Blood Transfusion Services and Blood Safety of Blood Banks In Ben-Suef Governorate

Doaa Mahmoud Khalil a, El-Morsy Ahmed El-Morsy a Hesham Ahmed Nafady b and Lamiaa Saleh a

a Public health and community medicine department, Faculty of Medicine, Beni-Suef University, Egypt
b General surgery department, Faculty of Medicine, Beni-Suef University, Egypt

Abstract:
The goal of this study is to assess various aspects of blood transfusion services and blood safety and assure the adherence of the studied blood banks to the WHO global blood safety guidelines in Beni-Suef blood banks. This cross-sectional study was conducted in 2018 by in depth interview in the University hospital blood bank and the regional blood bank of Beni-Suef governorate. The officially recognized and the nationally coordinated blood transfusion service (BTS) found in both banks. There is a national blood policy and a national BTS management committee in both banks. There is a medical director responsible for the BTS and a national quality system in both banks. There is a mechanism for calculating total BTS costs in both banks. The approximate cost in US$ of producing one unit of whole blood is approximately 10 dollars (about 170 LE) and a system of stock control in both banks. Both blood banks are working under the WHO guidelines for global blood safety.

Keywords: Blood transfusion; safety; blood banks.

1. Introduction:
Growing demand for blood and blood products alongside with increasing cost and transfusion associated diseases led to number of studies in the late 1970s to review blood ordering and transfusion practice [1]. Moreover, nowadays there has been an increased attention on the potential side effects of transfusion and evidence approving the use of lower transfusion thresholds [2].

Since the application of blood transfusion into clinical practice, the appropriate use of blood transfusion is still debatable. It has been recorded that there are 30% of blood transfusion is used in elective surgery. So, awareness of side effects of blood transfusion is becoming more evident due to the increase of different indications of blood
transfusion and the increased knowledge of transfusion science nowadays [3].

Blood transfusion services play an important role in patients’ resuscitation and management [1]. Many units of blood ordered by doctors are underutilized but are reserved and thus are not available for other patients in need. This can cause stock problems for blood banks and loss of shelf life of blood [4].

Also studies from all over the world illustrated that an unintentional disuse of services conducted by blood bank leading to a great burden on its resources in the form of wastage of blood, manpower and reagents [3]. Big differences exist in transfusion practice between institutions and countries and even between the clinicians within the same facility [5].

In order to meet the needs of the patient suffering from acute blood loss, trauma and non-trauma designated centers should have a massive transfusion protocol (MTP) in place. MTPs facilitate the rapid delivery of the massive amounts of blood products necessary for hemodynamically unstable trauma patients [6]. One challenge is the prompt identification of the patient in need of MT, which should occur during the initial assessment of patients. outcomes [7].

It was an important principle of the National Blood Policy that adequate, safe, and effective blood products and services for Egypt were ensured in the entire country (including remote areas). This policy therefore set out the intention and commitment of the Government of Egypt (GOE) to develop a modern blood transfusion service which had the responsibility for the collection, testing, processing and distribution of blood and blood products to the entire country. This policy also identified the responsible regulatory body for blood transfusion activities in Egypt [8].

As blood transfusion saves lives and improves health, but many patients requiring transfusion do not have timely access to safe blood specially the injured patients. Providing safe and adequate blood should be an integral part of every country’s national health care policy and infrastructure, this study was conducted to assess various aspects of blood transfusion services and blood safety and assure the adherence of the studied blood banks to the WHO global blood safety guidelines in Beni-Suef blood banks.

2. Patients and Methods:

2.1. Type and time of study:

A cross-sectional descriptive study was conducted in 2018 to assess the blood transfusion services in the blood banks of Beni-Suef governorate.

2.2. Study Settings and data collection tool:
There are two blood banks in Beni-Suef governorate. The regional blood bank and university hospital blood bank both were included in the study for assessment of blood safety and transfusion services according to the global database on blood safety. The study was conducted by an in-depth interview with personnel responsible for the blood transfusion services in the studied blood banks.

The questionnaire covers the four major components of the WHO integrated strategy for blood transfusion safety [9] to ensure:

1. The establishment of well-organized, nationally coordinated blood transfusion services (BTS)
2. The collection of blood only from voluntary non-remunerated blood donors from low-risk populations
3. The screening of all donated blood for transfusion-transmissible infections, including HIV, hepatitis viruses, syphilis and other infectious agents
4. A reduction in unnecessary transfusions through the effective clinical use of blood, including the use of simple alternatives to transfusion (crystalloids and colloids), wherever possible.

The two blood banks were:
1. Beni-Suef University hospital blood bank is affiliated to the Ministry of Higher Education. It is located inside the faculty of medicine.
2. The regional blood bank is affiliated to the Ministry of Health and Population. It is located at the New Beni-Suef city at the east of the Nile.

2.3. Statistical analysis:
Descriptive statistics of categorical variables were presented as number and percent. The prevalence of communicable diseases in both banks was presented as percent (rate). Description of scale variables was done in the form of mean ±SD.

2.4. Ethical Considerations and Review:
Study protocol was approved by Faculty of Medicine, Beni-Suef University, Research Ethics Committee.

3. Results:
The results show that the officially recognized and the nationally coordinated blood transfusion service (BTS) found in both banks. There is a national blood policy, but it is more implemented in the regional blood bank than the university blood bank. There is a national BTS management committee in both banks. There is a medical director responsible for the BTS in both blood banks. Also, there is a national quality system in both banks. There is adequate number of trained administrative staff in and specific budget
provided for blood transfusion services in both banks.

There is a mechanism for calculating total BTS costs in both banks. The approximate cost in US$ of producing one unit of whole blood is approximately 10 dollars (about 170 LE) in both banks. Also, there is a system of stock control in both banks. There is partial shortage of the general supplies in the last 12 months in the university bank. Concerning the responsibility for the management of blood transfusion services, the governmental hospitals were responsible for more than 90% of the services and the private hospitals were responsible for the minority of the services.

There is a specific department responsible for all activities related to blood donors in both banks. All donors have a hemoglobin estimation done before donation in both banks. There is a system of blood donor counseling in both banks. There is a system of blood donor records in both banks (paper in the university blood bank but computerized in the regional bank). Most of donations are collected from family and replacement donors. The prevalence of transfusion-transmissible infections is calculated in the blood donor population in both banks.

Both banks have a national strategy on blood screening. There is a confidentiality of blood donors assured in the laboratory of both banks. There is a full-time availability of test kits/reagents in both banks.

All blood donations are tested for HIV, HBV (HBsAg), HCV and Syphilis. HIV tests are performed by EIA (ELISA). The distribution of prevalence of HIV (1%, 1%), HBV (2%, 1.5%), HCV (4%, 3.5%), syphilis (0.5%, 0.5%) and Chagas (0%) was almost equal in the university and the regional blood bank, respectively.

The total percentage of blood discarded after testing for transfusion-transmissible infections is about 5% in both banks. The compatibility testing routinely performed before transfusion in both banks. There was no participation of both banks in the external quality management on the either on the national or the regional levels. Moreover, there are standard operating procedures in both banks. The blood, blood products and reagents are stored in temperature-monitored cold storage equipment both banks. The temperature is monitored in boxes used for the transport of blood and blood products in both banks.

In addition, there is a national policy and/or guideline on the clinical use of blood for both banks. There is a system for monitoring/evaluating clinical transfusion practice (audit) in both banks. The post-transfusion reactions are monitored and
reported by both banks. The blood is transfused as whole blood constitutes 90% for all transfusion done by both banks but, there is no colloids available as alternative to blood products in both banks.

The percentage of hospitals with hospital transfusion committee was unknown for both banks.

The blood coagulation factors (e.g. Factor VIII, Factor IX, prothrombin complex concentrate) are partially produced by both banks but, there are no other fractionated plasma-derived medicinal products produced by both banks.

There are other facilities in Egypt for plasma fractionation and both banks referred the cases that need the plasma fractions to the blood banks in Cairo.

There is 7000±500 liters of recovered plasma in the university blood bank and 6500±450 liters in the regional blood bank but, there were 500 liter of the apheresis plasma in both banks.

Despite the availability of the WHO learning materials, Safe Blood and Blood Products, available and in use, there is a shortage in some of the training courses in the university blood bank but the training process in the regional blood bank is available at different levels (blood bank level, directorate level and the ministry level). There is availability of the WHO learning materials, the Clinical Use of Blood in both banks.

In spite of the presence of the national regulations/legislation and authority for covering blood transfusion, it is not widely applied in the university hospital blood bank but, it is well applied in the regional blood and supervised by the ministry of health. There is a system of regular inspection of blood transfusion services in both banks.

There is a computerized system for data management in the regional blood bank, but it is still under developing in the university blood bank. Both blood banks are in need for more training to increase the capacity building of human resources.

4. Discussion:

The previous results are highly adhering to the WHO guidelines and the report of the WHO that concluded that 68% of reporting countries (122 out of 179 of reporting countries) had a national blood policy. Overall, 58% of reporting countries (105 out of 181) had specific legislation covering the safety and quality of blood transfusion, including: 74% of high-income countries, 14% of middle-income countries and 14% of low-income countries (9).

This study reported that there is partial shortage of the general supplies in the last 12 months in the university bank and this problem
is widely spread all over the world even in the middle-income countries as reported by the WHO in 2013 as the irregular supply of test kits was one of the most commonly reported barriers to screening all over the world (10).

On adherence to the WHO guidelines [11], this study found that there is a specific department responsible for all activities related to blood donors in both banks. All donors have a hemoglobin estimation done before donation in both banks. There is a system of blood donor counseling in both banks. There is a system of blood donor records in both banks.

The current results are agreed with the trend of the international increase of the unpaid voluntary blood donation. An increase of 10.7 million blood donations from voluntary unpaid donors has been reported from 2008 to 2013. In total, 74 countries collect over 90% of their blood supply from voluntary unpaid blood donors; however, 71 countries collect more than 50% of their blood supply from family/replacement or paid donors and the highest increase of voluntary unpaid blood donations is in the South-East Asian Region (75%) and African Region (37%). The maximum increase in absolute numbers was reported in the South-East Asia region (5.3 million donations), followed by the Western Pacific Region (2.8 million donations) (12).

This study showed that both banks have a national strategy on blood screening. There is a confidentiality of blood donors assured in the laboratory of both banks. All blood donations are tested for HIV, HBV (HBsAg), HCV and Syphilis. HIV tests are performed by EIA (ELISA). The total percentage of blood discarded after testing for transfusion-transmissible infections is about 5% in both banks. The compatibility testing routinely performed before transfusion in both banks. Our results showed that both banks follow the WHO recommendations that all blood donations should be screened for infections and ABO compatibility prior to use. Screening for HIV, hepatitis B, hepatitis C, and syphilis should be mandatory and follow the quality system requirements (9).

In this study the reported prevalence of HIV (1%) is agreed with its prevalence in the low-income countries (1.08%) on contrary to the high-income country prevalence (0.003%). In this study the prevalence of HBV among the screened donors is near to the prevalence of HBV in the Lower middle-income countries (1.65%) and much lower than that of low-income countries (3.7%). Unfortunately, the study shows that the highest prevalence of the infectious diseases was for the HCV in both banks about 4% on the other hands the WHO reports showed that the highest prevalence of HCV among the screened blood donors in the low-income countries was 1.8%. The prevalence of syphilis (0.5%) in this study is
follow the distribution of syphilis among the screened blood in the Lower middle-income countries (0.58%) and lower than its distribution in the low-income countries (0.9%) (13).

These differences reflect the variation in prevalence among population who are eligible to donate blood, the type of donors (such as voluntary unpaid blood donors from lower risk populations) and the effectiveness of the system of educating and selecting donors. Fortunately, this study demonstrated that there is a national policy and guidelines on the clinical use of blood for both banks. There is a system for monitoring/evaluating clinical transfusion practice (audit) in both banks. The post-transfusion reactions monitored and reported by both banks.

The previous results followed the WHO recommendations for the development of blood transfusion systems to monitor and improve the safety of transfusion processes and to avoid the unnecessary transfusions and unsafe transfusion practices that expose patients to the risk of serious adverse transfusion reactions and transfusion-transmissible infections. Also, the unnecessary transfusions also reduce the availability of blood products for patients who are in need as the injured patients (14).

This study showed that the blood coagulation factors (e.g. Factor VIII, Factor IX, prothrombin complex concentrate) are not produced by both banks and this shortage in blood coagulation factors is also proved in a report done by the WHO in 2017 that concluded that the capacity to provide patients with the different blood components they require was still limited in low-income countries: 50% of the blood collected in low-income countries is separated into components, 59% in lower-middle-income countries, 92% in upper-middle-income countries, and 97% in high-income countries (15).

There are fractionated plasma-derived medicinal products produced by both banks and this result follows the report of the WHO that Only 51 of 180 reporting countries produce plasma-derived medicinal products (PDMP) through the fractionation of plasma collected in the reporting country. A total of 96 countries reported that all PDMP are imported, 17 countries reported that no PDMP were used during the reporting period (16).

5. Conclusion and Recommendations

In conclusion, both blood banks are highly adherent to the WHO guideline but, it is recommended to increase the training courses to increase the capacity building among the personnel in both banks.
6. **Study limitations:**

The study was conducted in Beni-Suef governorate only and its results cannot be generalized on all blood banks.

7. **References:**

1. Olawumi, H. O., & Bolaji, B. O. (2006). Blood utilization in elective surgical procedures in Ilorin. Tropical Journal of Health Sciences, 13(1), 15-17.
2. Boralessa, H., Goldhill, D. R., Tucker, K., Mortimer, A. J., & Grant-Casey, J. (2009). National comparative audit of blood use in elective primary unilateral total hip replacement surgery in the UK. The Annals of The Royal College of Surgeons of England, 91(7), 599-605.
3. Khoshrang, Hossein, Madani A.H, Roshan Z.A, and Ramezanzadeh M.S. (2013). Blood Transfus, 11: 123-7”.
4. Hall, T. C., Pattenden, C., Hollobone, C., Pollard, C., & Dennison, A. R. (2013). Blood transfusion policies in elective general surgery: how to optimise cross-match-to-transfusion ratios. Transfusion Medicine and Hemotherapy, 40(1), 27-31.
5. Leahy, M. F., Hofmann, A., Towler, S., Trentino, K. M., Burrows, S. A., Swain, S. G., & Farmer, S. L. (2017). Improved outcomes and reduced costs associated with a health- system–wide patient blood management program: a retrospective observational study in four major adult tertiary- care hospitals. Transfusion, 57(6), 1347-1358.
6. Nunez TC, Young PP, Holcomb JB and Cotton BA, (2010). Creation, implementation, and maturation of a massive transfusion protocol for the exsanguinating trauma patient. Journal of Trauma, 68: 1498-1505.
7. Donald, C. L., Johnson, A. M., Cooper, D., Nelson, E. C., Werner, N. J., Shimony, J. S., & Flaherty, S. F. (2011). Detection of blast-related traumatic brain injury in US military personnel. New England journal of medicine, 364(22), 2091-2100.
8. National blood policy in Egypt (2007) available at http://www.mohp.gov.eg/?fbclid=IwAR2b0br 8oK5F___Q42_4HOIgVwDhpRpxDdd-iJL2wnF_G-wpcSUNvbr7Ul7w Accessed March 2020
9. World Health Organisation: Global Status Report on Blood Safety and Availability. Geneva, (2016). http://www.who.int/bloodsafety/global_database/en/ Accessed January 2020
10. World Health Organization: Blood Transfusion Safety — Part I. Geneva; (2015). http://www.who.int/bloodsafety/en/ Accessed January 2020
11. World Health Organization: Blood Transfusion Safety , Geneva; (2013).
http://www.who.int/bloodsafety/en/ Accessed May 2019
12. Bloch, E. M., Vermeulen, M., & Murphy, E. (2012). Blood transfusion safety in Africa: a literature review of infectious disease and organizational challenges. Transfusion medicine reviews, 26(2), 164-180.
13. Liu, Y. D., & Flynn, G. C. (2016). Effect of high mannose glycan pairing on IgG antibody clearance. Biologicals, 44(3), 163-169.
14. Van Hulst, M., Sibinga, C. T. S., & Postma, M. J. (2010). Health economics of blood transfusion safety–focus on sub-Saharan Africa. Biologicals, 38(1), 53-58
15. World Health Organization (WHO): Global Collaboration for Blood Safety (2018). Blood Transfusion Safety. https://www.who.int/bloodsafety/gcbs/en/ Published 2019. Accessed April 8, 2019.
16. World Health Organization: Global Database on Blood Safety. Geneva; (2011). https://www.who.int/bloodsafety/global_database/GDBS_Summary_Report_2011.pdf?ua=1. Accessed May 2020