

Iran National Blood Transfusion Policy; Goals, Objectives and Milestones for 2011-2015

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Abstract

Transfusion of blood and its components/derivatives is a life saving medical intervention. However, this life saving procedure depends mainly on the availability of sufficient blood and its components in national health sector. Therefore the overall safety of transfusion medicines including the safety of blood and its available components and the appropriate use of these components would directly influence the health care services. To reach to an optimal blood safety, strategies should be defined and implemented in a timely manner. These strategies should include all steps of “vein to vein” chain from blood donor recruitment to appropriate use of blood and blood components. In order to reach such goals Iranian Blood Transfusion Organization has defined essential strategies for developing a suitable blood transfusion system in Iran which are briefly described.

Key words: Blood transfusion, safety, policy, Iran

Introduction

Iran, a country with a population of over 74 millions, is one of the most populated countries of the Middle East. Due to substantial investments by the government of Iran on health care system in past decades the country now enjoys a fairly advanced health system infrastructure. Blood and blood components are essential and life saving components of today medical interventions. In addition to support patients suffering from cancer, blood diseases, trauma and emergencies transfusion services in Iran are also used to support advanced medical and surgical procedures e.g. cardiovascular surgery, neurosurgery and transplantation [1-2].

Despite the essentiality of blood and blood components for management of patients especially in low resourced countries, according to WHO statistics [3], about 48% of around 92 million blood donations, which are collected annually worldwide from all types of blood donors (voluntary, family/ replacement and paid), are collected in high-income countries when these countries are home to only about 15% of the world's population. On the other hand residents of 43 countries in Africa with more than 12% of the world population collect

only 4.3% of the global donations. Although there is a general consensus that blood donated by non remunerated volunteers has the highest level of safety, less than 25% of the national blood supplies are donated by voluntary blood donors in 40 countries. Fortunately in Iran, along with 62 other countries national blood supplies are based on a 100% voluntary unpaid blood donation system [4].

Despite substantial improvements in safety of blood and blood components in recent years there are still valid concerns regarding the safety of blood and blood products used in some of the countries worldwide [5-6]. In Iran blood transfusion is an integral part of the national health system. Blood donation is voluntary and unpaid and blood and its components are not a source of income and the cost of collection, component preparation, preserving and distribution of blood and its components are all paid by the government. Currently blood and its components are free of charge for all Iranian patients in need of such treatment.

The new era of blood transfusion in Iran started in 1940s following the establishment of blood centers both in Iranian Army and Red Lion and

Sun Organization in early 1950s. However until the early 1970s Iran had no organized blood service and blood requirements were supplied by commercial centers that relied mostly upon paid blood donors. In 1974 based on a parliamentary law, Iranian Blood Transfusion Organization (IBTO) was established in order to centralize all blood transfusion activities from donor recruitment to production of blood components and the delivery of blood and blood products under one umbrella. The law banned all other public and private organizations to perform any activity in blood transfusion section. The establishment of IBTO was a milestone toward emergence of a developed and scientifically based blood transfusion system in Iran.

Since then Iran has adopted the basic principles of blood safety criteria set by WHO for a national blood organization, including well organized nationally coordinated blood transfusion services with quality systems in all areas, the collection of blood only from voluntary non-remunerated blood donors of low risk populations, the quality assured testing of all donated blood, the safe and appropriate use of blood and blood products and global collaboration for blood safety.

IBTO is a public and non-profit organization that relies fully on the government of Iran for its financial budget and delivers all of its services including produced blood components free of charge both to the public and private hospitals. According to its

constitution the main scope and responsibilities of IBTO are:

1. To define standards for transfusion services.
2. To recruit voluntary donors and conduct donation screening tests.
3. To develop blood supply networks throughout the country.
4. To prepare blood components and deliver them to health centers.

Transfusion under supervision of trained personnel for all Iranian patients who need it irrespective of their economic or social status through comprehensive, efficient and a total quality management approach is one of the main goals and objectives of IBTO.

The Quality Assurance department of IBTO has prepared and implemented the national program for quality management, which must be followed in every step of the transfusion chain, from blood collection until the blood is transfused to the patient. Availability of blood components shall be ensured through the IBTO network of provincial and regional centers by production of adequate number of blood component separation units. IBTO has also the responsibility to encourage appropriate clinical use of blood and blood products. A patient should receive blood transfusion only when morbidity and mortality cannot be prevented or treated effectively by other means. Therefore as far as possible, the clinician should use blood substitutes

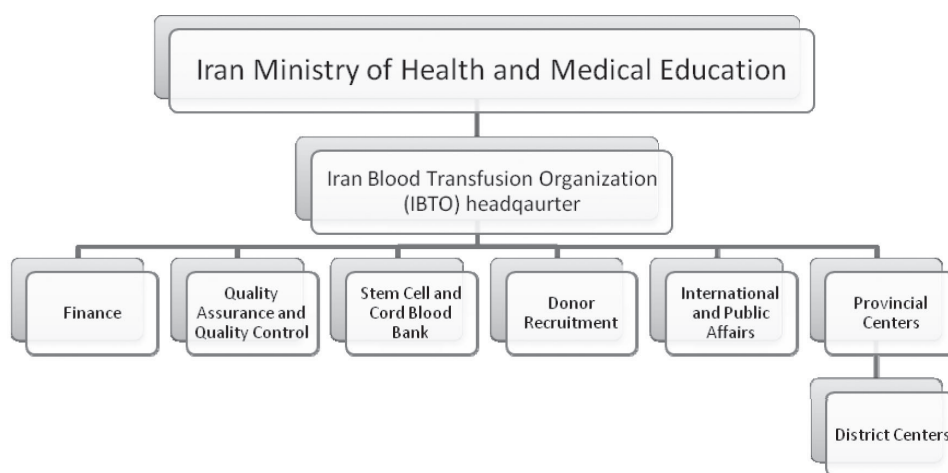


Figure 1: The organization chart of Iranian Blood Transfusion Organization.

for the patient management. Self sufficiently of country for blood and blood components is also one of the main objectives of IBTO. Blood transfusion service in the country is highly centralized and has adequate vital resources like manpower, adequate infrastructure and financial base. The standards are national and practically identical among all centers across the country. Hospital blood banks are not authorized for blood collection.

Due to life saving aspects of blood and blood components it is essential that blood products be available and accessible to the generality of Iranian patients, irrespective of gender, geographical distribution, socioeconomic standing and cultural backgrounds. Therefore Iranian Ministry of Health (MOH) accepted the ultimate responsibility of providing a comprehensive blood transfusion service in Iran by establishing IBTO. IBTO is set to be one the best known blood transfusion services worldwide.

IBTO organizational structure

IBTO is an integral part of Iran national health care system. Current top organizational and hierarchical structure of IBTO is depicted in Fig.1. All activities of the IBTO will be carried on by IBTO General Manager who will be elected by IBTO High Council for a period of 5 years. IBTO High Council which consists of national experts of transfusion medicine is chaired by Ministry of Health and is responsible for general policies and goals of IBTO. IBTO High Council will also provide guidelines for ensuring budget utilization of IBTO both in non-profit cost recovery system for some specific products as well as subsidized system for basic blood components produced by IBTO.

IBTO Financial Resources

IBTO is a public organization and has two main resources for its budget. Main portion of IBTO budget comes from governmental fiscal budget, which has to be ratified by the national parliament based on the government proposal. However, IBTO may also be authorized by its High Council to receive non-profit and cost recovery compensation for some of its services. At present IBTO is providing blood and its basic components including packed RBC, platelet and fresh frozen plasma free of charge for all Iranian patients both in private and public sector. However, IBTO is presently authorized to

receive compensation for some specific services it provides to the patients such as therapeutic plasma pheresis and platelet pheresis. Although IBTO is mainly dependent on the government budget, it has focused its efforts to raise funds from other sources such as production of new products and receiving charity funds. All types of donations are welcomed according to current laws and regulations. However, so far IBTO has not established a specific plan for a policy of partnership and fund mobilization.

IBTO Main Objectives

1. To supply 100% of the national needs for safe and high quality blood and blood components obtained from 100% non remunerated volunteer blood donors.

2. To ensure the availability of blood and blood components in all hospitals and for all patients in need of such products without any financial or geographical consideration.

3. To launch extensive awareness programs for informing, educating, motivating, recruitment and retention of volunteer donors in order to ensure adequate availability of safe blood.

4. To make available adequate resources for developing the blood transfusion services in the entire country.

5. To make latest technology available for operating the blood transfusion services.

6. To implement GMP regulations for constant improving of working procedures

7. To promote appropriate clinical use of blood and blood components.

8. To strengthen its manpower through human resource development.

9. To encourage research in the field of transfusion medicine and related technology.

10. To take adequate regulatory and legislative steps for monitoring and evaluation of blood transfusion services.

11. To develop guidelines for management of blood supply during natural and manmade disasters.

12. To maintain IBTO as a prominent organization in the region.

13. To improve public awareness on blood donation through mass media.

14. To reduce transfusion related risks through establishment of national hemovigilance system.

15. To use at least 75% of recovered plasma

produced from donated bloods for fractionation into plasma derived medicines.

16. To collaborate with national authorities for developing guidelines and regulating the establishment of private plasma pheresis centers.

17. To establish the national stem cell and cord blood bank.

IBTO General Strategies

To reach these objectives, IBTO has adopted following as its main strategies:

1. Development and implementation of a national blood policy.

2. Reinforcement of the blood collection structures and systems.

3. Establishment of blood transfusion centers and furnishing these centers with equipments, consumables and human resources.

4. Establishment of a centralized procurement system.

5. Making latest technology available for operating the blood transfusion.

6. Using high level of automation in all possible procedures.

7. Effective mechanisms of resource generation for the perpetuation of the system.

8. Promoting the appropriate use of blood and blood components.

9. Promoting transfusion medicine as a specialty and restriction of prescribing blood and its components by a registered medical practitioner.

10. Establishment of a system of collection and dissemination of information relating to blood transfusion.

IBTO Duties and Responsibilities

A. Main duties and responsibilities of IBTO

1. To collaborate with national health system to promote nation's health.

2. To provide blood and blood components for entire nation.

3. To prepare short and long term plan to achieve its objectives.

B. Main duties and responsibilities of IBTO High Council

1. To approve IBTO general policies, activities, national standards, short and long term plans and the internal rules and regulations of IBTO.

2. To control budget utilization in IBTO.

3. To guide IBTO through its national duties and responsibilities.

4. To oversee activities of IBTO.

C. Main duties and responsibilities of IBTO General Manager

1. To act as the highest responsible person for IBTO and its activities and responsibilities.

2. To implement the national policy of blood transfusion.

3. To execute the decisions of IBTO High Council.

4. To harmonies all activities in IBTO.

5. To liaison with national health sector for national coordination.

D. Main duties and responsibilities of IBTO Finance Department

1. To prepare IBTO fiscal budget.

2. To procure hardware, software and consumable for IBTO.

3. To monitor budget spending.

4. To arrange for staff recruitment.

E. Main duties and responsibilities of IBTO Quality Assurance and Quality Control Department

1. To develop IBTO strategies and plans on blood safety.

2. To develop IBTO SOPs for "vein to release" procedures.

3. To audit IBTO Provincial Centers and Districts for their compliance with national requirements.

4. To develop guidelines for preparing blood components including plasma for fractionation.

F. Main duties and responsibilities of IBTO Institute for Research and Education

1. To promote research on transfusion medicines.

2. To perform research projects on transfusion medicine.

3. To train students at MSc and Ph.D. levels on transfusion medicines.

4. To collaborate on continues training of IBTO staff.

G. Main duties and responsibilities of IBTO Department of Donor Recruitment

1. To develop plans and strategies to recruit voluntary non remunerated donors from low risk population.

2. To develop plans and strategies to retain safe blood donors.

3. To develop national plans on public education for blood donation.

H. Main duties and responsibilities of IBTO Dept of Stem Cell and Cord Blood Bank

1. To recruit volunteer donors for donation of stem cells and cord blood.

2. To establish national HLA registry and national cord blood bank.

I. Main duties and responsibilities of IBTO Department of International and Public Affairs

1. To organize public and media campaigns on IBTO goals and strategies.

2. To improve public awareness on blood donation.

3. To develop regional and international collaboration between IBTO and similar counterparts.

4. To organize long term collaboration between IBTO and international organizations.

J. Main duties and responsibilities of IBTO Provincial Branch

1. To recruit and bleed donors.

2. To implement IBTO plans and policies.

3. To execute IBTO SOPs.

4. To screen the donations.

5. To prepare blood components.

6. To deliver blood and blood components to hospitals.

K. Main duties and responsibilities of IBTO District Branch

1. To recruit and bleed donors.

2. To execute IBTO SOPs.

IBTO Specific Objectives

A. Specific objectives of IBTO Department of Donor Recruitment

Objective (1)

• To continue on 100% non remunerated voluntary blood donation

Current situation:

• 100% non remunerated voluntary blood donation

Milestone in 2015:

• 100% non remunerated voluntary blood

donation

Strategy:

• Improving public awareness among low risk population and motivating low risk population to donate blood

Objective (2)

• To increase yearly blood donation index.

Current situation:

• 25.2 units of whole blood donation per 1000 population

Milestone in 2015:

• To collect at least 27 units whole blood per 1000 population

Strategy:

• Annual increase of at least %0.4 per year

Objective (3)

• To increase share of regular blood donation

Current situation:

• %45 of blood donated by regular blood donors

Milestone in 2015:

• To collect at least %55 of blood from regular blood donors

Strategy:

• Annual increase of at least %2 of regular blood donation

Objective (4)

• To keep sufficient national inventory level of pRBC

Current situation:

• Entity of minimum 5 days of pRBC distributed throughout the country

Milestone in 2015:

• To hold on entity of minimum 5 days of pRBC distributed throughout the country

Strategy:

• Monitoring of national inventory level of pRBC and provide corrective action

B. Specific objectives of IBTO Quality Assurance and Quality Control Department

Objective (1)

• To prepare updated SOPs for "vein to release" procedures

Current situation:

• 100% of IBTO main activities are covered by more than 470 operational SOPs

Milestone in 2015:

• 100% of SOPs will be revised by 2015

Strategy:

• Regular revising of SOPs by expert committee

every two years

Objective (2)

•To screen blood donations for HIV, HBV, HCV, Syphilis and HTLV in selected provinces

Current situation:

•100% of donations are screened for HIV, HCV, HBV and HTLV using ELISA method and current prevalence for HIV, HBV, HCV and HTLV are 0.004%, 0.24%, 0.07% and 0.12% respectively.

Milestone in 2015:

•100% of donations will be screened by ELISA for HIV Ag/Ab by 2015. NAT testing of donated bloods will be established in some designated centers. Prevalence for HIV will remain constant and HCV and HBV will be reduced by 0.06% and 0.20% respectively

Strategy:

•Use of appropriate validated methods and automated systems for screening of donated bloods

Objective (3)

•To increase the volume of plasma allocated for fractionation

Current situation:

•In 2011 about 120,000 liters of surplus recovered plasma was fractionated

Milestone in 2015:

•To increase the volume of plasma allocated for fractionation to 200,000 liters

Strategy

•To increase volume of surplus plasma from centers and increasing the number of audited centers by relevant authorities

Objective (4)

•To establish nationwide hemovigilance system

Current situation

•Establishment of hemovigilance system in about 40 hospitals across the country

Milestone in 2015:

•To increase the number of established hemovigilance centers to 80% of hospitals

Strategy

•To increase the number of hospitals with established hemovigilance centers

Objective (5)

•ISO 9001-2008 certification for the provincial blood transfusion centers and district blood transfusion centers

Current situation:

•100% of blood transfusion centers are audited for ISO certificate

Milestone in 2015:

•100% of blood transfusion centers will be audited for ISO certificate

Strategy:

•Improvement of quality of operations in all blood transfusion centers for success in the audits

C. Specific objectives of IBTO Finance Department

Objective (1)

•To provide sufficient qualified staff for IBTO

Current situation

•Total number of IBTO staff is 4126

Milestone in 2015

•To recruit 500 more staff for IBTO

Strategy

•To secure appropriate government budget and required permission for recruiting new staff according to newly approved 5-year-national development plan

Objective (2)

•To secure sufficient fund for IBTO activities

Current situation:

•Overall annual budget of IBTO is 502Billion IRR (41million USD)

Milestone in 2015:

•To increase IBTO fiscal budget by 25%

Strategy:

•To obtain required budget from government through % 5 increase in annual budget for next five years

Objective (3)

•To increase the share of nongovernmental budget (through product sale)

Current situation:

•Nongovernmental budget share in IBTO budget is about 8%

Milestone in 2015:

•Nongovernmental budget share in IBTO total budget will increase to 12%

Strategy:

•To obtain authorities' approval for reimbursement of the new products produced by IBTO

Objective (4)

•To update national network of blood transfusion centers

Current situation

•There are 91 blood establishments and 124 blood collection centers across the country

Milestone in 2015

- There should be 95 blood establishments and 150 blood collection centers across the country

Strategy

- To revise current national network of blood transfusion centers and to establish new centers

D. Specific objectives of IBTO Institute for Research and Education

Objective (1)

- To establish post graduate program in Immunohematology discipline

Current situation:

- This discipline is not present

Milestone in 2015:

- To establish post graduate program in Immunohematology discipline

Strategy:

- To plan an appropriate curriculum and apply for necessary certificates

Objective (2)

- To expand current research hematology labs of IBTO

Current situation:

- Presence of two biotechnology and stem cell research labs

Milestone in 2015:

- To expand current research labs

Strategy:

- To allocate appropriate resources for new labs

Objective (3)

- To increase the number of the blood and components related academic members

Current situation:

- Presence of 12 faculty members

Milestone in 2015:

- To increase the number of academic members to 16 member

Strategy:

- To recruit new qualified academic members

Objective (4)

- To increase the number of the blood cells and components related research projects

Current situation

- Approval of 7 new research projects per year

Milestone in 2015

- To increase the number of hematology related research projects to 15

Strategy

- To start 2-3 new research projects every year

E. Specific objectives of IBTO Department of Stem Cell and cord blood bank

Objective (1)

- Establishing national HLA registry

Current situation:

- Two national registry centers with 2,200 HLA from registered volunteers

Milestone in 2015:

- Four national registry centers with 10,000 HLA from registered volunteers

Strategy:

- Adding two new national centers

Objective (2)

- Establishing national Cord Blood Bank

Current situation:

- Two hospital centers for collecting cord blood with 800 registered cord bloods

Milestone in 2015:

- Three hospital centers for collecting 10,000 cord bloods

Strategy:

- Adding one new hospital center and 2,000 cord bloods annually

F. Specific objectives of IBTO Department of International and Public Affairs

Objective (1):

- Taking advantage of opportunities provided by international organizations

Current Situation:

- Active involvement in scientific and educational projects of WHO, ISBT and other international organization

Milestone in 2015:

- To establish a WHO regional collaborating center on blood safety

Strategy:

- Cooperate more actively with WHO and holding joint activities with international organizations

Objective (2)

- Maintaining the leading position of IBTO in the region through regional activities

Current situation:

- There is already an established network of ECO members transfusion services through mediation of IBTO

Milestone in 2015:

- To expand an active regional and international cooperation network on blood safety

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Strategy:

- Fulfill the agreements signed between Iran and other countries and providing effective assistance to countries in need

Objective (3)

- Improving public awareness on blood donation through mass media

Current situation:

- IBTO has a well established communication with mass media for increasing public awareness on importance of voluntary blood donation

Milestone in 2015:

- To improve the current relation with mass media

Strategy:

- Timely communication with print and electronic mass media

Objective (4)

- Developing partnership with NGOs

Current Situation:

- There is already an established relation between IBTO and some NGOs such as Iranian Red Crescent

Milestone in 2015:

- To expand collaboration with other national NGOs

Strategy:

- To take more advantages from opportunities provided from NGOs and expand the cooperation with new NGOs.

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