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DEVELOPMENT OF NATIONAL BLOOD TRANSFUSION SERVICES IN THE COUNTRIES OF THE EASTERN MEDITERRANEAN REGION

Abstract The increasing need for blood and blood products and the increasing awareness of the importance of the safety aspects has led to a great concern for the development of blood transfusion services in the Eastern Mediterranean Region, which has been discussed in several recent meetings.

The present background document includes a brief description of the use of blood and blood products and the advantages and hazards associated with their use. It describes the risks of transmitting diseases, such as hepatitis and the acquired immunodeficiency syndrome (AIDS), and screening procedures intended to prevent such transmission.

In the document an analysis of the world situation as well as of the situation in the Region is made and the most pertinent problems are presented.

The main problems faced are: (1) lack of integration of blood transfusion services into national health care plans; (2) insufficient government support in the form of financial and human resources; (3) fragmentation and competition in blood transfusion services; (4) poorly planned and funded blood-donor recruitment; (5) lack of trained manpower in transfusion services; (6) poor grasp of quality assurance; and (7) deficiencies in support services.

The main recommendations aiming at improving the actual situation of blood transfusion services are: (1) to establish a national blood transfusion service (NBTS); (2) to develop an appropriate level of national self-sufficiency; (3) to foster voluntary blood donation; (4) to promote the integration of or close cooperation between the transfusion services of the Armed Forces and the NBTS; (5) to enact legislation to ensure the safety of donors, staff and recipients of blood; (6) to establish the speciality of transfusion medicine; (7) to ensure that blood transfusion technology is incorporated into the curricula of schools of medical laboratory sciences; (8) to provide for an attractive career structure for staff; and (9) to ensure that training in the rational use of blood and blood products is included in the curricula of medical faculties and nursing schools and that refresher courses are given to practising clinicians.

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1. INTRODUCTION

It is often asked what degree of priority blood transfusion should enjoy in the overall health planning of developing countries. The question should really be re-phrased to read: What is the priority of hospital health services? Blood transfusion does not after all exist to serve itself and cannot be considered in isolation from its medical, scientific and social context.

The past two decades have seen much government planning and the investment of substantial financial resources in health care. Implementation of these plans has most often taken the form of hospital building programmes and the creation of increasingly large, complex medical centres.

This is when blood transfusion services should have been considered, but the establishment of a sophisticated medical superstructure has not usually been supported by the development of transfusion and other laboratory disciplines which must serve and sustain it.

The increasing need for blood and blood products, and the increasing awareness of the great importance of the safety aspects in connection with the use of such products, has led to a great concern for the development of blood transfusion services in the Eastern Mediterranean Region. This was clearly reflected during the Intercountry Meeting of Directors of National Blood Transfusion Services held in Riyadh, Saudi Arabia, in 1984, and is illustrated by the Guidelines and Recommendations agreed upon at this meeting.

Recently at the Second Arab Seminar on Blood Transfusion held in Kuwait in November 1986 many of these aspects were reiterated.

The problems of blood and blood products were also discussed by the Programme Committee of the WHO Executive Board during its meeting in Geneva in October 1986.

1.1. Main use of blood and blood products

Blood as a replacement in cases of acute hypovolaemic shock is a standard clinical practice. Such acute shocks are usually associated with accidents, obstetric emergencies and surgical interventions. Certain specific conditions may require either the use of whole blood or blood products. In the developed countries, the use of whole blood is being slowly replaced by concentrated red-cell suspensions where the oxygen-carrying capacity of the haemoglobin is vital; by albumin solutions as replacement for blood when plasma derivatives are more important; by immunoglobulins for protection and treatment of disease; by cryoprecipitates, factor VIII and factor IX for treatment and management of haemophiliacs; by leucocyte transfusions and platelet concentrates for individuals on cancer chemotherapy or immunosuppressive treatment.

This has led to the development of two series of facilities:

1. Blood transfusion services for collection, storage, screening and testing, distribution and use of whole blood, cell concentrates or plasma; and

2. Plasma fractionation institutions using the plasma for the manufacture of the various plasma fractions. The demand for plasma fractions has in some countries created a shortage of plasma, which in turn has been met through the introduction of plasmapheresis. This method, by which the blood cells and the plasma are separated and the blood cells returned by transfusion to the donor, makes it possible to obtain larger volumes of plasma to be used as raw material for the fractionation procedures.

For historical and socio-economic reasons no two countries are alike in the development of their blood transfusion services and plasma fractionation facilities. The least developed countries usually rely on transfusion of whole blood and import some specific plasma products, while many developed industrialized countries are increasingly using blood products for specific applications.

Transfusion of whole blood, always with an anticoagulant (usually a citrate) is mainly used for the treatment of hypovolaemic shock, especially in connection with severe bleeding, since in these cases there is a need to replace the red blood cells, as well as to maintain a sufficient blood volume and blood presssure.

Blood should be given to a recipient only when the ABO and Rh(D) group of the donor is compatible with the patient and compatibility testing has ruled out other significant antibodies. This is imperative for all clinical use of blood and means that blood-grouping reagents, equipment and expertise are needed both at the time and place of blood collection and when the blood is used.

Blood can be stored at 4°C $\pm$ 2°C, but, even within this narrow temperature range, only for a limited period of time and the quality of the blood deteriorates during storage increasing the risks of side-effects. Through the development of improved preservative solutions it has been possible to increase the shelf-life from a maximum of 21 days to 35 or 42 days if other conditions are optimal.

Red cell therapy requires the administration of cells separated from most of the plasma. The cells may be suspended in physiological saline solution and should be used within six hours. Red cell preparations are given to anaemic patients with a normal blood volume; they are also used to replace blood lost in surgical operations.

Platelet concentrates are used primarily in thrombocytopenia, a condition which has become more common with the use of cytotoxic drugs for the treatment of leukaemia and malignant tumours. The platelets are separated from the blood and concentrated by centrifugation.

Plasma, although valuable in patients with severe burns, is nowadays mainly used for the production of specific plasma fractions. Fresh frozen plasma may, however, be used for treatment of clotting factor deficiencies when the specific factors are not available. It must be separated from the red cells within a few hours after collection and stored at below -30°C.

Factor VIII is the essential plasma protein fraction for the treatment of haemophilia A. It is prepared from fresh plasma by means of cryoprecipitations with or without further concentration. Many developing

countries rely on imported products for their needs. Similarly Factor IX, also prepared by fractionation, may be used for the treatment of Christmas disease (Haemophilia B), which is a bleeding disorder caused by Factor IX deficiency.

Fibrinogen can be concentrated by cryoprecipitation of plasma. Depletion of fibrinogen may occur in severe postpartum haemorrhage and in accidental haemorrhage during the third trimester of pregnancy. It has also been known to occur following total prostatectomy and in patients who have been exposed to severe trauma or crush injury. Cryoprecipitate is the product of choice for these patients.

Albumin is a useful plasma expander, but is costly and is excessively used in many countries. Because of its high molecular weight it maintains the osmotic balance in the blood vessels. It is subjected to heat treatment (usually at +60°C for 10 hours) without loss of its valuable properties. Such treatment is considered sufficient to inactivate the viruses of hepatitis B, hepatitis non-A and non-B and HIV (human immunodeficiency virus).

1.2. Transfusion reactions

One of the most important risks is that of human error. A mistake in the blood grouping and/or cross-matching, or a mixup causing the blood unit to be given to the wrong patient, may lead to incompatibility reactions. The commonest cause is clerical error resulting in misidentification of donor or patient. Such reactions are very serious indeed and may cause fatal intravascular haemolysis. Rigorous laboratory procedures and handling systems have made such reactions rare.

Even if the ABO and Rh(D) group of the blood donor and the patient has been properly established and found compatible there is, due to the existence of other blood group antigens, still a risk of an antigen-antibody reaction in the recipient. Cross-matching will eliminate some of these risks. Allergic reactions may nevertheless occur.

Improper storage of blood or the use of out-dated blood may also cause side effects.

1.3. Transmission of infectious diseases

It has been long recognized that the presence of a viable infectious agent in donor blood constitutes a potential hazard to the recipient. The risks of transmitting diseases such as malaria, Chagas' disease, leishmaniasis, syphilis, yaws and the more recently recognized hepatitis B, non-A and non-B hepatitis and AIDS (acquired human immunodeficiency syndrome) varies from one area to the other depending on the prevalence of the disease in the donor population and on the measures taken to prevent its transmission. Hepatitis and HIV infections are considered to pose the most serious hazards and efforts should be made to reduce these risks to a minimum.

1.3.1. Hepatitis

The viruses of hepatitis A, hepatitis B and non-A and non-B hepatitis, as well as the recently discovered delta agent may all be transmitted through blood and blood products. Due to the fact that in hepatitis A the period when

the virus is present in the bloodstream is comparatively short and carrier states are uncommon, transmission through blood transfusion is rare.

In hepatitis B the situation is the opposite. The virus may be present in the bloodstream several weeks before clinical symptoms appear and continue to be there for many months. Life-long carrier states are common. The prevalence of such carrier states varies considerably from one geographical area to another. In many European countries the prevalence is as low as 0.1.%, while in Africa and Asia figures of the order 10-15% are not uncommon. The prevalence may also vary depending on the selection of blood donors. In the United States as in several other countries, it has been shown that the hepatitis B carrier rate is much higher among paid donors than among benevolent donors.

The discovery of the hepatitis B antigen in the late 1960's made it possible to start screening blood donors for hepatitis B. This approach has successfully reduced post-transfusion hepatitis caused by this agent to a very low level. Many developing countries have, however, not yet the capability or the economic resources to implement such a screening programme and here hepatitis B still constitutes a serious hazard, especially since it often coincides with a high carrier rate in the donors. A strengthening of the blood transfusion services in this respect, therefore, has high priority.

Information concerning their prevalence of non-A and non-B hepatitis and the delta agent is incomplete. Although the screening of hepatitis B has sharply reduced the number of cases of post-transfusion hepatitis the risk cannot yet be completely eliminated.

1.3.2. AIDS (HIV infections)

AIDS has only been recognized since 1981; in 1983 it was found to be caused by a virus, initially called LAV or HTLV-III but later designated HIV (human immunodeficiency virus). The virus is capable of infecting the T-lymphocytes and certain brain cells. Its genetic material is incorporated into the genome of these cells. Here the virus material is protected against the body's defence mechanisms and is, therefore, not neutralized by the presence of antibodies. The blood of such an individual may be infectious at an early stage of infection and the patient must be considered as infectious for the rest of his life. As the T-lymphocytes are gradually destroyed, the patient slowly becomes immunodeficient. Symptoms such as uncontrollable infection, tumours and acute or chronic encephalitis become evident.

Although the disease may start with acute generalized symptoms shortly after exposure, it is usually not recognized at this stage. In most cases there is a long incubation period, and it may be several years before the recognizable symptoms appear. The maximum length of the incubation period is not yet known but probably it may continue for over 10 years. Symptoms usually start insidously and the first signs are lymphadenitis and/or Kaposi sarcoma, chronic diarrhoea, night sweats, fever and weight loss. As the immunological system becomes increasingly deficient, serious infections appear, often caused by agents which do not usually cause disease in healthy individuals. Since there is no specific treatment for AIDS, treatment with antibiotics etc. only has a palliative effect and the patient usually dies within months or a few years after the diagnosis has been established.

Originally the AIDS epidemic resulted largely from the spread of the virus through intimate sexual relationship or the use of contaminated needles. Transmission by blood transfusion and blood products played a relatively minor role. Recently, 2-3% of AIDS cases in Western Europe and North America have been caused by blood transmission. The situation in other areas of the world is less clear, but wherever AIDS is identified as a significant problem, transfusion-associated cases can be expected in the absence of preventive measures. In 1983, when the significance of AIDS as an international health problem began to be appreciated, the safety of blood and blood products became a matter of great concern. The main useful measures are pre-donation selection of donors, testing of donors blood for anti-HIV and for certain plasma fraction, post-donation inactivation or separation of the virus.

The selection of donors may be based on:

- specific screening of donors for antibodies against HIV;
- exclusion based on medical history and/or physical examination aiming at revealing an increased risk for the presence of AIDS;
- effective education leading to voluntary self-exclusion when persons with risk factors for AIDS refrain from giving blood;
- or a combination of these measures.

All these approaches have their limitations. Specific screening for HIV-antibodies, usually based on the ELISA (enzyme-linked immunosorbent assay) technique, has been found very useful in many countries. To carry out these tests adequately, trained staff and suitable photo-electric reading equipment are needed. The cost of ELISA kits varies considerably throughout the world; the lowest is approximately one US dollar per test, not including cost of staff and equipment.

Some tests give approximately 0.2-0.4% false positive results. This calls for careful verification of the positive tests by repeated investigation with the more specific immunoblot or immunofluorescent tests. The costs for immunoblot testing exceed ten US dollars per test for material only and a specialized laboratory with well-trained staff is required.

It is important to note that, since antibodies may not have reached detectable levels during an early stage of the disease, the tests cannot detect all infectious individuals.

At the WHO meeting in April 1985, it was recommended that where feasible, potential donors of blood, plasma and organs for transplantation be screened for the presence of antibody to HIV.

It may be concluded that in the absence of a simple, inexpensive, heat-stable, reliable, highly sensitive yet specific testing procedure with a long shelf-life, safeguarding the blood supply through screening of blood donors will continue to be relatively expensive.

Self-exclusion of donors requires effective information and education of donors and can only be totally effective when clear criteria for exclusion can be established. Such criteria have to be based on epidemiological studies identifying the risk factors in the given population area and such information is not always available. When it is available, it needs updating to keep

track of the evolution of the epidemic. Furthermore, continual education is essential and the method is likely to be more effective with unpaid than with paid donors.

Exclusion based on medical history and physical examination is essential to help reduce the number of infected donors. It should be kept in mind, however, that during the early stages of infection there may be no or very mild symptoms and that evaluation of a medical history cannot be totally reliable. Physical examination of the donor is nevertheless desirable.

Procedures directed towards the inactivation or separation of the virus are useful only for certain blood products. Heat treatment is known to make albumin safe. It has also been applied, as recommended by WHO in April 1985, to Factor VIII and Factor IX preparations, greatly reducing or eliminating the risk of transmitting viral infections. There is also considerable evidence that immunoglobulins manufactured by methods based on the conventional Cohn-Oncley ethanol precipitation methods do not transmit HIV.

1.3.3. Syphilis

The transfusion of blood infected with *Treponema pallidum* may cause syphilis in the recipient. Transmission has become less frequent with the increased use of stored blood since storing at 2-6°C for 3-4 days will kill the micro-organisms. Many transfusion centres screen all blood for syphilis antibodies using the VDRL or similar tests. This does not, however, give an absolute guarantee of safety since serum reactions are negative during the first weeks of infection.

1.3.4. Malaria

The risk of transmitting malaria is only slightly reduced by storage. In non-endemic countries, donors coming from malarious areas are usually excluded from donating whole blood whether known to have been infected or not. In endemic areas the use of malarious blood may be unavoidable. In these situations the recipient is usually given anti-malaria treatment.

1.3.5. Other diseases

A number of other diseases, such as African trypanosomiasis, Chagas' disease, leishmaniasis (Kala Azar) and relapsing fever, may be transmitted by blood transfusion. Donors carrying these diseases should be avoided.

1.4. Other complications

The staff of the blood donor centres as well as the users of blood for transfusion should monitor possible reactions or side-effects in the recipients or the donor. Although rare nowadays, complications due to growth of contaminating bacteria in the blood or blood products, accidents due to faulty transfusion sets or improper handling, still occur. These risks can be minimized by strictly adhering to established routines for the handling and use of the products and equipment.

1.5. Elimination of risks

In order to eliminate the risk of serious transfusion reactions, it is necessary to establish a well-functioning blood transfusion service, with

well-trained staff using good quality reagents and equipment and a safe handling system. It is, however, equally important that the users of blood and blood products are well acquainted with their proper use and handling and the risks involved in their use.

1.6. Quality assurance

The safety of blood products is a summation of the quality of all the processes and materials which have gone into producing them. This includes not only the quality of the blood, equipment and solutions used but also the proficiency and morale of the medical and laboratory staff participating in this chain of activities. Like in a pharmaceutical industry the principles of "Good Manufacturing Practice" and "Quality Assurance" must be included.

This means that all methods and production steps should be well defined and validated and sufficient controls included to allow an objective documentation of every aspect of the process of production.

2. SITUATION ANALYSIS

2.1. World situation

By means of a questionnaire issued by WHO in 1984, information was collected concerning blood transfusion services in developing countries. Although only 45% of the countries responded (26% in the Region) this information, and information collected from other sources, make it possible to draw some conclusions concerning the over-all situation.

The organization and management of transfusion facilities are generally hospital-based. The availability of district blood transfusion services, operating in close liaison with public health authorities and in consonance with agreed health care policies and strategies, supported by proper blood separation facilities and proper quality control practices, are the exception rather than the rule.

The general picture gained from the country reports is one of gross inadequacy of trained personnel and training programmes, and lack of facilities for essential continuing self-education.

Most blood is obtained either on a voluntary basis or through replacement donors, some of them remunerated. The blood obtained from the population is usually far from adequate to meet the essential transfusion needs. Blood substitutes for surgical procedures, such as serum albumin, are rarely produced within developing countries owing to the absence of plasmapheresis and fractionation facilities in more than 80% of the surveyed countries.

Many countries report major problems in quality and maintenance of routine transfusion equipment. The most frequent picture is of inadequate equipment and supplies preventing the continuous provision of service.

On the other hand, information from other sources shows that in some developed countries there is an overuse of blood products such as red cells, albumin and fresh frozen plasma.

Developed countries have considerably tightened their quality control procedures in an attempt to reduce the incidence of blood-transmitted diseases. The costs are, however, so high that most developing countries could not afford to apply the same measures.

2.2. The Eastern Mediterranean Region

The enormous variation in the population of the countries in the Region, ranging between a few hundred thousand to nearly 100 million; the wide spectrum of the GNP (gross national product) and *per capita* income, as well as the difference in the degree of sophistication attained in medical and surgical capabilities from one country to another, make comparisons between countries difficult. Nevertheless, certain broad common trends may be observed and some general comments can be made.

Despite the passage of many years, the development of blood transfusion services has remained disappointingly static.

Although efforts have been made, in a number of countries, to diminish the long-standing dependence upon paid, professional blood donors and blood imports, voluntary donor recruitment, and the provision of sufficient blood for transfusion, still stand out as the most salient difficulties. This appears, essentially, to be an organizational problem. In many countries there is a lack of a focus of long-term planning and decision-making. The funds and human resources invested in establishing a highly professional, sustained marketing exercise, which could gain public participation in a voluntary blood donor programme have been insufficient. Transfusion services are often profoundly isolated from the public and appear unable to bring about the behavioural revolution which is required. Instead, recourse is frequently made to "Blood Replacement" programmes which involve the coercion of relatives or of applicants for drivers' licences. This policy is counter-productive and it is an admission of failure to win public confidence.

In the Eastern Mediterranean Region, medical, scientific and technical staff career prospects in blood transfusion services remain very poor. Successful long-term planning must include a manpower development programme and the lure of an attractive career in transfusion science. Specific qualifications in blood transfusion medicine should be established in line with those available in many western countries.

Government authorities in some countries appear satisfied to run a "hand-to-mouth" service which will merely satisfy minimal, day-to-day requirements for blood and blood products, without perceiving that the investment of sufficient funds to create a permanent, institutional mechanism for changes will yield great dividends in the long term.

Blood utilization patterns in hospitals continue to demonstrate a poor grasp of blood transfusion medicine by hospital physicians and surgeons who order blood products for their patients. Certain blood products are over-used for doubtful clinical indications; in other cases, blood transfusion laboratories are producing vital components such as cryo-Factor VIII or platelets which are under-used and wasted.

Virtually all the Regional success stories in establishing transfusion services are based upon the existence of a dedicated, persistent individual

with the necessary vision. These individuals have succeeded in overcoming the isolation of blood transfusion from the public, government authorities and the medical and scientific communities. They must be supported in their endeavours and given the opportunity to acquire proper training and to communicate with their colleagues in other countries.

Initiatives have recently been developed amongst the Arab Member States, however, under the aegis of the Arab League and the Council of Arab Ministries of Health. An "Arab Scientific Advisory Board for Blood Transfusion" has been established, which has already created lines of communication between participating countries in a laudable effort to discuss and agree common standards, criteria and codes of practice. Resolutions have already been made which augur well for the future and regular meetings are planned to survey progress in this field. This focus of intercountry activity clearly deserves every support, although efforts need to be made, in the future, to involve some of the non-Arab countries of the Region.

It is also noteworthy that some countries have succeeded in forging closer ties between the transfusion services of the civil and military sectors.

2.3. Problems

1. The lack of integration of blood transfusion services into the national health care plans. The infrastructural importance of blood transfusion services, without which no modern hospital can function, is often not recognized.

2. Insufficient government support in the form of financial and human resources.

3. The enormous fragmentation and harmful competition prevailing in blood transfusion services which leads to wastage of limited resources, dangerous practices and mediocrity.

4. Poorly planned and funded voluntary blood donor recruitment. Unsustained sporadic drives are carried out instead of professional, unified, long-term programmes. Failure of voluntary blood donor recruitment leads inevitably to undesirable alternatives such as inducement of donors by payment.

5. Lack of trained medical and technical manpower in transfusion services. This, in turn is often due to the absence of career prospects for both doctors and technicians.

6. A poor grasp of quality assurance leading to an increased risk of adverse immune reactions and transmission of diseases such as AIDS and hepatitis.

7. Deficiencies in supportive services such as equipment maintenance and repair, efficient transport and communication networks, adequate power supplies, timely access to good quality laboratory reagents, scientific and medical literature.

3. APPROACHES TO THE DEVELOPMENT OF BLOOD TRANSFUSION SERVICES

3.1. Organization of a national blood transfusion service

Some of the most important constraints could, in many countries of the Region, best be met by the establishing of a strong national blood transfusion service. This could help to reduce the ill effects of the present fragmented transfusion services, where small scattered centres often make suboptimal use of blood and plasma and of financial resources, and where the quality of the service is variable and often inadequate. A national blood transfusion service may be organized as an autonomous body directed by a board which is accountable to the ministry of health. To be able to fullfil its functions, it is essential that the national blood transfusion service has at its disposal a well-functioning blood transfusion centre with a laboratory capable of providing reference functions.

A national blood transfusion service could:

- coordinate resources;
- provide reference functions;
- establish one set of standards for blood donor selection, screening and other quality control requirements;
- support the standardization of equipment, laboratory methods, and reagents;
- ensure application of quality control programmes and quality assessment schemes;
- act as a central purchasing agency, reducing costs by bulk buying and ensuring uniformity of quality by batch-testing of materials;
- organize nation-wide campaigns for the recruitment of blood donors;
- serve as a source and transmitter of important technical and epidemiological information;
- participate in planning for national disasters in close cooperation with the Armed Forces, ensuring that compatible equipment and procedures are used;
- serve as a national training centre for all levels of staff;
- support the proper collection of plasma for fractionation and, if national fractionation capacity is inadequate, negotiate terms for contract fractionation elsewhere.

3.2. Staffing and training of staff

In most countries of the Region, there is a shortage of well-trained staff in the blood transfusion services. This is often caused by the absence of a uniform pattern for basic training and the lack of periodic refresher courses. In order to improve the situation, it is necessary to establish a training programme leading to nationally recognized qualifications for the technical staff, providing practical and theoretical training for medical officers specializing in blood transfusion. Criteria for their clinical and laboratory training should be established resulting in a level of competence similar to that required for specialists in other fields of medicine. Part of this training could be provided in the reference laboratory of the national blood transfusion service, where one exists. In order to attract good candidates and to keep the already trained staff it is important to create a suitable career structure.

With the increasing use of blood components and plasma fractions, better education of medical and nursing staff in the proper use of these products is needed. Training in this field should be included in the curricula of the nursing and medical schools, as well as in postgraduate training.

3.3. Minimum requirements for blood transfusion facilities and equipment

As a part of the development of a national blood transfusion service, it may be suitable to establish minimum requirements for the facilities, equipment and staff needed to provide blood transfusion service at different health care levels. Here it should be recognized that due to variable resources it may not be possible to apply the same criteria to all countries. A set of criteria may, however, still be useful in order, as far as possible, to ensure an equal standard for the whole country. Such criteria may also be applied for private and other blood transfusion units and it may be used as a basis for the licensing of such units.

3.4. Recruitment of donors

The recruitment of donors is one of the most important parts of any blood transfusion service. It is not satisfactory for the blood services to live from "hand to mouth", merely hoping to obtain sufficient supplies to deal with hospital requirements on a day-to-day basis. It is vitally important to establish a stable blood donor base which must exist, for very cogent logistic and scientific reasons, to form the core of the donor panel. A permanent, institutional mechanism must be created to deal with requirements on a long term basis.

The recruitment of donors involves a continuous procedure of sensitizing and motivating and sometimes changing the attitudes of the general public through the dissemination of information as well as through eye catching recruitment campaigns. For this purpose, assistance from mass media, religious leaders, schools, universities and others may be most valuable. Coordination of such activities through a national blood transfusion service could make them more effective and lower the cost.

Since religion is an immensely powerful social force, religious leaders should be persuaded to assist in lending dignity and legitimacy to the act of blood donation by giving blood themselves and providing appropriate quotations from holy writs for posters. It is desirable that young people are brought up in keeping with the precepts of religion, to serve their community: to give, to love and not merely to consume and benefit.

It is essential that the blood donors are received by a smooth and effective organization for collection of the blood, whether this consists of mobile units or blood collecting centres ensuring the safety and comfort of the donor.

There should be clear criteria for the selection of blood donors to ensure the safety of the blood donor, as well as of the blood or the products made from it. These criteria should be strictly adhered to.

In most countries, blood transfusion services try to avoid using paid blood-donors since it is known that payment has a tendency to attract donors belonging to groups with higher than average prevalence of disease.

Many hospitals or transfusion centres in the Region institute a "blood replacement programme" in an effort to overcome blood shortages and avoid the difficulties of recruiting by putting the onus for finding donors upon the patient. In the long run, this kind of inflexible, coercive approach ensures that a stable population of repeat donors will never be formed. It will also undermine altruistic, voluntary donor recruitment programmes, favouring the continued activity of professional donors who are more likely to carry transmissible diseases.

It is most effective to start at the top when setting up blood donor sessions; persuading the most senior officials that they must set an example by exhorting their employees and giving blood themselves. The same principle applies to the Armed Forces, where officers must be urged to fulfill their leadership role and improve the confidence and morale of their men by being first in line. The peacetime military will usually welcome this opportunity for overtly demonstrating solidarity with the civilian population. The Army, of course, is a particularly valuable source of hyperimmune plasma, since large groups of men are simultaneously immunized at induction into the forces, and it must be carefully cultivated.

It is often easier to obtain sufficient quantities of blood from the public in situations of crisis. Coordination of resources between the national blood transfusion service and that of the Armed Forces may therefore turn out favourable to both organizations.

3.5. Screening of donors

The need for screening of donors for various infectious diseases varies from one geographical area to another depending on the epidemiological situation. In each country, the national blood transfusion service should be able to set the standard to ensure the provision of safe blood to all parts of the country.

Most countries have found it desirable to screen for syphilis and hepatitis B. Many countries which have not started routine screening for HIV antibodies are doing prevalence surveys. The technology and knowledge is, however, not yet available everywhere and costs are discouraging, especially if verification of the positive screening results is required. As more specific screening methods become available the verification costs will hopefully be reduced.

3.6. Modern technology for collection, handling and preserving blood

During the last decades, new technologies have been developed for the collection, handling and preservation of blood. This has become necessary in order to cope with the shortage of blood and the need to provide large amounts of plasma for fractionation purposes. New technologies have also provided safer methods. Disposable blood collection systems are easy and efficient to handle and provide good protection of the blood against bacterial contamination; multiple bag systems allow safe and easy separation of red blood cells from plasma, etc.

One of the most important advances in blood transfusion technology is the development of preservative solutions that allow an increase of the storage time of blood. This reduces the number of outdated blood units and allows the centre to keep a larger stock. When all these improved methods are combined it is possible to provide a very efficient blood transfusion service.

At the same time, many of these systems involve high costs and dependence on importation of equipment. It is, therefore, necessary for each country to decide the degree of sophistication to adopt for the various levels of transfusion service.

3.7. Proper utilization of blood

Considering the shortage and cost of blood, and in view of the risk of transmitting infections, it is important that blood is only given for strict clinical indications. Even in countries with an overall shortage of blood, unnecessary blood transfusions are not unusual. This is mainly due to a lack of knowledge and a wish to be "on the safe side".

The increased risk of transmission of infectious diseases through blood transfusion has in some countries led to the use of autologous blood transfusion. During the month preceding a planned operation, 2-8 units of blood are collected from the patient, stored in the blood donor centre and given to the patient if needed. The system has great advantages as it eliminates not only the risk of transmission of infections but also incompatibilities and allergic reactions. Blood which is not needed for the intended patient may instead be released for general use provided the usual safety criteria are met. The disadvantage is logistic, and a meticulous system for the storage and identification of the blood units is needed.

3.8. Regional collaboration

In the Eastern Mediterranean Region, there is a need for cooperation between the blood transfusion services of the Member States. It is not to be expected that all countries will be able to establish within a short time all the various activities outlined for a national blood transfusion service, and in some instances it might not even be advisable.

Instead, the establishment of one or two regional centres could provide the necessary support to the national blood transfusion services.

Such Regional centres could engage themselves in:

1. **Reference functions:** There is sometimes a need for advanced blood typing for which all national blood transfusion services may not have the necessary reagents or know-how. Countries may also need assistance to solve specific problems such as finding the reasons for inconsistent results. The reference function also includes the development and testing of new methods.

2. **Quality assessment scheme for the Region:** Even if all national blood transfusion services should run their own quality assurance and quality assessment schemes, there is a need for similar activities on a Regional basis. The Regional centres could also assist the national systems by preparing and distributing the standards, reference sera and proficiency testing materials.

3. **Preparation of blood components:** The reference centres should be well experienced in the preparation and use of blood components to allow them to advise other centres with less experience in this field.

4. **Plasma fractionation:** Among the countries responding to the WHO questionnaire distributed in the Region in 1985-86, only Egypt and the Islamic Republic of Iran reported that they had the capability to carry out plasma fractionations. Since the goal is to reach Regional self-sufficiency in all blood products, additional capacity will probably have to be developed in one or two countries and the necessary experience should preferably be available in the Regional centres. Increased Regional fractionation capacity may also lead to better utilization of the blood components since some of them, e.g. cryodepleted plasma after removal of Factor VIII, are not yet fully utilized for transfusion purposes.

5. **Storage of frozen blood components:** Cryoprecipitate, like frozen fresh plasma, can be stored frozen at below 30°C for a considerable length of time. Other preparations, and as red blood cells, can only be stored under special conditions (at -80°C in mechanical freezers or at -130°C in liquid nitrogen after glycerolization) which requires advanced and costly equipment. This method of storage is, therefore, only used in very special situations. Resources for such storage should be available at least in the Regional centres.

6. **Production and testing of reagents:** Every blood donor centre has to make regular routine checks on their typing sera and other reagents to make sure that they function as required. Other tests like comparisons of the performance of different brands of reagents are more complicated and should be carried out at national and Regional level. It may also, in order to reduce costs, be found suitable for a Regional centre to produce and standardize its own reagents which could be supplied to other countries of the Region.

7. ***Testing and evaluating supplies and equipment:*** As in the case of reagents, it would also be valuable to have in the Region the possibility of evaluating various kinds of equipment and supplies such as centrifuges, refrigerators, blood bags, trays and racks. Results of such evaluation may provide a good background for standardization of methods and equipment, as well as for the introduction of new methods.

8. **Arrange for local production of certain supplies:** Much specialized equipment and supplies will probably have to be imported but, for certain types of equipment, local production may result in products that are better adapted to local needs at a much lower cost. Regional centres could assist in identifying such products, find suitable producers and could participate in calibrating and standardizing the equipment.

9. **Research:** Apart from the value of developing the research potential there are a number of problems which are best studied within the Region. This is true for the development and application of new methods in the countries. It is also true for studies of the effects, for example, of blood component treatment in certain diseases. The development of such a research potential may provide an important support to other countries of the Region.

10. **Training:** One of the most important functions of a Regional centre would be to provide training to students from the Region. The knowledge and experience collected in such a centre is a perfect background for training of specialists at all levels, both in theoretical subjects and practical laboratory work.

4. RECOMMENDATIONS

It is recommended to:

4.1. establish a national blood transfusion service integrated with the national health services and provided with an adequate budget. Ideally this should be unified under a national director, but in some larger countries it may be appropriate to organize it on a provincial level coordinated by a national board;

4.2. develop an appropriate level of national self-sufficiency for the provision of blood and blood products (for definition see Annex);

4.3. foster the establishment by the transfusion services of entirely voluntary blood donation, through a well planned long-term programme. Adequate budgetary support is essential;

4.4. promote the integration of or close cooperation between the transfusion services of the Armed Forces and the national blood transfusion services;

4.5. enact appropriate legislation to ensure the safety of donors, staff and recipients of blood. Authority should be delegated to the national blood transfusion service to implement regulations governing standards in all hospital and other blood banks;

4.6. encourage the establishment of the speciality of transfusion medicine for doctors and scientists wishing to make a career in blood transfusion;

4.7. ensure that blood transfusion technology is incorporated into the curricula of schools of medical laboratory sciences;

4.8. provide for an attractive career structure for staff within the national blood transfusion service, including possibilities for further education and research;

4.9. ensure that training in the rational use of blood and blood products are included in the curricula of medical faculties and nursing schools and that refresher courses are given to practising clinicians.

ANNEX

In the context of the attached document the terms given below are used with the following meaning:

1. National self-sufficiency

National refers to each sovereign country.
Self-sufficiency means an adequate supply without importation.

There are different levels of self-sufficiency which may be considered.

	Item	Comments
1.	Whole blood	Essential goal can be achieved in all countries.
2.	Major blood components (platelets, red cells, plasma, cryoprecipitants)	Requires capital, equipment and organization - can be achieved in all countries.
3.	Blood grouping reagents	For serious consideration in all countries
4.	Plasma for fractionation	
5.	Plasma fractionation/ derivatives	Feasible only with advanced industrial capability
6.	Test kits for donor screening (HbsAg, HIV etc.)	Generally best handled by industry but joint venture may be favourable
7.	Plastic collection bags	
8.	Heavy equipment	Generally best handled by Industry
9.	Basic supplies (tubes, labels, etc.)	
10.	Training (a) basic	Local training is the goal
	(b) advanced	International training or interaction may be necessary and is valuable.

2. **Quality assurance** is a prospective, dynamic system of analysis which involves legitimizing or validating the entire process of manufacture and its various production steps.

3. **Quality control** is a retrospective analysis of what has already occurred, comprising of

- setting up of product specifications;
- testing of the product according to a specified testing programme;
- evaluation of the test results and release of the product.

4. **Transfusion medicine** is a specialized field of medical science. It includes not only the laboratory aspects of the blood and blood transfusion services, but also, the clinical utilization of the diverse spectrum of blood derivates and their safe and proper use. Specialists in transfusion medicine play an important role in the pre- and post-graduate training of clinicians of most specialities.