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Introduction to Iranian Blood Transfusion Organization and Blood Safety in Iran

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Abstract

Currently, in Iran blood transfusion is an integral part of the national health system and blood donation is voluntary and nonremunerated and blood and its components may not be a source of profit. In 1974 and following establishment of Iranian Blood Transfusion Organization (IBTO) all blood transfusion activities from donor recruitment to production of blood components and delivery of blood and blood products were centralized. The activities of IBTO are followed the laws and regulations of Ministry of Health and criteria of Iran National Regulatory Authority. In order to meet the country's demand in 2007 IBTO collected about 1.7 millions units of blood from the population of 70 millions. In 1979 coincided with the Islamic revolution the number of blood units collected throughout the country were 124,000 units or 3.4 unit per 1000 population whereas after about 30 years this increased to about 25 unit per 1000 population. With improving the pool of voluntary donors, IBTO has been successful in excluding "family replacement" donation since 2007 and reached to 100% voluntary and nonremunerated blood donation. Currently more than 92% of blood donors in Iran are male and contribution of female in blood donation is less than 8%. Although all donated blood in Iran screened for HBsAg since 1974, screening of blood units for HIV and HCV started since 1989 and 1996, respectively. The frequency of HBV infection in blood donors showed a significant decline from 1.79% in 1998 to 0.4% in 2007. The overall frequency of HCV and HIV infection are 0.13% and 0.004% respectively.

Keywords: *Blood Transfusion, Blood donation, Blood safety*, *Iran*

Introduction

As it is ratified in Seventy-Nine Session of WHO in Geneva on 1987, availability of blood and blood components is recognized as one of the most important goals of any health care system around the world (1). Fortunately, years before the above session, Iranian Blood Transfusion Organization (IBTO) was already established. The main responsibility of IBTO is the timely and adequate supply of safe blood and its components. However, the establishment of IBTO was not the beginning of efforts in the field of transfusion in Iran. Before establishment of IBTO since 1940s Iran Red Crescent (formerly named as the Red Lion and Sun Organization), university units and private sectors had started their activities to meet hospital blood demands (2-5). Despite some efforts to use nonremunerated donors, historical records show that remunerated blood donation particularly at 1950s and 1960s played a major role to supply blood and blood components to hospitals such as Imam Khomeini Hospital, Sina Hospital, and Razi Hospital. It was not until 1960s that safe blood advocacy strengthened and voluntary donation was encouraged. Later by increasing the number of blood donation centers and screening donated blood for pathogens enabled treatment centers in cities such as Shiraz, Ahwaz, Tabriz, Mashhad, and Isfahan to embark on big surgeries using safe blood (6, 7). The blood donation statistics in 1978-9 at the peak of the Islamic revolution show an increasing demand for blood. At that time due to injury of a considerable number of people in their clash with the Shah's police led to the raise of the number of voluntary blood donors. This trend was continued after Iraq imposed an eight year long war against Iran. This in turn led to the requirements for establishment of new clinics and

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hospitals in the south and west of the country along the Iraq's border. Obviously these centers were in need of blood to provide services to the combatants and injured civilians. People behind the frontlines, hoping to help the combatants in one way or the other, waited hours' long queues to donate their blood. Despite the long period of the war blood supplies had been always adequate to meet needs of the war related injuries. These events played a major role in establishment of the culture of blood donation among Iranian.

It is not of course just these two events that have made Iran superb in the Middle-East region as far as safe and adequate blood supply and nonremunerated voluntary blood donation are concerned. The benevolence culture of Iranians on one hand and their religious beliefs inspired with their adherence to the holy book of Koran stating "*if any one saved a life, it would be as if he saved the whole humanity*" (8) plus the culture of Ashura with the mourning anniversary commemorating the high status of Karbala martyrs and Imam Hussein (PBUH) also play critical role. As a matter of fact, Iranians consider blood donation a religious and faith-based duty included in their life calendar as a vow to God.

IBTO was established in 1974 as a centralized organization with its provincial blood centers affiliated to the central headquarters within the scope of laws, regulations and guidelines. In 1984 the new IBTO constitution in which it was assigned the sole responsible body for ensuring supply of safe and adequate blood was ratified by Iran parliament and the Red Crescent was entitled to hand over all its centers, duties and human resources involved in transfusion activities to IBTO. IBTO was assigned the responsibility to act on its constitution according to which beside being a service providing entity ensuring blood demand of the country it is also allowed to embark on educational and research activities addressing medical groups and establish reference labs for delivery of lab services in the fields of HLA, coagulation, serology, and so on.

The High Council of IBTO is the main policy maker in IBTO organization chart which is chaired by the Minister of Health consisting of five specialists in the field of transfusion medicine and relevant disciplines. Out of these five one is selected as the managing director of IBTO responsible for executing responsibilities for a three year term. The activities of IBTO are followed based on the laws and regulations of Ministry of Health and under its supervision in simultaneous abidance to definitions and criteria of Iran National Regulatory Authority. All donor recruitment, blood collection, and testing procedures and fundamentally the establishment of any blood centers in the country require the approval and audit of IBTO so that compliance with the national standard across the whole country is guaranteed.

Current situation of blood and blood components supply

The availability of a safe blood supply is critical for both medical interventions and national security (9). In order to meet the country's demand in 2007 IBTO collected about 1,735,008 units of blood from the population of 70 millions (Fig. 1). Although more than 98% of donated blood converted to varieties of components, it should be mentioned that both whole blood and blood components delivered free of charge to the patients in need of such products. In 2003, approximately 25% of the national blood supply was used for thalassemic patients (10).

In 1979 coincided with the Islamic revolution the number of blood units collected throughout the country were about 124,000 units or 3.4 unit per 1000 population whereas after about 30 years this increased to about 25 unit per 1000 population. A significant growth rate (44.2%) in blood collection was seen between the years 1984-1987 coincided with the war imposed by Iraq on Iran (Fig.1). Trend of blood components production included Packed Cell (PC), Fresh Frozen Plasma (FFP) and Platelets (PLT) has been shown a significant increase since 1990, although there is a decrease in production of Cryoprecipitate (Cryo) (Fig.2). This is due to

increased use of clotting factors concentrate by hemophilia patients.

It is known that donors who give blood voluntarily with altruistic motivation have the lowest prevalence of transfusion transmitted infectious (TTI) as compared to family replacement and paid donors (11-13). Therefore, IBTO implemented a long term plan to achieve 100% voluntary blood donation. This plan includes educating people about importance of blood donation via media or opinion leaders and face to face education, direct communication with safe blood donors in order to retain them and expansion of blood collection centers. Currently 283 fixed blood donation sites are available throughout the country which collected 80% of blood and the remaining of blood collected by mobile teams in work places, educational institutes and cities not served by fixed sites. With improving the pool of voluntary donors, IBTO has been successful in excluding family replacement donation system since the year of 2007 and reached to 100% voluntary and nonremunerated blood donation. The 2006 WHO data reveals only 54 countries had reached the goal of collection 100% of their blood supplies from voluntary non remunerated donors and many developing and transitional countries still rely on unsafe family replacement donors and paid donors (14).

Regular donors have been shown to have lower incidence of infectious diseases than first time donors (15-16). According to IBTO standard operating procedure regular donors are individuals who donate blood at least twice a year. In Iran, 40% of all blood was collected from regular blood donors during the year 2007. Analysis of the 2007 IBTO data shows that 21-30 yr old males are the major blood donors. It is important to notify that the permitted age for blood donation is 18-65 yr old in Iran. Furthermore women are 8% and men are 92% of all blood donors at the present time. As more than 28% of females are deferred and approximately one-forth of them are due to low hemoglobin (17), a short term iron supplementation program has been implemented for female blood donors since 2006.

Since all blood donors should be carefully screened to minimize the risk of adverse consequences to the donor and to the recipient of the blood, in Iran all volunteers are interviewed by a physician about suitability for blood donation. The screening process includes two steps, the first step is the donor history questionnaire and the second step is a brief physical examination. In 2007, 19% of all volunteers who intended to donate blood, deferred to ensure donor and blood safety.

Since Iran is one of the most disaster prone countries in the world (18), it is important to provide safe blood following national or local disaster. In recent years the IBTO was successful in providing sufficient blood supply in the period of disaster. During the first four days of the devastating Bam earthquake blood collection increased about 7-fold, although there were some short comings in management of response plan (19).

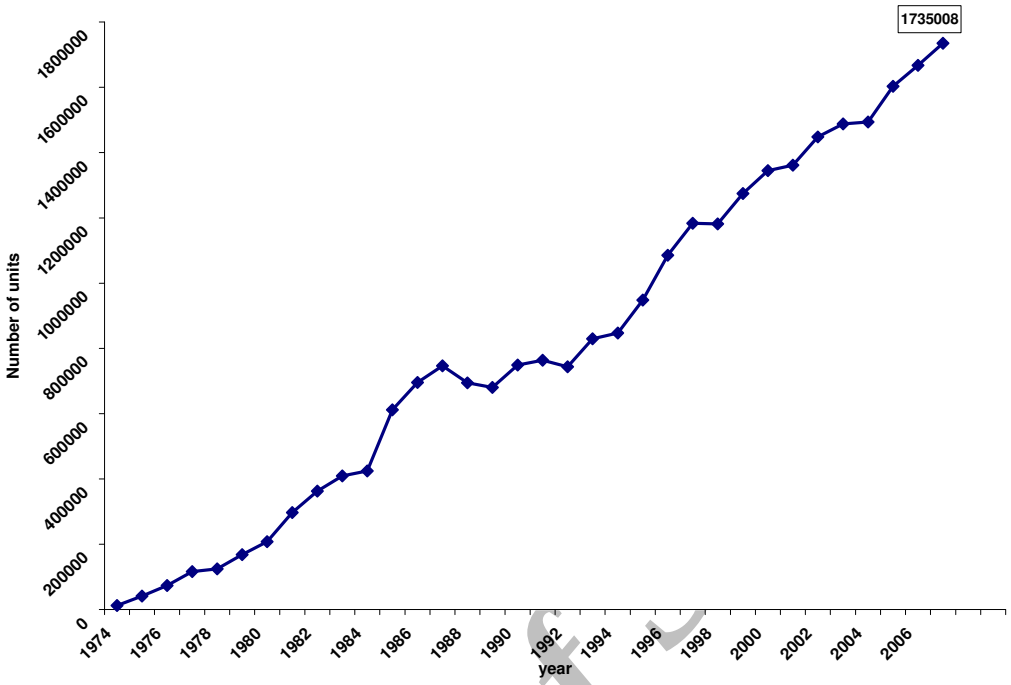

Fig. 1: Trend of Blood Donation in Iran, 1974-2007

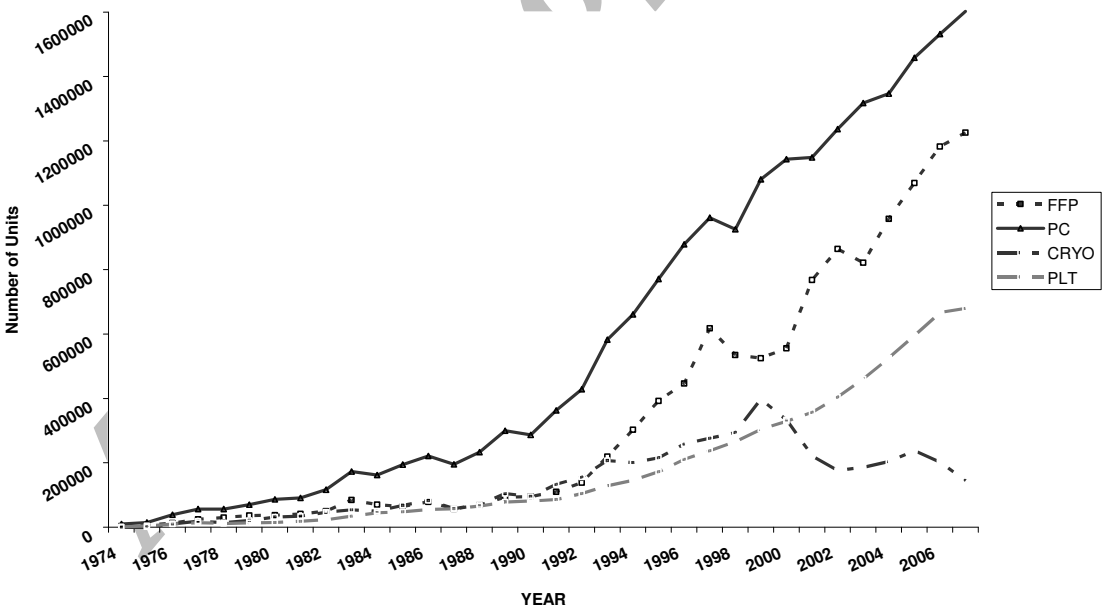

Fig. 2: Trend of Blood Component production in Iran, 1974-2007

Blood safety in Iran

The essential purpose of IBTO is a sufficient supply of blood and blood components with maximum efficiency and minimum risk to the donors and recipients. The main purpose of donor selection procedures including donor interview and physical examination by a qualified physician, testing procedures including evaluation of hematocrit/hemoglobin, blood pressure, pulse, temperature and weight are protection of the donors and minimize the adverse reaction from blood donation. Improvement in donor se-

lection and use of sensitive and qualified serologic tests has drastically reduced the risk of TTI to recipients in recent decades. In Iran screening of blood donations for HBsAg became mandatory since 1974. However screening of blood units for HIV and HCV started from 1989 and 1996, respectively. For improvement of the blood safety anti-HIV I/II test was changed to HIV Ag/Ab in 2005. The prevalence of HTLV infection is evaluated in 1993 and according the results of this research anti-HTLV I (and then Anti-HTLV I/II) became mandatory in north east of Iran in Khorasan provinces.

The safety of blood supply and risk of potential risk of TTI among the recipients of blood and blood products can be estimated by monitoring the prevalence of viral markers among the donor population. The frequency of HBV infection in blood donors showed a significant and impressive decline from 1.79% in 1998 to 0.4% in 2007 (20) and in comparison with prevalence of HBV infection in general population which is 2-3%, it seems to be a good achievement and it is predicted to improve in next ten years because recruitment of significant of vaccinated young donor are coming for donation (21-22). The overall frequency of HCV infection in recent 4 years was 0.13% and declined from 0.14% in 2005 to 0.12% in 2007 (20). The prevalence of HCV infection in general population has estimated between 0.3-1% (23). The prevalence of HIV infection in blood donations in Iran was 0.004% in 2007. Whereas the frequency of HIV infection had rise in general population the prevalence of HIV infection in blood donations during 2004-2007 was gradually decreased from 0.005% to 0.004% (24-26).

Various factors are contributed to the decline of prevalence of TTI and the most important contributing factors are as following:

-Use of uniform regulations and standards, donor questionnaires, Standard Operating Procedures (SOPs), guidelines, testing kits, blood bags, instruments, validation of procedures and training courses across the country.

-Efficient donor selection, similar deferral criteria and self-deferral procedure since 1997, confidential unit exclusion since 2002, removing replacement donation, increasing in number of regular donations, educational efforts to increase public knowledge on TTI, improvement in automation, data registry of blood donors with history of screening positive results and hepatitis B immunization.

-Usage of high sensitivity and best quality screening test kits, uniform confirmation procedure, similar proficiency and technical capabilities of screening laboratories and external quality assessment

-Regular audits and inspections by internal auditors and external inspectors.

Although currently IBTO is evaluating implementation of a NAT system for improvement the blood cellular components safety, and implementation of an efficient look-back and haemovigilance system can be contributed to improve safety of blood and blood products (20).

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