issues even in 2016; the gaps identified in the screening practices are very bridgeable now. Bridging these gaps can go a long way in preventing TTIs.

Key Words: Vein to Vein Transmission Chain, Screening & associated practices, TTIs, HIV, HCV, HBV.

Introduction

Blood transfusion is a lifesaving intervention. "Sufficient supply of safe blood is a key part of an effective health care system and is essential for disease prevention".[1] Blood transfusion can help patients of various haematological disorders, traumas, major surgeries, bleeding ulcers, cancers, transplantations etc; it is however the most common mode of transmission of infectious diseases also; Haemophiliacs & Thalassemia patients needing regular blood transfusions are among those at maximum risk.

Every blood bag obtained and administered in pursuance of the recommended guidelines is a lifesaving intervention. However, blood administered without proper screening could be a root cause for spread of many diseases. Huge demand of blood for transfusion and high cost of proper screening are hence emerging as issues of great importance for public health. Even today WHO estimates that "globally more than 112.5 million units of whole blood are collected annually and 16 countries were not able to screen all the donated blood for one or more of the infections"[2] .Situation was far worse two decades ago when WHO estimated that globally up to 13 million (20%) blood donations annually were not being tested for HIV, HBV and HCV[3 and transfusion of unsafe blood was estimated to account for 8–16 million HBV infections, 2·3–

4·7 million HCV infections and 80000–160000 HIV infections each year.[4]

No wonder, blood safety was identified as one of the priority areas by WHO at the turn of this century when Proliferation of HIV and Hepatitis, through improper blood screening brought global attention to the importance of blood safety. WHO has been spearheading the drive towards improving safe blood availability with the goal of ensuring universal access to safe blood and blood products with added vigor since then.

For our part of world, WHO and our national guidelines recommend screening for following TTIs: Malaria, Syphilis, HIV, HBV and HCV.[5]

Very little research on screening practices in Islamabad or their impact on TTIs had existed till 2005. Our study assessed public and private sector blood banks of Islamabad, in terms of TTI coverage, screening parameters, availability of main and associated equipment/facilities, storage & general practices and proficiency of blood technicians. The purpose of our study was to compare the screening practices of blood banks in 2006 and in 2016 to assess the progress being made and highlight gaps in practices that still exist. Additionally, our study helps reflect on the performance of the Islamabad Blood Transfusion Authority (IBTA) which was constituted by the Government of Pakistan in 2005.[6] We studied blood banks of Islamabad in 2006 just after IBTA establishment when its guidelines had not been disseminated fully & implementation was yet to take effect and then again in 2016 after a 10 years gap when IBTA was firmly entrenched for a reasonable time and implementation of its rules was at advanced stage.

Methodology

This longitudinal comparative study was conducted in two phases, the first phase was conducted in 2006 and 9 registered banks of Islamabad were included, the second phase was conducted in 2016 and 20 registered banks of Islamabad were included. WHO and National guidelines for blood transfusion were our gold standard and a comparison was made, keeping these guidelines as benchmarks.

Before the commencement of both phases, Official permission from heads of all blood banks was taken. All interviewed subjects of the study were briefed on the purpose of the data collection and their verbal consent was obtained. An intensive desk study was carried out to ascertain international and national quality standards of blood screening for preparation of the data collection instruments.

Several recognized national and international specialists of this field, active in Pakistan were interviewed including Program Manager National AIDS Control Program, National Program Manager Blood Transfusion services, Scientist Emeritus National Institute of Health and Chairman of Islamabad Blood Transfusion Authority (IBTA). Questionnaire by WHO Global Database on Blood Safety[6] was adapted as a draft questionnaire to be used as prospective data collection instrument. Delphi technique was used to request specialists for comments. Refined questionnaire and observation checklist were pre-tested in two blood banks of Rawalpindi and were further refined accordingly.

All public and private institutions having their own blood banks in Islamabad formed our prospective sample. Blood banks not involved directly in manufacturing process of blood or blood products, i.e. not carrying out the blood screening themselves and using blood from other sources, were excluded. Technicians who were directly involved hands on in blood screening participated in the study.

Data was gathered through questionnaires and direct observation for assessing the TTI coverage, screening parameters, practices/policies, procedures, facilities, equipment/instruments, reagents and human resource. A check list was prepared to assess the knowledge, skills and practices of blood bank technicians.

In 2006, study was done in 9 registered Blood Banks of the capital city. All federal government blood banks, some autonomous organizations and Private sector blood banks were included. However, blood banks owned by Pakistan Air force, Navy and KRL were excluded because of restricted access. The administration of two blood banks belonging to autonomous (semi government) organizations also refused to participate in the study. Whereas; backed by IBTA in 2016, we were able to get data from all 20 registered Blood banks of Islamabad.

The first phase of the study was spread over a period of 11 weeks including one week for desk study, four weeks for field work, four weeks for data analysis and another two weeks for report writing whereas in spite of head-start from experience gained from first phase, the second phase took considerably longer (15 weeks) due to 8 week's field work in a significantly bigger sample size.

Statistical Analysis: Completed Questionnaires were reviewed and checked on daily basis and any missing/double or inconsistent entries were cross checked and corrected before data entry. After data entry, software package SPSS

version 10 was used for data analysis. Results were expressed in proportions, percentages and frequencies.

Results

In 2006 it was observed that only 2 out of 9 blood banks (22%) were screening for all five recommended parameters including Malaria and Syphilis whereas in 2016, 17 out of 20 (85 %) were found to be screening for all five recommended parameters (table I). All the blood banks reported 100% testing for HIV, Hepatitis B and C infections in both years; albeit using three different techniques.

Table no I: Blood Screening: Parameters Coverage		
Name of Assay	Blood Banks(2006) Total =9	Blood Banks(2016) Total =20
Malaria	2/9	17/20
Syphilis	2/9	18/20
HIV	9/9	20/20
HBV	9/9	20/20
HCV	9/9	20/20

Regarding screening equipment, our survey in 2006, revealed that 6 out of 9 (67%) blood banks employed ELISA (enzyme-linked immunosorbent assay) method. Remaining one third (33%) were performing screening tests on simple/rapid devices.

However, in 2016, 4th generation ELISA known as Chemiluminescence (CLIA) had been adopted in 11(60%) of blood banks, ELISA in 5 (25%), rapid devices in 3 (15%) and NAT/CLIA technology in one of the blood bank of Islamabad.

The availability of various main/peripheral screening equipment, allied facilities and consumable materials in public and private sector blood banks is shown in table 2. Main screening equipment was functional in almost all the blood banks. However, though provision for these might have been made at some point in time, some allied facilities/equipment were not functional in the small public-sector blood banks in 2006. The consumables like kits and reagents were available in adequate quantities in all public and private sector blood banks in both the surveys.

Various aspects of storage practices have been compared in table 3. In 2006, Five out of nine (55.5%) public blood banks were storing screened and unscreened blood units separately. Only four out of nine (44%) blood banks had separate storage for positive and negative bags. Similarly, seven out of nine blood banks had separate storage facility for blood units and kits. Most of the blood banks i.e. eight out of nine (89%) had the required capacity for storage of kits. It was found that

expired kits were being used in one out of nine blood banks. Whereas; in 2016 no malpractice in storage practices was observed.

Additionally, the blood banks were categorized based on annual workload and compared. During both the surveys; the Blood banks with larger workload were generally found to be better in terms of practices in (Table4).

Table no II: Availability: Main/Peripheral Screening equipment and Allied Facilities & Consumables		
Name	(Year 2006)	(Year 2016)
NAT	0/9	1/20
CLIA	0/9	11/20
ELISA	6/9	5/20
Simple/rapid	3/9	3/20
Functional ELISA equipment	5/6	5/5
Functional kits Refrigerators	9/9	20/20
Functional Microscope	9/9	20/20
Functional Generator/UPS	9/9	20/20
Functional Centrifuge	9/9	20/20
Functional blood refrigerators	9/9	20/20
Functional Temperature Alarm	8/9	20/20
Availability of kits & reagents	9/9	20/20

Table no III: Storage Practices Comparison		
Storage Practice	YEAR 2006	YEAR 2016
Separate storage for Screened & Unscreened units	5/9	20/20
Separate storage for Positive & negative units	4/9	20/20
Separate storage for Blood units & kits	7/9	20/20
Adequate Capacity for storage of kits	8/9	8/20
Not discarded Expired kit	1/9	0/20

Discussion

According to Larkin, 20% of global population has access to 80 % safe blood supply, whereas 80 % of world population has access to only 20% of safe blood supply.[4] Although home to a predominant majority of the worlds' population, limited research about developing countries is available. Whatever little information is available suggests that developing countries face considerable challenges in ensuring safe blood transfusions as practices are not in accordance with WHO guidelines for safe blood transfusions. TTI therefore, continue to mushroom in these countries.

Amongst other factors, economic constraint stands out as a major reason for compromise on supply of safe blood. According to Wake's study only 66% of developing and 46% of the least developed countries screen blood for HIV since such testing can double the basic cost of a unit of blood [7]. If blood from tainted donors is not rejected, it could lead to a serious proliferation of diseases like HBV, HCV, HIV, Malaria and Syphilis whose respective average Global Sero-prevalence in blood donors has been reported at 2.2%, 3.9%, 0.01%, 0.6% and 0.1%. [8]

Comparison of General Practices (Small VS large banks)				
	YEAR 2006		YEAR 2016	
	Small Blood Banks(04)	Large Blood Banks(05)	Small Blood Banks(17)	Large Blood Banks(03)
Availability of organization chart	0/4	2/5	0/17	1/3
Availability of SOP	1/4	3/5	17/17	3/3
Availability of WHO /National guidelines	0/4	2/5	17/17	3/3
Serve as reference lab	0/4	2/5	0/17	0/3
Incineration for waste disposal	3/4	5/5	17/17	3/3
Positive & negative units stored separately	1/4	3/5	17/17	3/3
Blood & kits stored separately	3/4	4/5	17/17	3/3
Pooling	1 /4	0/5	0/17	0/3
Internal Quality checks(IQC)	4/4	5/5	17/17	3/3
External Quality Assessment Scheme	0/4	1/5	0/17	1/3

Till the turn of this century, TTI has remained a major concern even in a relatively well-off country like China. Institute of Blood Transfusion of China developed a quality control program for testing all the 30 blood centers in Sichuan Province several years ago.[9] It was found that some of the centers made basic errors in testing samples for HIV, mostly due to non-compliance with standard operating procedures and inadequate quality control processes. Other developing countries; Pakistan being no exception, face similar challenges.

Pakistan has been ranked as the sixth most populated country where every year 3.5 million blood donations are collected [10]. Screening malpractices therefore, can lead to alarming increase in incidence of HBV, HCV and HIV.

Although Pakistan is a low prevalence country (0.1%) for HIV infection, yet it has been placed in high risk category. Moreover, the prevalence of blood-borne hepatitis virus infections are quite high in different areas of Pakistan and has been reported as HBV: 2.5% and HCV: 4.9%.[11] However, according to the latest study conducted in one of the biggest city of Pakistan, the prevalence amongst blood donors of HBV, HCV, HIV, Syphilis and Malaria was found to be 1.84%, 1.7%, 0.04%, 2.1% and 0.07% respectively.[12] This recent study has again raised concerns regarding the increasing trends including other TTIs especially Syphilis. Things can therefore, get out of hands quickly if transfusion malpractices are not taken seriously.

Studies conducted in Kenya had suggested that proper screening of blood leads to reduction in all TTIs specially the HIV which posed a major problem in that part of world.[13]

A study similar to ours previously conducted at Karachi showed that although 95% of blood banks had appropriate equipment and reagents to screen for hepatitis B, but only 55% screened for HIV and 23% for hepatitis C [14]. Lubsy et al also mentioned that practices at most Karachi blood banks fell well below WHO standards and in Karachi an average patient receiving two units of blood had a 10% chance of acquiring hepatitis C infection .[14] At least 91 blood banks in Karachi were closed down between 2004 to 2006 by Government for not adhering to safe practices. [15] As a result screening practices improved and a subsequent study conducted in 23 blood banks of Karachi revealed that donors were being screened for HIV, HBV, HCV and syphilis by all 23 blood banks, whereas; malaria was screened by all but one blood banks.[16]

In Islamabad similar intervention by Government came about in the form of IBTA in 2005. Our study found that 100% screening for at least HIV, HBV and HCV was being carried out in all the blood banks of Islamabad both in 2006 and 2016. Malaria and syphilis were mostly being ignored in 2006 though; only two out of nine (22.2 %) were fulfilling the criteria of screening for all five in spite of it being mandatory under the clause 10, section (d) of the Islamabad Safe Blood

Ordinance, 2002. Besides national guidelines, WHO guidelines also recommend screening for all the five diseases.[5] Results were much better in 2016 with 100% found to be screening for HIV, HBV and HCV and 89.47% & 95 % were found to be also screening for Malaria & Syphilis respectively (table I)

Techniques employed for screening have also improved since 2006 when none of the centers were doing CLIA, the figure has risen to 11 in 2016. The use of rapid devices for TTIs has declined to 15% from 33.33% and they are now used in 3/20 centers mainly for Syphilis & Malaria only compared to 3/9 centers using rapid device for all 5 diseases in 2006 (table 2). In 2006 Private sector fared better as all blood banks in this sector were found performing more elaborate ELISA testing for HBV and HCV whereas; half of the public sector blood banks omitted it because of the large number of anti-HCV and Hepatitis B reactive donors and the high cost involved in ELISA (table II). During the course of 2016, one blood center initiated the screening for these markers through Nucleic Acid Technology (NAT) also. This was an encouraging finding as automation and use of quality kits on advanced sophisticated equipment ensures better safety standards.

Proper Storage is an important aspect affecting the quality of transfusion blood. Early expiry of stored blood and kits may result from improper refrigeration. With WHO recommended guidelines as benchmark the shortcomings in storage practices of Islamabad blood banks were observed in 2006 where exactly half of refrigerators used for storage of kits were out of order in public sector blood banks, reflecting inadequate arrangements for repair and maintenance. But backup power supplies in the form of emergency generators were available in all public and private blood banks. In 2016 more robust and reliable two tier backup was available with addition of UPS on critical equipment in most blood banks.

Violations with respect to separate storage of kits and donated blood with further separation of storages for screened and unscreened blood units were also observed in year 2006 which confirmed earlier studies that proper blood storage and transportation facilities were not available in most blood banks which impacts quality and leads to wastage of significant proportion of the collected blood.[17]

Some of the problems regarding storage of donated blood were found resolved in 2016. Separate storage of kits and donated blood with further separation of storage of screened and unscreened blood units was observed in year 2016.

The percentage of blood being discarded due to expiry was generally noted to be higher in small-sized blood banks for obvious reasons in 2006 and again in 2016 e. g many small blood banks discarded up to 30% of their blood due to expiry.[18] This wastage of the scarce blood resource is inexcusable and can be avoided by centralization and better coordination with large blood banks. Some of this is attributable to poor data management and documentation.

All the studied blood banks were compared in respect of their annual loads as well. Blood banks were categorized as small (catering annual load up to 2000 bags) and large (catering annual load of more than 2000 bags). The results shown in table 4 clearly reflect that larger blood banks were better in almost all the general aspects like presence of SOP, organization charts, WHO guidelines etc. Similarly, higher percentage of large blood banks were using CLIA /ELISA and disposing waste by incineration as promoted by WHO guidelines. A very striking fact that came out of the data collected in 2016 is that the distribution of the burden of work is very uneven. About 65% of the blood supply in Islamabad 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 18 public and private blood banks. This evidence of uneven workload strongly supports the concept of the centralized model of blood transfusion services. Most blood banks functioning in the Federal Capital do not justify their existence as they do not have sufficient workload. In some of these 18 blood banks less than one blood donation is collected per day for which expensive equipment is maintained unnecessarily, technical manpower employed without enough work. Where swift transportation is possible, diversion of workload from some of these underutilized blood banks towards the two banks with major workload can be considered. Islamabad being a small city, a centralized model as against the current fragmented model of blood transfusion services delivery can be considered. This can lead to economies of scale which in turn permit further investment in infrastructure, equipment and automation. Centralization will not only be economical but will also promote blood safety. Duplication and wastages inherent in the current fragmented system can be prevented which in turn can improve blood safety further. Additionally, the centralized system will be far easier to regulate as well.

An important finding that we highlight through these studies is that both in 2006 and 2016 almost the entire screening was being performed post donation. This practice leads to wastage of blood, blood bags, consumables and time. More

importantly, lots of reactive blood bags accumulate which are not only difficult to dispose but are also extremely hazardous for health. Even in very few instances where it was being performed, rapid methods employed for pre-donation testing impaired the effectiveness.

An encouraging finding of our survey though; is that pooling was not being done in any blood bank in both years. This result is significantly different from similar study conducted in Karachi [14] which showed 16% blood banks were involved in pooling of the samples. This could be due to the fact that previous study was conducted several years ago in Karachi and at that time the prices of kits were much higher, so pooling was a common practice. But owing to the lowering of kit prices, pooling is rarely being practiced now.

Comprehensive Standard operating procedures (SOPs) were not available in the blood banks in 2006 as only two out of 9 blood banks had operating procedures for equipment and forms for cleaning, maintenance, and service. Handbooks and service manuals were not available nor any training records of laboratory staff and the practice of handling tubes and blood bags was found to be different compared to the written instructions. Availability of comprehensive SOPs had improved drastically by 2016; though gaps in their proper utilization by laboratory staff still remained. Education and training is fundamental to every aspect of blood safety. Lack of uniformity and standardization in formal /informal education for blood bank staff can result in a wide variation in quality in the vein-to-vein transfusion chain. But widely diverse educational background of blood bank technicians (either formally educated or just trained on the job in pathology laboratories and blood banks) was observed both in 2006 and 2016. However, another positive finding of our study was that technicians working in both public and private blood banks despite of extremely diverse educational background were adept, proficient and quite knowledgeable about blood borne diseases like Malaria, Syphilis, AIDS, Hepatitis C and Hepatitis B.

Prior to IBTA reactivation in 2013, due attention was not paid to documentation in the ICT blood banks. In 2006, the data was manually recorded on registers but in 2016 small workload blood banks still relied on manual system but bigger blood banks used a computer based Blood Transfusion Information System (BTIS).

WHO recommends that every blood bank should participate in External Quality Assessment Scheme (EQAS). Only one large Blood bank was found following it during both the surveys. Most blood banks were at best following minimum Internal Quality Control (IQC) checks. Deficiency in this area may be attributed to higher financial cost in participating in EQAS as all such program are to be arranged from abroad; there being no local EQAS program available in the country. We observed that insufficient economic resources restrict access to information and technology which create gaps in the local blood bank industry.

The total number of blood centers of Pakistan are estimated to be 1,830 of which 85% are hospital based. If hospital based blood centers of Islamabad constitute a representative sample, our study suggests transfusion practices of Pakistan in general to have improved significantly by 2016 to contribute in TTIs reduction. This is a remarkable picture for a developing country like Pakistan. However, Islamabad blood banks may not be true representative of hospitals in other areas of Pakistan, as Islamabad being the capital has the best possible facilities. Factors like higher socio-economic status and better literacy level of inhabitants of Islamabad also add bias to this sample. The improvement in other areas particularly in far flung remote districts of Pakistan may not be as encouraging though.

Conclusion

For all the limitations our study, it points out encouraging improvement while still bringing to fore various issues in blood screening practices and identifies gaps to be bridged. Bridging these gaps can go a long way in arresting transmission of the blood borne diseases in Pakistan.

Abbreviations: Enzyme Linked Immunoabsorbent Assay (ELISA), Venereal Disease Research Laboratory Test (VDRL), Statistical Package for Social Sciences (SPSS)

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