BLOOD TRANSFUSION SERVICES

Report on the

REGIONAL MEETING OF DIRECTORS OF BLOOD TRANSFUSION SERVICES

Tunis, Tunisia, 25-29 September 1995

World Health Organization
Regional Office for the Eastern Mediterranean
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1. INTRODUCTION

A Regional Meeting of Directors of Blood Transfusion Services was held in Tunis, Tunisia, from 25 to 29 September 1995. The meeting was attended by 22 participants from 21 Member States of the Eastern Mediterranean Region of WHO (EMR) and Algeria in the European Region.

The objectives of the meeting were to:

- exchange information concerning the situation and development of blood transfusion services;
- follow up and evaluate the implementation of the Plan of Action endorsed in the previous Regional Meeting of Directors, which took place in Nicosia, Cyprus, in April 1991, and revised in Amman, Jordan, in 1993;
- modify the plan of action, if needed, for some countries, based on experience gained during the past two years.

The meeting was inaugurated by H.E. the Minister of Health of Tunisia, Dr El Hedi M'Henni. While welcoming the participants, Dr M'Henni mentioned that the health sector, including the blood transfusion services, has achieved remarkable development and received continuous support. As a result, the blood transfusion services have greatly improved, including meeting safety requirements at all transfusion stages. Within the framework of the eighth development plan, 1992-1996, a blood transfusion services programme with clear objectives to develop and upgrade these services has been prepared. Particularly important among these objectives are:

a) Generalized use of plastic, instead of glass bottles, with 73% of blood transfusion activities using plastic bags. The target by the end of the current development plan is 90%, with a view to ensuring rational use of blood and achieving "selective, adapted haemotherapy".

b) Establishment of a new blood transfusion centre and a bone marrow transplantation unit (BMTU). The centre has become operational and is carrying out all blood transfusion activities. It will also act as a technical reference centre for the planned BMTU which will hopefully become operational in 1996.

c) Establishment of a national blood transfusion network consisting of five regional centres affiliated to the National Blood Transfusion Centre. Four such centres have been established, the fifth being built and expected to be inaugurated in 1996. The creation of the blood transfusion network will enable to serve the whole country and apply an integrated, coherent blood transfusion policy.
d) Increasing the number of blood donors through a sensitization campaigns at all levels. Efforts to this effect are made within the health education and school health programmes as well as all types of media.

e) Upgrading plasma collection and fractionation activities. Using plastic bags in collection has been instrumental in this respect. It is to be noted that the Military Hospital in Tunis now has a fractionation unit.

In general, the Ministry of Health Blood Transfusion Programme aims at achieving the target set by WHO, i.e. to achieve self-sufficiency in blood and blood products.

In the light of the fact that the national blood transfusion programme of Tunisia has an academic nature, a new university degree has been set up as part of the programme that concentrates on the biological aspects related to blood transfusion. This degree has been adopted by the Ministry of Higher Education.

He also mentioned that the Government pays due attention to all types of training and continuing training. The Minister had expressed his pleasure at the fact that WHO had designated the National Blood Transfusion Centre in Tunisia as a WHO collaborating centre in the field of blood transfusion, and had welcomed candidates from various countries.

Blood safety requirements in blood transfusion receive due attention. A prominent example in this respect is the obligatory screening for HIV since 1987; screening for hepatitis C, despite its high costs, since 1994, and the planned hepatitis B vaccination programme.

Also to be commended, he continued, are WHO initiatives to promote blood safety requirements in blood transfusion, e.g. the Paris Summit on AIDS and the formation of a follow-up task force in this connection.

The Minister concluded his speech by stating that the Ministry of Health will spare no effort to intensify support and development of this important sector, trusting that the findings of this meeting will be of great help in this regard.

Dr Hussein A. Gezairy, Regional Director for the WHO Eastern Mediterranean Region, in his message, welcomed the participants and thanked the Government of Tunisia for hosting the meeting.

Dr Gezairy reminded the participants that in 1975 the Twenty-eighth World Health Assembly adopted a resolution (WHA28.72), urging Member States to "promote the development of national blood transfusion services based on voluntary non-remunerated donation of blood". He also said that the development of blood transfusion services in all countries of the Region and ensuring a supply of safe blood and blood products have been always of great concern to the WHO Regional Office for
the Eastern Mediterranean. A number of meetings, workshops and training courses covering different aspects of transfusion medicine have been organized by the Regional Office for the Eastern Mediterranean; the most recent were the two workshops conducted during 1995—one dealing with distant learning and the second on appropriate use of blood and blood products.

The Regional Director mentioned that support has not been limited only to WHO regular budget resources, but it was also possible to obtain some voluntary funds in support of efforts to ensure blood safety. The WHO/AGFUND collaborative project has had a significant impact on the development of blood transfusion services in a number of Member States in the Region. The development of national expertise is one of the priorities for WHO collaboration. In this regard, steps have been taken, in consultation with the national authorities in Jordan and Tunisia, to develop two regional training centres on blood transfusion— one in Amman, Jordan, and the other in Tunis, Tunisia.

Dr. Gezairy said that computerization, recombinant DNA technology, improvement in cell separation, changing patterns of blood usage, the growing use of plasmapheresis and cytapheresis, and the use of autologous donation and intraoperative blood salvage are among technical advances affecting transfusion medicine. While such advances have been made in most industrialized countries, the development of blood transfusion services in many developing countries still faces problems, such as financial limitations, political instability, blood transfusion-transmitted infections and insufficient numbers of adequately trained staff.

The Regional Director expressed his pleasure to note that Member States of this Region were making efforts to further develop and improve the blood transfusion services in their countries. The regional plan of action formulated by the directors of blood transfusion services of countries of the WHO Eastern Mediterranean Region during their meeting in Cyprus in 1991 represents a milestone in the development of blood transfusion services in the countries of the Region. The results of the implementation of this plan of action were presented at a similar meeting in 1993 in Jordan. It was found that significant progress had been made by most countries towards achieving the targets established in 1991. However, it was found that a small group of countries were facing difficulties in meeting the targets. It was, therefore, decided that it would be more practical for each country to formulate its own national plan of action for realizing and extending the objectives formulated in 1991. Highly populated and heterogenous countries were advised to adopt an organizational model with the establishment of provincial centres that are coordinated at national level.

Professor K. Boukef (Tunisia) was elected as Chairperson, and Dr. A. Kitchen as rapporteur.

The agenda and the programme are in Annexes 1 and 2 respectively. Annex 3 contains a list of participants.
2. COUNTRY REPORTS

2.1 Afghanistan

Organization and management

Each hospital in Afghanistan has a small blood bank and blood transfusion service unit attached to it. In the beginning, collection of blood was done in glass bottles, while at present plastic bags are used. There were no volunteer donors; donors are mainly relatives of the recipients. In the 1970s a central blood bank and transfusion centre was established in Kabul. It was serving Kabul and the nearby provinces.

The central blood bank in Kabul has a General Director who has vice-directors in all other blood banks and transfusion services in hospitals of Kabul and other provinces. They have responsibility of supervising the functioning of blood transfusion services in their respective hospitals.

The Government has the responsibility of supporting the services financially and morally. During the civil war, other international organizations, such as the ICRC and Federation of ICRC and MSF helped the hospitals to provide blood transfusion services. The targets of the plan of action of 1991 and 1993 were not met due to the civil war.

In a country like Afghanistan, to establish a blood transfusion service there are essentially four limiting factors which need attention:

1) Restricted financial resources
2) Limited expertise
3) Lack of adequate infrastructures
4) Limited numbers of volunteers for blood donation.

Once adequate financial resources become available, the plan would be to rebuild the transfusion service based upon the following aspects:

Organization of the services
Recruitment of donors
Collection, processing, storage and distribution of blood and blood components in disposable bags
Laboratory investigation
Training and teaching
Research and development.

Organization of blood donor services

In 1991 and 1992 the policy was to record names and addresses and blood groups of voluntary donors. Each hospital had its own list of donors. During the years of war the policy failed and the central blood bank was completely disrupted. Wounded patients who needed blood had to be supplied by their relatives.
National screening policies

There is no general screening policy at present. Some hospitals are supported by international organizations to screen the blood collected for anti-HIV, HBsAg, syphilis, and malaria.

Staff training

Since staff training needs financial resources, which are lacking at present, training is not done professionally, not only due to lack of funds, but also due to lack of experts. The hospitals supported by some international organizations have provided some training to technical and blood collection staff.

Use of blood and blood products

The implementation of the regional policy to educate staff on appropriate use of blood and blood products did not take place.

Quality assurance

Quality assurance is not as yet in place.

Data on hereditary haematological disorders

There is no testing for hereditary haematological disorders and no records or exact figures are known.

Problem areas

Civil war is the greatest problem at present which is preventing going ahead with the implementation of the regional plan of action for the development of blood transfusion services.

Future plans

There is a need for support from international organizations, both financially and technically.

There is a need to train nationals on different aspects of blood transfusion.

2.2 Bahrain

Organization of blood transfusion services

There are two blood banks in the country which cater for the population of 500,000. The Central Blood Bank at Salmaniya Medical Centre (SMC) is the main and largest blood bank in the country which is under the Ministry of Health and serves almost all the smaller government and private hospitals. A smaller blood bank located in Bahrain Defence Forces (BDF) Hospital caters to the military personnel and those patients undergoing open heart surgery, since the open heart centre is located in the BDF Hospital. There is close cooperation between the Central Blood Bank and the BDF Blood Bank.
The Red Crescent Society in Bahrain plays an important role in donor recruitment and motivation. A blood bank committee in the Red Crescent Society is composed of 6 members who help in donor recruitment and education. There are about 4 to 5 monthly outdoor campaigns which are organized by the Central Blood Bank in coordination with the Red Crescent Society.

There are no national regulation or a national director. The central blood bank at SMC is directed by the medical consultant who is the director of the centre.

The blood transfusion services are fully funded by the Ministry of Health, and there is no system to recover the cost of these services, as health services are provided free of charge to all inhabitants of Bahrain.

Organisation of blood donor services

There is no written government policy which regulates the system of blood collection; however, the acceptable international regulations/policies of blood collection are followed by the two blood banks in the country.

The different existing blood donation systems used by the central blood bank and their ratio of collection as of 1995 are given below:

- Autologous donation 0.005%
- Family replacement (relatives or donor directed) 11.8 %
- Voluntary, unpaid 22.195%
- Voluntary, paid 66.0%

The existing demands for blood for the population is estimated approximately 10,000 donations per year. At present the rate of donations is around 10,000 per year. The demand is increasing at the rate of 3-5% every year. Bahrain is self-sufficient and no blood is imported from outside. In order to meet these needs, the central blood bank at SMC is working towards implementation of voluntary, non-remunerated blood donation, to implement various methods of donor promotion, to computerize data concerning blood donors, patients, and their compatibilities which has been started in 1994 and will be finished by the end of 1995, and to strengthen community involvement in voluntary non-remunerated blood donation.

National screening policy

According to a ministerial order all blood should be screened for HIV, HBsAg, and HCV. In March 1987, the screening of blood for HIV was made mandatory. No blood is used for transfusion without screening for HIV, HBsAg, and HCV. The method of screening is ELISA. Those samples testing positive on initial screening are retested using the same system along with an ELISA from a different manufacturer. Western Blot confirmatory is used to confirm those samples with repeated Elisa positive. Western Blot results are reported according to the manufacturer's specifications and evaluation by an expert.
All results are reported confidentially to the physician in charge. As an extra precautionary step blood units with ELISA positive and Western Blot negative are discarded. Such donors are repeatedly tested at regular intervals to monitor the rise in titre.

The reagents for screening are purchased by the Government through the local agents of different companies. However, purchase of these reagents are initiated after careful evaluation and selection by the senior members of the laboratories concerned.

A panel of true and false positive samples collected over the years are used for quality assurance purposes. These panels are mainly used for newly recruited staff before they are entrusted with the job of screening blood bank samples for HIV and other tests, e.g. hepatitis B.

Staff training

The minimum qualifications required for entry into service for different medical and technical posts are as follows:

Medical consultant: M.D. or M.R.C.(Path.) or its equivalent
Resident doctor: M.B.B.S., or its equivalent
Medical technologist: B.Sc. degree or equivalent
Laboratory technician: Associate degree or equivalent.

At present, no training programmes exist for medical doctors and donor recruiters. The central blood bank offers practical training in transfusion services for the associate degree students in medical technology programme from the College of Health Sciences in Bahrain.

Use of blood and blood products

The proportion of blood converted into components for the year 1994 is as follows:

- Cryoprecipitate: 0.4%
- Fresh frozen plasma: 6.2%
- Platelet conc. (single unit): 18.9%
- Packed red cells: 74.3%

Quality assurance

Quality assurance system was introduced in 1994. A standard operation procedure (SOP) manual which follows the international regulation policy is used for daily quality assurance in the central blood bank at SMC. Anti-sera vials are checked daily for any abnormal appearance. Reagent red cells are checked daily for haemolysis and turbidity. AHG is checked daily for anti-immunoglobulin activity.

Cell washers are checked for accurate dispensing of saline volume. Centrifuges and refrigerated centrifuges are checked daily for their proper function and temperatures. Water baths, and incubators are checked and observed for proper temperature daily. Temperatures are all refrigerators and freezers are checked and recorded daily on each shift, and compared with the temperature reading on the temperature recording chart, and thermometers inside the refrigerators.
Data on hereditary haematological disorders

The incidence of hereditary haematological disorders amongst non-neonatal cases in Bahrain are as follows:

<table>
<thead>
<tr>
<th>Hb patterns</th>
<th>No. of Cases</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hb A/A (normal pattern)</td>
<td>15 802</td>
<td>31.18</td>
</tr>
<tr>
<td>Hb S/A (sickle cell trait)</td>
<td>28 675</td>
<td>56.56</td>
</tr>
<tr>
<td>Hb S/F (sickle cell disease)</td>
<td>4 437</td>
<td>8.75</td>
</tr>
<tr>
<td>Hb S/S (sickle cell disease)</td>
<td>857</td>
<td>1.69</td>
</tr>
<tr>
<td>Hb A/F/A2 (B-thal major)</td>
<td>82</td>
<td>0.16</td>
</tr>
<tr>
<td>Hb A/A2 (B-thal minor)</td>
<td>446</td>
<td>0.88</td>
</tr>
<tr>
<td>a-thal (multiple pattern)</td>
<td>227</td>
<td>0.46</td>
</tr>
<tr>
<td>Rarer forms</td>
<td>161</td>
<td>0.32</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>50 695</strong></td>
<td><strong>100.00</strong></td>
</tr>
</tbody>
</table>

G6PD deficiency in male blood donors is 26.4%.

The proportion of red cells which is useful for different haematological disorders for the year 1994 are as follows:

<table>
<thead>
<tr>
<th>Red Cells</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>G6PD</td>
<td>4.4%</td>
</tr>
<tr>
<td>SCD</td>
<td>17.1%</td>
</tr>
<tr>
<td>Thalassemia</td>
<td>26.7%</td>
</tr>
<tr>
<td>Anaemia</td>
<td>49.8%</td>
</tr>
</tbody>
</table>

Plan of action

There is a plan of action.

Problem areas

The reluctance of the public and patients' relatives to donate blood.

Future plans

- To establish and develop the Central Blood Bank at SMCA as a national Transfusion centre, an autonomous body under the Ministry of Health, and rename it as "National Blood Transfusion Centre".
- To establish the National Blood Transfusion Centre on an entirely voluntary non-remunerated blood donation basis.
- To move the Central Blood Bank to the new building which is under construction at present time, and expected to be finished by mid-1996.
2.3 Cyprus

Organization and management

There is no change in the management structure of blood bank in Cyprus, but the Law Commissioner was asked to produce legislation and regulations for approval by the House of Representatives.

Organization of blood donor services

Blood donor services are well organized and based on the involvement of the whole community. Special computer programmes are used to programme and coordinate blood donation.

National screening policies

All blood donations are screened for HIV 1 and 2, hepatitis B, hepatitis C and syphilis. Self-deferral is encouraged for donors belonging to at-risk groups, and blood safety is promoted with the establishment of a panel of regular blood donors.

Staff training

Staff are trained through participation in seminars and workshops. In-service education is promoted.

Seminars and meetings are regularly organized for the users of blood.

Use of blood and blood products

About 38,000 units of blood are collected per year, and about 80% of blood collected is processed. Clinicians readily accept the use of red cell concentrates. Platelets and fresh frozen plasma are available in all blood banks. The demand for these products is rising. Multitransfused patients are now given leucocytes-depleted erythrocytes.

Quality assurance

Although no quality control officer has been appointed, quality in the blood banks is well maintained.

Achievements and future plans

Some more time will be necessary for the implementation of the plan of action formulated and endorsed during the Nicosia (1991) and Amman (1993) meetings. The Government accepts the need for the changes, and is in accord with the plan of action suggested.

Self-sufficiency in plasma derivatives is the aim for the near future. Staff upgrading and the establishment of an independent blood transfusion service are planned during the next 12 months.
2.4 Egypt

Organization and management

The Blood Transfusion Service (BTS) started in Egypt in 1938 by the formation of the Society of Blood Donors, a social nongovernmental organization. In 1947, the first blood bank in Alexandria was established, followed by the Egyptian Red Crescent blood bank in Cairo in 1948. Now there are 212 blood banks in Egypt.

The issuance of a Presidential Decision (Law No. 178) which required the formation of the Blood Transfusion Control Council in 1960 was the first legalization of the official organization of the BTS. In 1975, Ministerial Decree 171 established the General Directorate for Blood and Blood Derivative Affairs.

The Ministry of Health (MOH), represented by the Blood Transfusion Control Council, and with the General Directorate for Blood and Blood Derivative Affairs, has the responsibility for upgrading, organizing and administering the BTS all over the country.

The primary task of the BTS is to cover the country's needs for blood and blood derivatives, qualitatively rather than quantitatively.

Blood banks in Egypt are categorized into three levels, according to the Ministerial Decree 104 of 1985, depending on personnel (number and qualification), area and population served by the blood bank, premises, and equipment.

There are 36 main blood banks: 24 under the Ministry of Health, 7 linked to university hospitals, 3 hospitals and teaching institutes, 1 Red Crescent, and 1 General Organization for Vaccine and Biological Products.

The total number of satellite blood banks is 98: 80 under the Ministry of Health, 5 University, 4 hospitals and teaching institutes, 4 health insurance, and 5 curative organization.

There are 78 storage blood banks: 73 under the Ministry of Health, 3 university, 1 hospital and teaching institute, and 1 curative organization.

Organization of blood donor service

There is no special organization for blood donors. Recruitment of donors depends mainly on personnel effort, and there are no regular donors.

In Egypt, there are still three types of donors: paid donors (£E10 per donation, which is about US$3), volunteer donors, and replacement donors. In most hospitals relatives of cold surgery cases have to donate blood before admission and the patients do not have to pay for their care.

In emergencies it is the responsibility of the hospital and the blood bank to offer blood/products.
National screening policy

Screening tests are performed on every unit of blood collected. This is regulated by the Ministerial Decree 101 of 1993.

* Syphilis is tested for by RPR
* Hepatitis B surface antigen is tested for by:
  - Latex particles
  - Reversed passive haemagglutination
  - ELISA
* Anti-HIV testing became routine in 1990 in most blood banks (main and satellite). Confirmation of initially positive cases by Western Blot is performed in the Ministry of Health central laboratory.
* Anti-HCV screening was introduced in 1993 by ELISA. No confirmatory testing is performed.

Staff training

- Orientation programmes for new employees and refresher courses for all employees.
- Training programmes abroad, to keep up to date with new trends in transfusion medicine.
- Postgraduate studies for physicians and technicians in clinical haematology.

Use of blood and blood products

About 260,000 blood units are collected per year to overcome the shortage of blood, and, to avoid the hazards of whole blood transfusion, the MOH equipped most of the main blood banks with the facilities necessary to prepare blood components (red cell concentrate; fresh frozen plasma; platelet concentrate and cryoprecipitate).

The percentage of component preparation is still very low—about 25% of available units, because the clinicians still insist on using whole blood instead of specific components.

The MOH will take the necessary steps to enlighten the clinicians to the importance of using specific components, for the sake of the patients and to optimize blood use. This will be through circulars and meetings between clinicians and blood transfusion staff.

The rate of blood collection is 4.5 units/1000/year (that is for governmental sector only), but if the military and private sectors are added together the rate may be about 10 units/1000/year.

Quality assurance

To achieve the goal of the Egyptian BTS in offering safe blood, the MOH believes that quality control is essential in any scientific work, especially in the BTS.

- A comprehensive organization chart stating assignment responsibilities, administrative, technical and clerical.
A written procedure manual, describing in detail all procedures and policies, is available in all blood banks. Central supply of all blood banks with packs, antisera, diagnostic kits and equipment for:
- Standardization of component of the service
- Ensuring the potency and effectiveness of antisera and diagnostic kits
- Facilitating the provision of spare parts and maintenance of equipment
- The introduction of new equipment and techniques.

Data on hereditary haematological disorders

Blood banks are responsible for screening and issuing safe blood. Investigations and diagnosis of haematological disorders is the responsibility of haematological laboratories.

Problem areas
1) Lack of regular donors; the presence of paid donors (through limited numbers, still a problem).
2) Financial problems.
3) Lack of training courses abroad for senior staff to keep up to date of progress in transfusion medicine.

Future plans
1) Establishment of a reference blood bank in the main blood bank in Alexandria after upgrading it.
2) Component preparation in a large number of blood banks and the enlightenment of clinicians and surgeons about the use of blood components.
3) Establishment of a new central data managing project.

Achievements towards the targets of the regional plan of action, Cyprus, 1991

Organization and management

There is a National Director of Blood Transfusion Services.

The Ministry of Health has designated the Alexandria Main Blood Bank as a future reference blood bank and will contact the WHO Regional Office for technical advice in order to upgrade it appropriately.

The functions of the National Blood Transfusion Central Council have been reviewed.

Screening policies

All blood banks—whether governmental, university or private blood banks—are properly equipped to efficiently undertake mandatory routine
serological tests for HIV-1/HIV-2 by ELISA on all blood units since 1986. Confirmation of initially positively reacting specimens is performed by retesting by another commercial kit, and by IFA in selected centres.

Sero logical tests for HBsAg are also mandatory, and have been used since 1980.

Availability of blood and blood products

There is self-sufficiency in the country, although the number of donations collected is still relatively low. This has been supported by a law, preventing the import or export of blood or blood components.

Some central blood banks are presently able to prepare blood components, to reach a self-sufficiency in blood components.

Training

Orientation programmes for new employees and refresher courses for all employees are available.

2) There are postgraduate studies for physicians and technicians in clinical hematology.

Quality Assurance

1) Quality standards are used now (they will be incorporated into a quality assurance programme, to be implemented with the assistance of WHO).

2.5 Islamic Republic of Iran

Organization and management

The Iranian Blood Transfusion Service (IBTS) was established in 1974 and is a non-profit organization under the Ministry of Health and Medical Education. It is governed by a technical High Council appointed by the Minister, who is the director of the council. The Managing Director of the IBTS is appointed by the High Council. The main task of the IBTS is to provide safe blood and components for the whole country.

The IBTS has 66 branches in the provinces; some of those that are in large cities, are educational centres. These centres, besides their regular task in preparing blood and its components, perform the necessary educational programmes for the staff of the smaller centres and the hospital blood banks in the region.

Organization of blood donor services

About 80% of donations are from voluntary non-remunerated blood donors and 20% are from family replacement donors. Blood collection in 1994 was 850,000 units, in 350 ml and 450 ml plastic bags. The criteria for selecting all donors include: written history, measurement of blood pressure and weight. Pre-donation anaemia screening is used for some
donors, when required by physicians. There is a record system for all donors who have donated blood at any collection centre.

National screening policies

All donated blood is tested for:

1. Anti-HIV 1 and 2, by ELISA (confirmed by WB)
2. HBsAg by ELISA
3. Syphilis (RPR) by ELISA.

In one of the large provinces, Mashhad, because the prevalence of HTLV-1 is high (1.9%), all donations are tested for HTLV-1.

The incidence of positive donations are:

<table>
<thead>
<tr>
<th>Test</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-HIV</td>
<td>&lt; 1 in 400,000</td>
</tr>
<tr>
<td>HBsAg</td>
<td>3%</td>
</tr>
<tr>
<td>Syphilis (RPR)</td>
<td>0.13%</td>
</tr>
<tr>
<td>HTLV-1</td>
<td>0.29%</td>
</tr>
<tr>
<td>HCV</td>
<td>0.3%</td>
</tr>
</tbody>
</table>

Training

It is now intended that the larger regions will act as educational and training centres. Advanced training courses for personnel have been started. In this respect, 50 students are being trained for an AA degree in the field of blood transfusion, and 15 students have obtained M.Sc. degree in immunohaematology.

There is close cooperation with medical universities in the field of education. A distance learning programme has been started following a regional workshop in April 1996.

The clinical pathologists of IBTS conduct medical seminars for physicians in order to introduce the concept of appropriate use of safe blood and blood products in the country. IBTS specialists conduct workshops in new techniques and methods in blood transfusion for clinical and laboratory staff.

Use of blood and blood products

Blood is used mainly for haemorrhage (pregnancy-related), trauma, surgery, and hereditary anaemia (thalassaemia, 26%). About 80% of the collected blood is processed into components: packed red blood cell, platelet concentrate and cryoprecipitate, as well as all the usual plasma fractions that are used frequently. The amount of plasma collected during 1994 was 600,000 units, including (FFP, 420,000 units) and (SDP, 180,000 units).

In order to be able to become self-sufficient as far as plasma products are concerned, a plasma fractionation centre has been established. About 80,000 litres of plasma per year could be processed in this plant.
The products of this centre include Factor VIII (1,600,000 IU), Factor IX (2,000,000 IU), albumin 5% (1,000,000 cc), albumin 15% (600,000 cc) and albumin 20% (600,000 cc) annually. Also anti-rabies immunoglobulin (1,700,000 IU), blood group reagents (anti-A, B, AB, D) and anti-serum for HLA typing are obtained by plasmapheresis. Preparation of blood group reagents (namely anti-A, -B, -H), using monoclonal techniques has been started.

Quality assurance

A quality assurance department which covers the entire spectrum of transfusion services, including donor selection, process validation, proficiency testing and quality control of products is now in place at the IBTS.

Data on hereditary haematological disorders

The main hereditary haematological disorders are major thalassaemia and haemophilia. The number of thalassaemic patients is 17,000 and the number of haemophilia patients is 5,000 (majority of these are haemophilia A).

Implementation of the regional plan of action of 1991 and its amendments of 1993

The IBTS has already applied most of them; for example: IBTS has a national committee (High Council), a National Director, cooperation with army and other related organizations, testing all blood for infectious diseases transmitted by blood transfusion, etc. In the use of blood and its components: the experts from the IBTS give seminars in hospitals about the use of blood for medical staff. In addition, two sets of regulations have been proposed to the Ministry: one for the control of hospital blood banks, and the other for the establishment of hospital blood transfusion committees. These committees would be able to improve the practice of blood transfusion in their hospitals. It is hoped that with IBTS cooperation this will have good results in the near future.

Problems

The main problem at the moment is the lack of hard currency to cover all the needs; for example, the cost of anti-HCV kits is very high.

Future plans

a) To upgrade the fractionation department. It will be a separate, but affiliated, company to facilitate its operations and achieve its capacity, namely 800,000 litres of plasma per year.

b) To find an international organization for scientific cooperation and quality control of the products.

c) To establish different workshops for training in the different aspects of blood transfusion.
2.6 Iraq

Organization and management

The National Blood Transfusion Centre (NBTC) in Baghdad is the major centre in Iraq, and provides services for more than 40 hospitals. There are also 17 regional blood banks in the provinces which are responsible for blood supply to these local areas.

Blood donor system

All donations, apart from replacement donation, are voluntary.

Blood is collected from donors between 18-50 years of age, either locally in the NBTC or by mobile units.

Availability of blood and blood products

About 60% of the blood collected by the NBTC is used for component preparation, mainly packed red cells, fresh frozen plasma, platelets concentrate and Factor VIII rich cryoprecipitate.

Screening policies

Each unit of blood is examined for different diseases, mainly viral, which are transmitted by blood transfusion.

Training

Training is a continuous process and courses are run at different levels providing different levels of qualification.

Quality assurance

Quality control procedures are applied to all imported blood and blood products, and reagents.

Hereditary haematological disorders

Thalassaemia is the major hereditary haematology disorder in Iraq. More than 1000 patients are registered at the Iben Al-baladi Thalassaemia Centre. Sickle cell anaemia and haemophilia are less prevalent. Iraq was not invited to the meeting in 1991 in Nicosia because of the Gulf war, and had not adopted the recommendations resulting from that meeting.

Implementation of the regional plan of action

Although Iraq was invited to take part in the meeting in 1993 in Amman, and has accepted the recommendations made, the implementation of the quality assurance programme has been postponed due to current difficulties because of the embargo.
2.7 Jordan

Organization and Management

The population of Jordan is 4 million. The Ministry of Health (MOH) controls all blood transfusion centre activities and is directly responsible for the National Blood Bank, West Amman National Blood Bank and the 16 hospital blood banks in peripheral hospitals. The Royal Military Service is responsible for the King Hussein Central Blood Bank, the Queen Alia Hospital Blood Bank and 4 peripheral blood banks. In addition, there are the Jordan University Hospital Blood Bank, the Red Crescent Blood Bank and the Islamic Hospital Blood Bank.

All blood transfusion services are free of charge. The MOH recognizes the blood transfusion service as an important specialty in medicine. There is excellent cooperation between all blood banks.

Blood donor system

There are 84,680 donations per year in 1994, of which 25% are from voluntary non remunerated blood donors (VNBD), and 75% from family related donors. About 2.1% of the population donate blood. There is no directed donation. Autologous donation has started for some scheduled operations.

There is a need to increase the number of VNBD. Blood component production will increase by 5% by 1996.

All units are screened for HBsAg, anti-HIV, syphilis, malaria (not mandatory), and anti-HCV. Testing is by ELISA, haemagglutination and latex.

Quality control is performed routinely. Results are confidential and all positive donations are autoclaved and incinerated. The HCV seroprevalence among blood donors is 2%.

Availability and use of blood and blood components

Continuous evaluation is carried out of the quantity of blood and blood components needed. Blood component production is 67% of all donations. Two provincial blood banks have started to produce blood components (30% of their collection, with 5-10% annual increase).

A national meeting of blood bankers and users was held in Amman and guidelines for appropriate use of blood and blood products were formulated and distributed to all hospitals.

Training

Training programmes for blood bank staff were evaluated. There is a continuing education programme for medical doctors and nurses (lectures, weekly visits to the blood bank, and in-service education programme for all staff).
Introduction of the WHO distance learning programme is planned and will be introduced in two provincial blood banks by January 1996. Training for medical technicians is available from local universities.

Quality assurance

A quality assurance manager has been appointed and a quality assurance system is in place. Standard operating procedures are available for all staff preparing blood components. A computer system will be in service by July 1996.

2.8 Kuwait

Organization and management

The Kuwait Central Blood Bank (KCBB) was first established in May 1965 as a section in the General Laboratory Department at Amiri Hospital. In 1970, the KCBB was recognized as a separate Governmental Administration. In 1987 the KCBB was relocated at Jabriya.

The Blood Bank provides all the necessary blood and blood products to government and private hospitals in Kuwait.

The KCBB has been granted accreditation by the American Association of the Blood Banks (AABB) as a blood transfusion and collection centre. The accreditation follows an intensive on-site inspection by the Association to ensure that the levels of medical, technical and administrative performance in the facility meet or exceed the standards set by the AABB.

The KCBB is an active participant in the College of American Pathologists (CAP) survey, as a part of the external proficiency testing programme.

The KCBB is divided into distinct departments, each with its own purpose and function. They include the following:

1. Donation Section where donor selection is performed
2. Laboratory Section
   - Issue Room
   - Component Preparation and Storage Unit
   - Post-Grouping Unit (Patient/Donor pre-transfusion testing)
   - Groupomatic Unit for donor blood group testing.
   - Donor Processing Unit, which performs all the transfusion-associated disease (TAD) screening required to determine the suitability of blood products for transfusion.
   - Quality Control Unit. This unit has the function of ensuring that reagents, equipment and methods function as expected, and that there is compliance with agreed standards.
   - Therapeutic Apheresis Section, which applies apheresis procedures, following written request from the patient's physician, for short-term relief in some cases; for example, sickle cell crisis, hyperleukocytosis, etc.
3. Computer Section
4. Quality Management and Continuing Education Section
5. Administration Section
   - Public Relations Unit
   - Reception Personnel
   - Employee Affairs.

National screening policies and organization of blood donor services

Evaluation of the individual medical history follows AABB guidelines and relevant memoranda from the Food and Drug Administration (FDA), and is followed by physical examination. In addition, donor self-exclusion is encouraged.

Screening policies

1) ABO and Rh type
2) Antibody screening for the detection of irregular red cell antibodies
3) Infectious disease tests: HBsAg, Anti-HBc, Anti-HCV and Anti-HBs.

Additional tests performed on donors' blood are:

1) Cytomegalovirus (CMV) status of the donors
2) Malaria testing
3) Selected red cell typing.

"Look Back" (Donor, Recipient)

KCBB follows certain national policies in cases of suspected post-transfusion infection. Briefly, the guidelines are:

1. Look-back and donor notification are performed for HIV, hepatitis and HTLV-infected donors.

2. Details of the donors and the recipients of any positive donations will be submitted to the Department of Preventive Medicine, and donors will be permanently excluded from the donor pool.

Staff training

Staff training is monitored through an employee checklist covering all sections. Staff competency assessments are carried out twice a year, in addition to at the start of employment. The individual's performance and the supervisor's evaluation are recorded in the individual's personnel file.

A continuing education programme is provided within the facility. It is done in collaboration with professionals from the Allied Health School, Medical Technology and the Ministry of Health, Laboratory Services Administration. The programme consists of seminars, problem-solving exercises and lectures. Each employee should participate in a minimum of 3 hours of continuing education every year. This is recorded on each employee's personnel file.
Use of blood and blood products (availability and appropriate use)

KCBB prepares the following blood components:

1) Whole blood
2) Red cells
3) Washed red cells
4) Leukocyte-reduced red cells
5) Platelet concentrates from random donors
6) Plateletpheresis: platelet concentrates by apheresis
7) Irradiated blood
8) Granulocyte concentrates by apheresis
9) Neocytes.

A publication for all users of blood and blood components, known as the Circular of Information, is available for medical doctors and healthcare Personnel who have direct contact with blood transfusion. The Circular of Information contains all the necessary information for product indication, dosage, side effects and contraindications.

Training

KCBB offers a specially designed course in blood banking sciences (immunohaematology) for medical technologists in the hospital blood banks. The objective of the course is to prepare the trainee to be a technologist in blood banking.

KCBB is affiliated to the Kuwait University Faculty of Allied Health Service Medical Technology Department. The affiliation provides an intensive practical course for senior medical technology students.

A review course is provided to trainee candidates of M.R.C. Path, which covers intensive clinical and practical knowledge in transfusion medicine.

Quality assurance

The fundamental mission of the KCBB is to provide, when needed, blood products that are safe, and effective. In addition, it provides a range of patient services such as laboratory testing and education.

The quality assurance programme works together with the Quality Management and Continuing Education Unit and the Quality Control Unit.

KCBB follows the United States guidelines on Good Manufacturing Practices for Blood and Blood Products (Food and Drugs Administration) and some guidelines from the "European Guide to Good Manufacturing Practices for Medical Products" (European Union).

The KCBB achieves the required quality through:

Documentation. The use of standard operating procedures.

Standardization. The minimum levels of quality acceptable for a particular product or service. AABB standards are followed.
6) Platelethpheresis; platelet concentrates by apheresis
7) Irradiated blood
8) Granulocyte concentrates by apheresis
9) Neocytes.

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KCBB achieves the required quality through:

Documentation. The use of standard operating procedures.

Standardisation. The minimum levels of quality acceptable for a particular product or service. AABB standards are followed.

Records. These provide proof of compliance with the standards. The records are correctly and fully completed.

External quality assessments. Through CAP surveys.
Data on hereditary haematology disorders

Data have been collected on hereditary haematology disorders for many years. However, these data have not been updated since after liberation. The population of Kuwait comprises 44% Kuwaiti nationals and 56% expatriates.

The most up-to-date data available are from Sabah Hospital which has the largest Haematology Unit that deals with hereditary haematology disorders.

- Thalassaemia major: 148
- Leukaemia: 126
- Sickle cell thalassaemia: 24
- Sickle cell anaemia: 35

2.9 Lebanon

In Lebanon, many activities have been initiated to ensure adequate preparation and use of blood and its components. However, these efforts are still sporadic and need to be focused for improvements to occur in practice.

Organization and management of blood transfusion services

The Blood Transfusion Service (BTS) is hospital-based, and the health authorities, while reorganizing the public health sector, have chosen so far not to undertake active blood programmes but to leave it to the private hospitals to solve their problems directly. However, a National Blood Transfusion Committee was formed by the Government, although a national director was not appointed.

The eight Lebanese Red Cross (LRC) blood collection centres are active (26% of total blood units are collected through these centres).

Private blood banks no longer exist.

Organization of blood donor services

A total of 62,163 blood units were collected during the year 1994. The existing blood donations systems are still mostly dependent on family replacement. The role of the Lebanese Red Cross (LRC) in the blood safety strategy is mainly through voluntary work in collection and care of blood donors. The LRC makes blood available to patients in hospitals.

A blood donation coordinating committee, promoting the ideals of voluntary blood donation, has been formed to build on the existing network of the LRC centres which have some experience with short-term campaigns.

National screening policies

Every unit of blood is tested for hepatitis B, syphilis and anti-HIV 1+2. Hepatitis C testing (anti-HCV) has started at four centres. Screening reagents are purchased by the transfusion laboratories. Bulk
purchasing of HIV testing reagents through the National Office for Drugs is being considered.

Prevalence in blood donors:

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-HIV 1+2</td>
<td>0.0%</td>
</tr>
<tr>
<td>HBsAg</td>
<td>2.3%</td>
</tr>
<tr>
<td>Anti-HCV</td>
<td>4.0%</td>
</tr>
<tr>
<td>Syphilis</td>
<td>0.5%</td>
</tr>
</tbody>
</table>

Staff training

A university qualification (B.S. in Laboratory Technology) is required by many centres to work in the blood transfusion service.

Blood donor screening and deferral training sessions have been held in some university hospitals.

Use of blood and blood products (availability and appropriate use)

In the Hakassed Hospital, a 200 bed general hospital, the analysis of 902 medical records of patients who received blood or blood products revealed the following:

Indications of transfusion in the Adult Age-Group

| Medical diseases | 38.00% |
| Symptomatic anaemia | 30.00% |
| Operating room loss | 17.77% |
| Bleeding | 4.62% |
| Platelets <30,000 | 4.34% |
| Liver diseases | 3.92% |
| Trauma | 1.35% |

Indications of transfusion in the pediatric age-group:

| Medical diseases | 61.98% |
| Symptomatic anaemia | 22.01% |
| Platelets <30,000 | 9.08% |
| Operating room loss | 3.87% |
| Bleeding | 3.06% |

Indications of transfusion in the neonatal age-group:

| Medical diseases | 40.69% |
| Haematocrit <40% | 34.54% |
| Haematocrit <45% | 10.66% |
| Exchange transfusion | 13.91% |

Proportion of blood and blood components:

<table>
<thead>
<tr>
<th>Component</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentrated red cells</td>
<td>41% (10% filtered)</td>
</tr>
<tr>
<td>Whole blood</td>
<td>25%</td>
</tr>
<tr>
<td>Fresh frozen plasma</td>
<td>19%</td>
</tr>
<tr>
<td>Cryoprecipitate</td>
<td>9%</td>
</tr>
<tr>
<td>Platelets</td>
<td>6%</td>
</tr>
</tbody>
</table>
**Training**

Many workshops for HIV testing have been held for blood transfusion technicians working in the public sector in Lebanon during the last two years.

**Quality assurance**

A blood transfusion committee has been established in many centres.

Medical audits, carried out through a working group, evaluate the actual use of blood transfusion to ensure compliance with established local transfusion practice.

An update of the clinical criteria for blood usage has been prepared and will be published.

**Data on hereditary haematological disorders**

The carrier state for thalassaemia is 2.9%. The birth rate of homozygous thalassaemia is 0.5–0.6 per 1000 with 40–50 new cases expected each year. To this must be added, the cases of sickle cell disease, roughly estimated at 10 cases per year.

**Evaluation of the implementation of the plan of action**

(Cyprus 1991, Jordan 1993)

The feasible targets attained were:

- Development of a national network based on the existing network of the Lebanese Red Cross centres; mostly in the capital and the Southern Region.

- Implementation of a continuous review of screening methodology mostly concerning HIV testing.

- Improvement of the availability of blood products by better coordination between different hospital blood bank centres and the Lebanese Red Cross centres.

- Stress on the criteria for blood donors screening and deferral.

- Development of guidelines for the appropriate use of blood and blood products, aimed at medical graduates and hospital medical staff.

- Initiation of a medical audit programme to evaluate the impact of these guidelines.

- Production of blood components, such as red blood, leukocyte-poor red cells, leukocyte-poor platelets, FFP and cryoprecipitate.

- The holding of workshops on HIV screening methodology.
Problem areas

- Establishment of a national authority and responsible person to plan national policy.
- Blood donor recruitment programme aimed at increasing the proportion of voluntary non-remunerated blood donors and a corresponding decline in the number of donors induced by family replacement donation.
- Increase Ministry of Health support with facilities, staff, and an adequate budget.
- Poor quality assurance programmes.
- Staff training and job descriptions for all categories of staff.
- The rising costs of screening of blood.
- The establishment of national minimum specifications for reagents and blood bags.
- Regional manufacture of plasma derivatives and blood grouping reagents.

Future plans

- To seek support and assistance from regional and international organizations.
- Ministry of Health support for the creation of a national blood transfusion coordination programme, similar to the national AIDS programme (NAP).
- Enhancement of new transfusion practices, such as preoperative autologous blood collection.
- Development of blood irradiation plants.
- Development of a bone marrow transplant unit at Makassed General Hospital.
- Enhancement of the prenatal diagnosis for inherited diseases, such as thalassemia and haemophilia.

2.10 Morocco

Organization and management

The blood transfusion system is a State organization and is under the MOPH. It comprises of a National Centre for Blood Transfusion and 44 regional centres.

The National Centre for Blood Transfusion depends on the hospital management.
Its role is to apply the policies of the MOPH regarding blood transfusion and haemovigilance:

- To supervise, direct and coordinate the activities of the blood transfusion centres
- To promote blood donation
- To supply all blood transfusion centres with material and equipment necessary for blood collection, separation and testing, as well as educational material to promote blood donation.

The regional centres are under the administrative supervision of the MOPH delegate of the province.

The regional centres of blood transfusion are under the control of the National Centre for Blood Transfusion, and responsible for:

- promoting blood collection
- performing obligatory tests on all donations
- Irregular antibody screening and cross-matching
- supplying the needs of hospitals and private clinics in blood products
- ensuring an urgent blood delivery service
- providing the separated plasma to the National Blood Transfusion Centre
- providing monthly statistics to the National Blood Transfusion Centre.

Blood donor system

A blood donor who presents to a blood transfusion centre will undergo the following:

Donation conditions

a) Particulars of the donor
   - Name
   - Date of birth
   - Personal address
   - Telephone: domicile
   - Telephone: office
   - Profession.

b) Medical history

   After registration the donors interviewed by the doctor to check for any contraindication to donation by questioning, weighing, and checking blood pressure.

c) Blood collection

   Between 400 and 450 ml is collected in double or triple bags according to needs. Collection is performed by nurses under the supervision of a responsible doctor. Two tubes are used to make the obligatory tests and both tubes and donation forms are all labelled appropriately.
d) Post-donation care

After donation each donor is offered a drink (coffee, tea, milk, or juice) and biscuits.

e) Blood donor card

After 24 hours the donor receives a blood donor card.

f) Practical Tests

Testing and screening policies

a) Blood grouping is done by two different technicians, using two lots of different reagents and by two different techniques.

b) Immunohaematologic tests are routinely performed to detect any irregular antibodies and haemolysins.

c) The following serological tests are performed routinely:
   - Detection of syphilis by VDRL and TPHA
   - Detection of anti-HIV 1+2 (with confirmation by Western Blot)
   - Testing for HBsAg
   - Testing for anti-HCV

The above tests are done systematically on each donation.

The frequency of transfusion-transmitted diseases, according to the 1994 statistics on 150,000 donations, are:

<table>
<thead>
<tr>
<th>Infection</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV (after confirmation)</td>
<td>0.036%</td>
</tr>
<tr>
<td>Hepatitis B</td>
<td>3.5%</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>1.6%</td>
</tr>
<tr>
<td>Syphilis</td>
<td>1.5%</td>
</tr>
</tbody>
</table>

Training

The training of a specialist in haematology and blood transfusion takes four years. They are responsible for the Regional blood transfusion centres.

The training of competent doctors in blood transfusion takes 6 months.

The training of nurses and technicians specialized in blood transfusion is done at the blood transfusion centre in Rabat and Casablanca for two months before being employed in the blood transfusion service.

Finally, staff rotation is performed regularly, every three months.

A seminar on hepatitis C was held from 26 to 30 June 1995 (financed by WHO). Following this seminar, the opening of a Laboratory of
Molecular Biology took place which will permit the identification of the HCV type in Morocco to help in the treatment of infected individuals.

A seminar on apheresis, AIDS and transfusion was held from 30 May to 3 June 1995. The training of the doctors in the apheresis technique on equipment received, especially for this from Paris, France.

A seminar was held on quality control of blood transfusion from 9 to 13 October 1995, financed by WHO.

Use of blood and available blood products

In the other centres all the blood is separated systematically into packed red cells, plasma and platelets. Due to the existence of haematologic services at the BTCS in Casablanca and Rabat, the preparation of concentrated red cells is done at the request of the other centres.

The blood transfusion service has made available a number of important documents to hospitals to ensure appropriate use of blood and blood products, and appropriate transfusion practice across the country.

Available blood products are:

- Packed red cells
- Fresh frozen plasma
- Platelet concentrates
- Platelet concentrates obtained at the blood transfusion centre in Casablanca and Rabat.

Quality assurance

Courses are held for medical and paramedical personnel with the objective of better control of laboratory tests.

In each blood transfusion centre, quality control is performed daily in the laboratory using a standard reactive control.

A laboratory technician visits every six months the 44 blood transfusion services to make sure that laboratory tests are being performed correctly.

The National Laboratory for Quality Control started in July 1995; control is done every 3 months by sending out samples to be tested for anti-HIV 1+2, HBsAg, anti-HCV, VDRL, and red cell serology.

Future plans

1) The laboratory of molecular biology is financed by WHO and the National Centre for Blood Transfusion. Production of monoclonal antibodies is expected by November 1995.

2) The fractionation of plasma: contact has been made with foreign laboratories to obtain albumin, gammaglobulins and Factors VIII and IX.

3) The prevention of the neonatal haemolytic disease by injection of gamma-globulins to all Rh negative women.
2.11 Oman

Organization and management

Oman has a population of 2.5 million. The Blood Transfusion Service is a department under the Directorate General of Health Affairs of the Ministry of Health, and it consists of two sections:

The Central Blood Bank - situated in the Capital Region, and nine satellite blood banks in the regions (the Sultanate is divided into 10 health regions).

There are other hospital-based blood bank services in the university, police and army hospitals. There is only one private hospital blood bank in the country and this is also supervised by the Ministry of Health.

The Department of Blood Services has its own budget, which covers the medical and nonmedical supplies and laboratory equipment for the Central Blood Bank and the regional blood banks. The university, police and army hospitals have their own budgets from their respective Ministries.

In 1993 a National Committee for Blood Transfusion Services was formed and the members of this committee are professionals from the Ministry of Health, Sultan Qaboos University Hospital, the Armed Forces Hospital and the Royal Oman Police Hospital. This committee is responsible:

- To lay down a unified policy for Blood Transfusion Services in the country;
- To regulate all procedures relating to blood transfusion such as blood collection, blood testing, component preparation, storage and dispatch;
- To coordinate all activities related to blood transfusion in all government establishments;
- To increase the awareness of society about the importance of regular blood donation, through a continuous programme of donor recruitment and motivation;
- To carry out continuous and regular evaluation of blood transfusion practices and to update practices where necessary;
- To work as a national body to cooperate with Arabic and international organizations for blood transfusion; and
- To edit and publish a Handbook on Blood Transfusion Medicine and a manual of standard operating procedures, and to update them.
Organization of blood donor services

Three categories of blood donors exist:

Volunteer blood donors attending mobile teams
Volunteer walk-in donors to the Central Blood Bank
Directed (relatives) donations.

The Central Blood Bank team and the regional blood bank teams conduct mobile blood donation sessions in which they cover the government and private sectors. The blood transfusion centres have donor recruiters and motivators. They prepare the schedule of blood drives 8-10 weeks prior to the visits and have the final programme ready at least one month in advance. They despatch the programme letters to the concerned organizations at least one month before the blood drive, to give sufficient notice and awareness among the donors.

Apart from preparing the schedule they have the following responsibilities:

- Calling donors of rare blood groups in emergencies;
- Visiting different firms to recruit new places for mobile visits;
- Help in preparing master cards of blood donors;
- Taking part in some lectures and seminars to increase awareness about blood donation;
- Taking part in designing the printed matter produced by DTS to motivate society about blood donation.

The procedures for blood collection from donors, whether in the centre or outside, follow international guidelines. SOPs are available in all the blood banks. Blood donors are given symbolic incentives. No paid donor system now exists.

National screening policy

In the Central Blood Bank all units of blood are subjected to the following tests:

ABO & Rh grouping (manual tube, direct & reverse)
AB screening (manual tube)
VDRL (carbon antigen)
HBsAg
Anti-HIV 1+2 (Abbott Bead technology)
Anti-HCV.

N.B. Rh D negative are tested for Du;
- Two positive samples by VDRL are sent for confirmation by TPHA;
- Two anti-HIV positive are sent for confirmation by WB;
- Two HBsAg positives are confirmed by determining a full hepatitis B.

Blood units collected in the regions are subjected to the following tests:

ABO & RH grouping (slide or tube)
VDRL (Carbon antigen)
HBsAg (Latex)
Anti-HIV 1 (Toest pack for rapid testing)

N.B. Two positive samples are sent to the capital for confirmation.

Staff training

<table>
<thead>
<tr>
<th>Designation</th>
<th>Qualifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Superintendent</td>
<td>M.B.B.S.</td>
</tr>
<tr>
<td>2. Doctors (2)</td>
<td>1) M.B.B.Ch., M.Sc. (Clinic Path.) + Experience in BTS</td>
</tr>
<tr>
<td></td>
<td>2) M.B.B.S. + Experience in BTS</td>
</tr>
<tr>
<td>3. Donor recruiters (2)</td>
<td>B.Sc. in Social Work (one with training of 6 weeks in Aberdeen)</td>
</tr>
<tr>
<td>4. CMLSO</td>
<td>HNC (Med. Lab. Science), FIMLS (BTS)</td>
</tr>
<tr>
<td>5. Administrator</td>
<td>B.Sc.</td>
</tr>
<tr>
<td>6. Laboratory technicians (7)</td>
<td>Diploma of IHS (two of them were trained in USA for 18 months in BTS)</td>
</tr>
<tr>
<td>7. Lab. technicians (6)</td>
<td>Diploma in MLT</td>
</tr>
<tr>
<td>8. Nurses (2)</td>
<td>Diploma of IHS</td>
</tr>
<tr>
<td>9. Medical orderlies</td>
<td>Elementary</td>
</tr>
<tr>
<td>10. Secretary</td>
<td>Diploma in secretarial course</td>
</tr>
</tbody>
</table>

Graduates of IHS (MLT) spend six weeks in the BTS during their one-year internship. A medical continuing education programme is being updated to include the staff from regional blood banks.

Use of blood and blood products

About 93% of the units collected by the main Centre are processed to produce red cell concentrates, platelet concentrates, and Fresh Frozen Plasma. The remaining 7% are used as whole blood for certain cases requiring massive rapid transfusion.

The following blood bags are in use (Terumo)

- Single CPD 450 ml (5%)
- Single CPDA1 250 ml (2%)
- Double CPDA1 (5%)
- Triple CPDA1 (18%)
- Quadruple CPDA1 (35%)  
- Quadruple CPD-SAGM (35%).

Regional blood banks use only single and double bags. Whole blood and red cell concentrates are in use. Red cell concentrates are prepared by settlement.

Plasma derivatives (e.g. Factor VIII, immunoglobulins, etc.) and synthetic volume expanders (e.g. normal saline, dextrose, etc.) are widely in use all over the country. These products are imported from abroad by the MOH.
Quality assurance

Plans are under way to start a quality assurance system covering the entire spectrum of transfusion service activities, from donor selection to blood issue, and comprising a manual of detailed standard operating procedures (SOPs), process validation, proficiency testing and quality control. It will be in place by the end of 1995 to ensure compliance with pre-determined national standards and specifications.

Data on hereditary haematology disorders

The aim of the committee is:

- To develop public awareness of genetic blood diseases.
- To conduct a survey to estimate the magnitude of the problem of the genetic blood disorders. (The survey will start in October 1995 until the first quarter and go on in 1996).
- Early diagnosis of the disease, and management through health services available in the country.

Evaluation of the implementation of the plan of action

The three main areas in the plan of action following the regional meeting held in 1993 in Amman and which were specifically addressed to Oman were:

1) To increase the blood donations throughout the country;
2) screening policy;
3) Components preparation.

The total number of units collected during the years 1992 to 1994 were 16,000 (1992), 21,941 (1993) and 22,849 (1994). Voluntary non-renumerated donations were 70%, while family/replacement donations (unpaid) were 30%.

National screening policy

All donations collected in the Capital region are tested as mentioned previously. The screening of blood in the regions includes all the above, except anti-HCV. This parameter will be implemented as soon as possible, and by early 1996. A manual, which includes all practices related to blood transfusion medicine, donor selection, blood collection, donor care, screening, cross-matching, preparation of blood components and transporting blood and blood products from the blood banks in the Sultanate, has been prepared and is in the final stage of editing and publication.

Components. Ninety-three per cent of the units collected in the Central Blood Bank are processed. The 3 regions out of the 9 will start component preparation by mid-1996. A handbook on blood transfusion medicine has been prepared and will be published shortly. It includes all the necessary information regarding blood transfusion medicine, and the correct use of blood and blood components.
Problem areas

Although there has been an increase in the number of blood donations, the blood transfusion services are still suffering from a shortage of donations. This is due to:

- Inadequate awareness of the importance of blood donation among the public;
- Insufficient staff to collect more blood;
- Inadequate specialized training in blood transfusion.

These problems can be solved through:

1) Adoption by this National Blood Transfusion Committee a continuous organized campaign, mainly through the mass media;
2) Recruitment of more staff;
3) Sending local BTC staff for specialized courses (short and long) in countries where a BTS is well established.

Future plans

A new fully equipped blood transfusion centre has already been designed. Construction should start in January 1996 and be completed by mid-1997.

Screening for malaria for donors coming from areas considered to be hyperendemic (using Parasight - F kits - still under trial).

Establishment of screening for HIV-1 subtype O in 1996.
Establishment of anti-HCV screening in regional blood banks.
Setting up of component preparation in regional blood banks.

2.12 Pakistan

Organization and management

Blood transfusion in Pakistan is well organized on the following pattern:

Government organization
Private organizations
Social welfare organizations
Voluntary organizations
Professional organizations.

a) Government organizations

All Government hospitals, small or big, are equipped with blood banks where blood is collected, stored and distributed to patients according to needs. These blood banks are mostly attached to the pathology department and work under the supervision of either the senior pathologist, haematologist or other senior doctor.
b) Private organizations

In almost every town or city private organizations are working to provide blood:

Private hospitals and maternity homes have their own blood banks where blood is collected and provided to the patients.

c) Welfare associations

There are different welfare associations who have established blood banks where blood is collected and provided as required for different diseases, operations and emergencies. Well-known associations are the Edhi Organization, the Fatimid Trust and, on a small-scale Khanam Cancer Hospital.

d) Volunteer organizations

These organizations do not have blood banks, but they have registered members, with full address and their blood groups. Members are called to donate blood when required.

e) Professional organizations

These organizations provide blood on a commercial basis. They have registered persons who are:

- Either poor or unemployed and they donate their blood for their living, and
- Drug addicts who donate blood to meet their own needs.

The blood transfusion services are managed by the organizations mentioned above and the following arrangements are made in every blood bank.

- Availability of a haematologist, a pathologist, and blood bank technicians, around the clock
- Special refrigerators to maintain required temperatures
- Availability of antisera, centrifuges and microscopes
- Haemoglobin kits
- Slides
- Kits for HIV screening
- Kits for hepatitis "B" and "C" screening.

With the above arrangements, each donor is examined for physical fitness, the blood group is done and the donation collected. After it is screened for infectious diseases, it is stored in the blood bank. This service is available around the clock.

National screening policies

The following screening policy has been established:

- All the blood should be donated under the supervision of the haematologist or the senior pathologist.
- All the blood is properly grouped and subgrouped before its transfusion.
- Blood should be collected from donors between the ages of 25 and 45 years.
- Blood is taken only from those donors whose haemoglobin level is 13g/l (in males) and 14g/l (in females).
- Blood should never be collected from donors who have a history of malaria, hepatitis, syphilis, jaundice, uraemia, malignancy or any other suspicious disease.
- All blood is tested for Anti-HIV 1-2; HBsAg and anti-HCV; malaria; and leukaemia/lymphoma.

Not all donors are actually screened for HIV, and hepatitis, because the country cannot afford the cost. But there are facilities in Government and in private sector to screen out the blood for above problems.

Staff training

There are 22 medical colleges and each college has facilities to train doctors, haematologists, and blood bank technicians.

There are also four paramedical institutions where at least 800 blood bank technicians are trained each year and after obtaining their diploma they start work in different blood banks.

Postgraduate facilities are also available at the College of Physicians and Surgeons at Karachi; the Institute of Medical Sciences at Islamabad, and the Aga Khan Medical College at Karachi.

Health personnel are periodically trained in advance haematological techniques in these institutions.

Liasat medical college hospital is 1300-bed hospital and the donations collected are:

<table>
<thead>
<tr>
<th>Type of Donation</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total units cross-matched</td>
<td>60 000</td>
</tr>
<tr>
<td>Total blood donations collected</td>
<td>23 623</td>
</tr>
<tr>
<td>Total free voluntary donations</td>
<td>21 213</td>
</tr>
<tr>
<td>Family replacement</td>
<td>15213</td>
</tr>
<tr>
<td>Voluntary</td>
<td>6000</td>
</tr>
<tr>
<td>Professional</td>
<td>2 030</td>
</tr>
</tbody>
</table>

Use of blood and blood products

Whole blood is used to replace blood loss in: (a) operations, (b) trauma, (c) gynaecological (postpartum haemorrhage) cases, in anaemia where haemoglobin is less than 7g, and blood diseases, such as thalassaemia, leukaemia and cancer patients.

Blood products that are available are: packed red cells, plasma, platelet concentrates, Factors VIII and IX. Packed red cells are used only to increase haemoglobin, but not blood volume. Plasma is used to expend blood volume and replace proteins. Platelets are collected by more specialized methods and are only routinely available in big centres in Karachi, Lahore and Islamabad, but are available in emergencies to other centres. Factors VIII and IX are available in large centres and are used only under the supervision of the haematologist.
Training

There is frequent training of blood bank staff: pathologists, haematologists, and blood bank technicians. Refresher courses are held in Islamabad and Karachi.

Quality assurance

To improve the quality of blood, policies exist covering the:

- Selection of donors (outlined previously)
- Collection of donations (blood should be collected in a septic atmosphere in special bags.)
- Storage of donations (blood should be stored at 4C for not more than 21 days.
- Screening (outlined previously)
- Grouping (All blood should be properly grouped and cross-matched and relevant information should be recorded on the label attached to the blood bank.)
- Centrifugation

Before issuing blood it should be centrifuged to look for any lysis red cells.

Data on hereditary haematological disorders

Due to the short time available, a survey on hereditary haematology disorders could not be carried out.

Leukaemia is the commonest blood malignancy in childhood, constituting 33% to 38% of the malignancies and at a level of 4/100 000/year.

Evaluation of the plan of action of 1991 problem areas

The following problems are encountered with respect to:

These services are all separate
There is no communication between centres
Confirmatory tests are not available in peripheral centres.

In Pakistan there are areas which are under development such as Thar near Karachi, and the mountainous areas in the north of Pakistan where communication still does not exist and blood facilities are at a low level.

Future plans

Provision of screening facilities by all private and government hospitals.

Public should be educated about the problem of the blood transfusion and transmitted diseases through electronic media, newspapers, pamphlets and posters, public meetings, seminars, and community involvement.
Health personnel should be highly trained in haematology.

By publicity and trust voluntary donors should be encouraged.

Intercommunication between different organizations should be established to provide and spread information between centres.

Strict rules should be adopted to implement the policies.

2.13 Palestine

The Gaza Strip is a small region, roughly estimated at 360 km², which lies as narrow zone on the Mediterranean sea, "between Israel and Egypt" where approximately 900 000 Palestinians are living.

The health services for the Gaza Strip are provided mainly by the Palestinian National Authority (Ministry of Health) from one side, and from the other side by UNRWA Health Department and other NGOs. The health services focus on a comprehensive system combining the curative and preventive health services.

There are five government hospitals with a capacity of 900 beds and two other hospitals (private) with a capacity of about 90 beds. There are plans to establish new hospitals, one 230 bed hospital is to be built by the EEC. Details of presently working hospitals are given below:

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Type</th>
<th>Location</th>
<th>Bed Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>El Shifa Hospital</td>
<td>Government</td>
<td>Gaza City</td>
<td>454</td>
</tr>
<tr>
<td>El Nasir Hospital (Paediatric)</td>
<td>Government</td>
<td>Gaza City</td>
<td>135</td>
</tr>
<tr>
<td>Khan Younis Hospital</td>
<td>Government</td>
<td>Khan Younis</td>
<td>233</td>
</tr>
<tr>
<td>Ophthalmic Hospital</td>
<td>Government</td>
<td>Gaza City</td>
<td>30</td>
</tr>
<tr>
<td>Psychiatric Hospital</td>
<td>Government</td>
<td>Gaza City</td>
<td>28</td>
</tr>
<tr>
<td>El Ahli El Arabi Hospital</td>
<td>Private</td>
<td>Gaza City</td>
<td>75</td>
</tr>
<tr>
<td>Other private hospitals</td>
<td>Private</td>
<td>Gaza City</td>
<td>15</td>
</tr>
</tbody>
</table>

In addition to the above hospitals, there are about 31 PHC government centres, nine UNRWA centres, and many NGO clinics all over the Gaza Strip.

There are three major blood banks in the Gaza Strip and three small blood bank branches:

a) El Shifa Hospital laboratory blood bank which is considered one of the major blood banks in Gaza Strip with the capacity of collecting, screening, processing approximately 5000 units of blood annually. It is considered to function as a transfusion centre.

b) Khan Younis Hospital laboratory blood bank, which has a capacity of collecting, screening, processing approximately 2000 units of blood annually. It is considered as a transfusion centre.

c) The Blood Bank Society, Gaza City, with three additional small branches, has the capacity to collect about 3000 units annually. They
are all collecting centres only, and the blood collected by these centres is utilized in the hospitals.

**Screening Policy**

All collected blood units are screened for anti-HIV 1+2, HBsAg, anti-HCV, VDRL, ABO grouping and Rh typing, and specific antibodies.

During the years 1989-1994, approximately 41,465 units of blood were screened for anti-HIV 1+2, HBsAg, VDRL, ABO type and Rh group. The following prevalences were found:

- HBsAg 5.5%
- Anti-HIV 0.0%
- Syphilis 0.0%

Anti-HCV screening started on the 1st of January 1995. Current results indicate a prevalence of 2.4%.

**Blood Grouping and Rh Typing**

<table>
<thead>
<tr>
<th>Blood Type</th>
<th>Rh (+) %</th>
<th>Rh (-) %</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>31</td>
<td>4</td>
</tr>
<tr>
<td>B</td>
<td>20</td>
<td>2</td>
</tr>
<tr>
<td>AB</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>O</td>
<td>32</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>88</td>
<td>12</td>
</tr>
</tbody>
</table>

All blood banks in the Gaza region are using special blood bank refrigerators connected to emergency generators.

In Shifa Hospital, a small blood component separation unit consists of two refrigerated centrifuges, and two deep freezers. This small unit has the capacity of providing the hospital's patients demands of fresh frozen plasma and cryoprecipitate. There are plans to eventually prepare platelet concentrates.

Most of the donations collected are transfused to patients as:

- whole blood
- packed RBCs
- fresh frozen plasma
- cryoprecipitate
- platelets.

In 1994, a total number of 5,370 blood units were transfused to the patients in both El Shifa Hospital and El Naser Pediatric Hospital (total of 606 beds) as follows:

<table>
<thead>
<tr>
<th>Section</th>
<th>Whole Blood</th>
<th>Packed RBC</th>
<th>Frozen fresh Plasma</th>
<th>Platelets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical</td>
<td>213</td>
<td>570</td>
<td>1,230</td>
<td>118</td>
</tr>
<tr>
<td>Surgical</td>
<td>1,635</td>
<td>229</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Gynaec/Oha.</td>
<td>1,090</td>
<td>430</td>
<td>134</td>
<td>36</td>
</tr>
<tr>
<td>Paediatric</td>
<td>86</td>
<td>1,117</td>
<td>443</td>
<td>8</td>
</tr>
</tbody>
</table>
More than 55% of blood is transfused as whole blood. In accordance with the new transfusion policy, the use of whole blood will be minimized.

The programme of distance learning from WHO in safe blood and blood products has been approved by the Ministry of Health.

1. A steering committee has been established.
2. Plan of action has been approved.
3. Trainers have been selected.
4. National coordinator for the distance learning programme has been nominated.
5. Learners (12) have been selected from blood banks.
6. The programme was opened officially by the Minister of Health on 4 August 1995.

Future plans

Future programmes include establishment of a National Transfusion Committee to conduct the following:

1. Establish a National Blood Transfusion Centre
2. Establish a National Blood Transfusion Policy
3. To plan for budgeting and allocated financial resources either governmental, NGOs or other agencies
4. To organize a standard panel of voluntary remunerated and non-remunerated blood donation to cover the hospitals' requirements without the need of family replacement donors
5. Establish standards and controls to ensure the quality of blood collection, screening and donation
6. Establish a standard management and records system for all blood transfusion activities.

The requirements are:

1. Need to widen the ABO & Rho screening, for example sub groups, genotyping etc.
2. Screening for HLA, platelets, granulocytes antibodies.
3. In addition to screening for HBsAg, anti-HCV, anti-HIV 1/2, VDRL, it is also necessary to screen donations for:
   - HTLV (Human T-lymphotocytes virus)
   - CMV (Cytomegalovirus) to face the demand of neonate transfusion
4. Use of special blood transfusion filters for minor transfused-patients
5. Apheresis machines for leukocyte and platelet separation
6. Washed red cell machine
7. Long storage of red cells (rare blood groups and Rh types).
<table>
<thead>
<tr>
<th>Year</th>
<th>ELISA-LP400</th>
<th>ELISA-LP400</th>
<th>Western Blot confirmatory test</th>
<th>Still under follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total Tests</td>
<td>Suspected</td>
<td>Negative Positive</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Results</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1987*</td>
<td>1 075</td>
<td>6</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>1988</td>
<td>4 800</td>
<td>10</td>
<td>10</td>
<td>-</td>
</tr>
<tr>
<td>1989</td>
<td>4 590</td>
<td>11</td>
<td>10</td>
<td>1</td>
</tr>
<tr>
<td>1990</td>
<td>4 131</td>
<td>7</td>
<td>7</td>
<td>-</td>
</tr>
<tr>
<td>1991</td>
<td>4 240</td>
<td>8</td>
<td>5</td>
<td>- 3</td>
</tr>
<tr>
<td>1992</td>
<td>4 570</td>
<td>5</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>1993</td>
<td>5 682</td>
<td>3</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>1994</td>
<td>7 476</td>
<td>7</td>
<td>3</td>
<td>1 3</td>
</tr>
<tr>
<td>1995</td>
<td>5</td>
<td>4</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

* Screening for HIV started in Gaza in October 1987.

The following tables give details of the results of the study during 1990-1994 about HBSAg.

### Shifa Hospital Blood Bank - Blood Donors

<table>
<thead>
<tr>
<th>Year</th>
<th>Total No.</th>
<th>Reactive</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1990</td>
<td>3 270</td>
<td>94</td>
<td>2.90</td>
</tr>
<tr>
<td>1991</td>
<td>3 695</td>
<td>88</td>
<td>2.40</td>
</tr>
<tr>
<td>1992</td>
<td>4 262</td>
<td>128</td>
<td>3.00</td>
</tr>
<tr>
<td>1993</td>
<td>3 350</td>
<td>170</td>
<td>5.00</td>
</tr>
<tr>
<td>1994</td>
<td>5 831</td>
<td>304</td>
<td>5.20</td>
</tr>
</tbody>
</table>

### Khan Younis Hospital

<table>
<thead>
<tr>
<th>Year</th>
<th>Total No.</th>
<th>Reactive</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1993</td>
<td>2 985</td>
<td>181</td>
<td>6</td>
</tr>
</tbody>
</table>

### Shifa Hospital Blood Bank - Patients

<table>
<thead>
<tr>
<th>Year</th>
<th>Total No.</th>
<th>Reactive</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1990</td>
<td>386</td>
<td>70</td>
<td>18.10</td>
</tr>
<tr>
<td>1991</td>
<td>423</td>
<td>57</td>
<td>13.40</td>
</tr>
<tr>
<td>1992</td>
<td>486</td>
<td>86</td>
<td>14.00</td>
</tr>
<tr>
<td>1993</td>
<td>630</td>
<td>105</td>
<td>16.60</td>
</tr>
<tr>
<td>1994</td>
<td>1 917</td>
<td>145</td>
<td>14.25</td>
</tr>
</tbody>
</table>

### Blood Bank, Gaza

<table>
<thead>
<tr>
<th>Year</th>
<th>Total No.</th>
<th>Reactive</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1989</td>
<td>2 690</td>
<td>134</td>
<td>4.98</td>
</tr>
<tr>
<td>1990</td>
<td>2 717</td>
<td>133</td>
<td>4.89</td>
</tr>
<tr>
<td>1991</td>
<td>2 716</td>
<td>115</td>
<td>4.23</td>
</tr>
<tr>
<td>1992</td>
<td>2 857</td>
<td>133</td>
<td>4.65</td>
</tr>
<tr>
<td>1993</td>
<td>2 867</td>
<td>129</td>
<td>4.49</td>
</tr>
<tr>
<td>1994</td>
<td>4 225</td>
<td>213</td>
<td>5.04</td>
</tr>
</tbody>
</table>
Classification of Blood Groups of Donors

<table>
<thead>
<tr>
<th>Group</th>
<th>O</th>
<th>AB</th>
<th>B</th>
<th>A</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>%</td>
<td>No</td>
<td>%</td>
<td>No</td>
</tr>
<tr>
<td>Rh+</td>
<td>3399</td>
<td>32</td>
<td>585</td>
<td>5</td>
<td>263</td>
</tr>
<tr>
<td>Rh-</td>
<td>528</td>
<td>5</td>
<td>75</td>
<td>1</td>
<td>260</td>
</tr>
<tr>
<td>Total</td>
<td>3927</td>
<td>660</td>
<td>2410</td>
<td>3671</td>
<td>10668</td>
</tr>
</tbody>
</table>

2.14 Qatar

The health services in Qatar are mainly delivered by the Ministry of Health. The services can be divided into two main channels: namely, Hamad Medical Corporation (HMC) in Doha and primary health Centres (PHC) distributed all over the country, numbering 24, twelve of which are outside Doha. Additionally, there are minor ambulatory services in the Petroleum Company, the Army and Police.

Hamad Medical Corporation has three hospitals: Hamad General Hospital, the Women's Hospital and Rumaila Hospital. It has a common laboratory and a blood bank. The former is the reference laboratory for the state laboratories, as well as for private laboratories, and the latter is the only blood transfusion centre in the country. There are laboratories in 21 of the 24 PHCs.

Organization of blood transfusion services in HMC

<table>
<thead>
<tr>
<th>Supervisor of BB</th>
<th>3 Residents</th>
<th>Supervisor of Donor Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Senior Technologists in Haematology BB (Qataris)</td>
<td>3 Nurses</td>
<td></td>
</tr>
<tr>
<td>2 Technologists (Qataris)</td>
<td>2 Clerks</td>
<td></td>
</tr>
<tr>
<td>7 Technicians</td>
<td>Receptionists</td>
<td></td>
</tr>
<tr>
<td>1 Assistant</td>
<td>1 Clerk Typist</td>
<td></td>
</tr>
</tbody>
</table>

The blood bank currently shares the same consultant with the Haematology and Cytogenetics Division of the Laboratory.

The blood bank and its laboratory are located within the main Hamad General Hospital. The Donor Unit is currently situated within the Emergency Department of Hamad General Hospital, but a separate building within the campus is being built. Donor access to the present unit is easy and car parks are plentiful in the vicinity of the Emergency Department. The new building will be more easily accessible to donors as it would be located on the main road.

There is no mobile donor unit in Qatar, but a team is formed to collect blood outside the hospital, whenever such an opportunity arises. It uses the premises of the institution where blood is being collected.
An apheresis programme exists in the blood bank. Technologists of the blood bank run the service assisted by blood donor nurses. Thrombapheresis is the commonest procedure, followed by leukapheresis on husbands of those who have had repeated abortions.

The blood bank works 24 hours a day and seven days a week (3 shifts). The Donor Unit is open for 14 hours a day, six days a week (2 shifts).

**National screening policies**

HMC Blood Bank incorporates a serology laboratory which screens not only donors, but also inpatients, outpatients and individuals applying for a residence permit or its renewal. RPR is performed in the main serology laboratory.

Blood is screened as per AABB policies, namely: anti-HIV 1/2, HBsAg, HBcAb, anti-HCV, anti-HTLV-1, RPR and ALT.

Malaria screening follows a special policy.

ALT-screening is now carried out as a pre-donation screen in the Donor Unit. Donors giving ALT above 70 IU/l (1.5 x upper normal limit) are rejected. For results between 60-70 IU/l, samples are taken and referred to the Chemistry Laboratory. Results below 60 IU/l are acceptable for blood donation.

A positive RPR result is followed by a TPHA test. If positive, the donor is rejected.

Screening for CMV proved impractical as a high percentage of the indigenous and expatriate population are positive (95%). It is performed on a limited number of EPO donations for neonatal use. Leukocyte depletion filters help eliminate the virus in unscreened blood given to immunocompromised patients.

Western Blot test is available for HIV-1 only. An HIV antigen test (ELISA) is available for confirmation. Unfortunately, the screening tests for most donors are performed only after donation, due to the reluctance of donors to attend twice. A lot of blood and efforts are being wasted because of this.

**Staff training**

a) Medical staff

Training is provided based on a plan with the aim of preparing Qatari specialists in the laboratory disciplines. For blood transfusion, the training is considered as part of a wider schedule in haematology and blood transfusion as the qualifications for the two are still taken jointly in most parts of the world. The HMC blood transfusion/haematology training programme takes two years after which the resident is sent abroad to complete the training and qualify.
b) Technical Staff

HMC Laboratory takes part in training Qatari technical staff at two levels:

1) Students of the Biomedical Sciences programme in the College of Sciences are given a full course on blood transfusion (3 credit hours) both theoretical and practical, by the staff of the Blood Transfusion Medicine Division.

2) Newly appointed Qatari graduates of the above programme (B.Sc.) are given full training in the five disciplines of the laboratory taking 14 months for rotation. At the end of this period they are stationed in one of the five specialties to undergo a further 4 months' training. They are assessed and a report made to the education coordinator of the Department at the end of each period of the rotation. When successful they will be formally appointed as technologists.

Use and availability of blood and blood products

HMC blood banks process almost all donations drawn to prepare the following products:

- Whole blood units
- Packed red cell units
- Fresh frozen plasma units
- Platelet concentrate units
- Cryoprecipitate units - from some of the FFP units.

Statistics of 1993, 1994 and the past 8 months of 1995 clearly show the procurement, availability and utilization of all the above products.

Staff education on the proper utilization of blood and blood bank services is an ongoing process. The consultant gives frequent talks on the subject to various departments, clinical and nursing. He also discusses this with individual requesting physicians, directly or through representatives of departments on the Blood Transfusion Committee. Cooperation has improved and blood utilization is continuously improving as a result.

Fields that have been subject to improvement include:

- Indications for transfusion of the various products.
- Use of leukocyte depletion filters as well as the washing of red units.
- Use of the apheresis programme.
- Organizational matters of ordering, transportation and return of the unused blood units.
- Investigation of suspected transfusion reactions.

A daily stock report is produced every morning showing the available stock of each blood group against the minimal acceptable stock. Call-up of volunteer donors of the specific blood groups needed would start from the Donor Unit on instructions from the consultant. Under exceptional conditions the media may be used to call donors. An education leaflet has also been prepared for distribution.
Type-and-screen (Group and save) procedure has been in use for obstetrics and gynaecology patients for four years. It was introduced in general surgery and orthopaedics at the end of 1994. Auto-donation represents a small but definite proportion of blood collected, and is slowly increasing.

There is as yet no intraoperative blood saving practice in HMC.

**Quality assurance**

a) International QA programmes

The Blood Transfusion Medicine Division now has a comprehensive internal QA programme on all instruments procedures and blood products. In addition to controls and daily machine checks (all documented) the Blood Bank does weekly schedules of QA on products as follows:

* Week 1. Check on red cells for bacterial culture (Expired and one-day-old blood that is destined for discarding due to factors such as anti-HBc and high ALT are used).

* Week 2. Quality assurance is performed on platelet counts of platelet concentrate units (units meant for discarding). Also red cell contamination is checked on random bags.

* Week 3. Coagulation Factors VIII and V are checked on FFP units of various storage ages.

* Week 4. Cryoprecipitate coagulation factor assays are performed.

QA is performed on all apheresis products.

b) External QA programmes

Qatar participates in the QA programme of the College of American Pathologists (CAP) for both blood transfusion and viral serology parts. The results have been highly satisfactory in the last two years.

Specimens are occasionally sent to Germany or Central Public Health Laboratory, Colindale (UK), for viral serology confirmation, and there is an agreement with the WHO Red Cell Serology Collaborating Laboratory in UK to help with difficult irregular antibodies. Incident reports are filed on all erroneous procedures performed by technical staff.

**Blood transfusion for hereditary haematologic disorders**

Haemolytic anaemias are relatively frequent in Qatar. \( \alpha \)-thalassemia represents the main type of haemoglobinopathy. There are 52 thalassaemic patients on regular blood transfusion, and received a total of 800 units in 1994. Four sickle disease patients need regular transfusion. \( \alpha \)-thalassemia is common and there are at least five known HbH disease patients, although they rarely receive blood.

Red cells given to thalassaemics used to be washed or filtered in the blood bank, but now filtration is done for at least 50% of transfusions.
Irregular antibodies pose a problem especially when they are multiple. The commonest antibodies encountered are Lewis.

Evaluation of the implementation of the plan of action endorsed (1991) and its amendments (1993)

The following are points pertinent to Qatar where there is one blood bank providing all the Blood Transfusion Services of the State.

1) Organization and management

It is not realistic for Qatar to set up create an independent service with its own financial management for the reason given above.

2) Donor education and motivation

This is being implemented through cooperation between the Blood Bank and the Public Relations Department of HMC. Mass media are often utilized with the help of the latter. Educational leaflets have been printed and are being distributed fairly widely.

From 1994, certificates of gratitude have been given to donors who reach certain numbers of donations. Also, certificates are being given to institutions that cooperate in starting a donation campaign.

3) Screening Policies. Implemented

4) Availability

With the minimum stock levels it has been possible to cope quite well most of the time. Only in certain seasons, the fasting month, peak of summer holidays and pilgrimage season the Public Relations Department has to be requested to help through TV, radio and newspapers.

Availability of platelets is very satisfactory. However, due to the short shelf-life, the need to revert to thrombapheresis occasionally arises during periods of drop in stocks as mentioned above.

5) Training

Training is proving efficient and job descriptions have been prepared.

Two senior Qatari staff are on scholarship in the U.S.A. for qualifying as SBBs.

6) Quality assurance

Internal and external QA practices have been reported above. A practical manual is at hand for all technical staff to use.

Problem areas

1) Sources of blood

Donation is not paid for, nor forced. In 1995, a little less than 50% of donors were volunteers as compared to 18% in 1993. However,
the rest are still semi-volunteers. They represent friends and family members of the patient being admitted for cold surgery.

2) Space for the Donor Unit

Only four donor chairs exist at the present time. A new building has been approved which, when finished, will suffice for 10 beds for males and 6 for women. It will also have waiting areas and a spacious reception area. The present donor unit is so small that if there were 6 waiting to be bled the place becomes overcrowded.

Apheresis does not have a space of its own and it is done in the same donor room amongst the four donor chairs. This will have its own room in the new building.

3) Shortage of staff in Donor Unit

The small number of nurses makes working hours very rigid and it is difficult to accommodate any increase in donors or dispatch of a mobile team. Nurses from the ward are called upon when needed.

4) Lack of purpose-built mobile blood donor vehicle.

5) Low level of education about blood donation. This is improving gradually.

6) Shortage of staff in the Blood Transfusion Laboratory. The current number of staff covers three shifts. Sometimes, staff are required to do two shifts a day. Local Qatari staff are not happy, due to family reasons, to do late shifts.

Future plans

1) The establishment of a well-staffed and equipped blood donor centre. The building has been approved and budget allocated. It is hoped that it will be ready for use by the end of 1996. Staffing is hoped to improve with the building of the new centre. Request has been made for one apheresis nurse and 5 phlebotomy nurses, a clerk/receptionist for each of the two shifts, and a public relations officer. The plan is to have a second apheresis machine later.

2) A completely equipped mobile unit is still in the plan, awaiting funding. The University has plans to launch a campaign for donation of money from various sources to buy the vehicle. It is hoped to start this campaign in the 1995-96 academic year.

3) Education. More education leaflets and public lectures are planned. Last year the consultant and senior female technical staff gave a total of 4 lectures in sports clubs and schools on blood donation. There was one long TV programme in which the situation of blood stocks (depleted at the time) was presented to the public. Another programme involved an interview with the consultant. It is hoped to increase these presentations as they have proved to be of great help.
4) Encouragement of volunteer donations by emphasis on the steps below. The aim is to raise the percentage by at least 5% of total donations every year.

- The mobile unit visiting donors at sites of their work, education, etc.
- More publicity for donation.
- More education.
- Symbolic gratitude gifts and gestures additional to the certificates launched last year.

5) Encouragement of autologous donation and transfusion by staff education and public education.

2.15 Saudi Arabia

The Blood Transfusion Services in the Kingdom of Saudi Arabia represents an important part of the Health Services available in all the regions. The Ministry of Health (MOH), through its 173 hospitals (26,878 beds) spread over 19 health regions, has the main responsibility for providing blood transfusion services to the 16 million population. 34 hospitals (8,357 beds) belonging to the Armed Forces, National Guard, Security Forces, Universities and King Faisal Specialist Hospital & Research Centre also offer their blood transfusion service to all those who need it. However, few of the 72 private hospitals (6592 beds) offer blood transfusion service to their patients. The total number of hospitals is 279 with a total of 41,827 beds.

Organization and management

A National Committee for Blood Transfusion Services was set up by the Deputy Minister of Health and is composed of representatives from the Ministry of Health, King Saud University, National Guard Hospitals and Military Hospitals. It is required to prepare a national plan for improvement of blood transfusion services.

The MOH supervises 118 blood banks which are classified into:
- 11 central blood banks
- 37 main blood banks
- 49 Peripheral A blood banks
- 31 Peripheral B blood banks

Each category of these covers designated areas and is furnished with the personnel and equipment needed to discharge their duties.

Organization of blood donor services

The MOH blood banks collected a total of 220,000 units of blood in 1994, covering the needs of the Kingdom. A plan was drawn up to increase the number of donors in order to make use of plasma fractionation. Some projects are under study. The Custodian of the Two Holy Mosques, in order to encourage voluntary blood donation, honors each donor with a gold medal when he/she donates voluntarily 10 units of blood. New programmes, such as the "Programme of the Society of Blood Banks Friends", were launched to increase the number of voluntary donors.
Forty per cent of the donors are volunteers, 55% are patients' relatives and 5% driving license applicants.

National screening policies

Screening tests are carried out in all central and main blood banks for HBsAg, anti-HCV, anti-HIV 1&2, anti-HTLV 1, malaria and syphilis.

All positive results are repeated in duplicate and then confirmed. They are referred to the related specialized clinics for follow-up.

Staff training

The training of blood bank staff is arranged in collaboration with paramedical health colleges under the Ministry of Health and medical colleges. In addition, some manufacturers, such as the Pasteur and the Abbott, arrange periodical training sessions in all health regions. Also, scientific symposia are held on hepatitis B and C and AIDS in large populated regions. There are also local plans for regional training programmes in central blood banks for physicians and technicians from regional blood banks.

Use of blood and blood products

The central and main blood banks carry out the preparation of blood products according to the methods recommended by the AABB for: packed red blood cells; fresh frozen plasma; platelets concentrates and cryoprecipitate. These components are despatched under proper shipment and transportation procedure to all blood banks in the Kingdom on demand.

Evaluation of the implementation of the plan of action endorsed in Nicosia in 1991 and Amman 1993

All points of the plan of action have been discussed and it was found out that most of them were implemented because they are quite similar to the National Plan started in 1990.

Internal quality control for all blood banks is carried out, especially for testing of blood for infectious diseases. In addition, external quality control is performed in some blood banks to ensure complete and safe blood transfusion services.

Rare blood groups and irradiation. In central blood banks some rare blood groups are kept frozen until they are needed. Irradiation of blood and its components is carried out for some patients who require this treatment (acute leukaemia patients). Automatic plasmapheresis programme is carried out for transfusion and therapeutic purposes.

Problem areas

There are a large number of blood banks in the Kingdom which need regular monitoring to evaluate their implementation of the correct procedures.
Saudi national and qualified personnel are still short of the estimated number needed for the blood banks, and the turnover of expatriates is fast. Time is needed to create a stable system and human resources.

**Future Plans**

Plasma fractionation and production of albumin, immunoglobulin and coagulation factors will be started, hopefully soon.

Application of the computer link system to the Central Blood Bank in Riyadh is under trial to assess its performance before connecting all the blood banks in the Kingdom.

**Organization and management**

In July 1994, the Ministry of Health appointed a Director to be responsible for blood transfusion services.

A proposal for restructuring the present service was submitted to the Federal Ministry of Health with a suggestion that the blood transfusion service should be a separate directorate with a separate budget as suggested by the previous Meeting of Directors of Blood Transfusion Services in the Region. No national steering committee has been formed as yet.

**Blood donor system**

A group of people experienced in blood transfusion from the University of Khartoum discussed the present state of the donor system and future plans to improve it. They concluded that at the present time family replacement, and directed family donations are the only viable options. However, voluntary donation systems now have to be planned and started.

Contacts with two national NGOs are under way to make use of their potential for recruitment and motivation.

Contacts with some national newspapers were fruitful and a series of articles will start to appear in these newspapers to educate and to start the process of motivation that hopefully will be continued in TV, mosques, schools, workplaces, etc.

At the present time there is no qualified person available to be appointed as the donor coordinator. The plan is to choose two medical officers and train them in donor motivation and recruitment.

**Screening policies**

From the field visits done, it was clear that screening is inadequate outside the capital. During the field visits, the Director urged the state officials to consider blood screening as top priority, to form blood transfusion committees, to look after the service, and to formulate a work plan to make blood transfusion safe.
It is felt that blood screening has to be enforced by law, and to be monitored by a strong central blood transfusion service.

**Appropriate use of blood and blood products**

A total of ten workshops directed at doctors, nurses, and laboratory technicians were conducted in Khartoum and other towns to raise awareness about the rational use of blood. The staff also participated in other workshops on the rational use of blood in collaboration with NACP for doctors and nurses.

Guidelines have been prepared and funds are awaited to print and distribute the document.

Participants in the workshops were urged to share their views. These views illustrated clearly that the absence of guidelines in the past has created poor practices.

It was clear that from the last population census that the quantity of blood need is about 250,000 units/year. The actual amount collected is about 60,000 units/year.

On a very small scale, production of packed cells, plasma, platelets and cryoprecipitate production has been started in Khartoum Teaching Hospital Blood Bank. Hopefully when funds become available, this centre can be expanded to cover all the needs of the hospital, and act as a training centre.

Factors VIII and IX are imported and the country has to continue to rely on external sources for many years to come.

**Training**

It was clear from the field visits conducted that all staff in blood banks all over the country need retraining and updating.

The Ministry of Health has approved the use of a distance learning programme. A pilot project will be started. A steering committee was formed, a plan of action was prepared, and identification of participating centres, trainers and supporters has been completed.

Necessary funds to launch this pilot project are awaited.

**Quality assurance programme**

A programme of quality assurance will be started as soon as the central unit is properly equipped.

2.17 Syrian Arab Republic

The Syrian Arab Republic has a population of 14 million. The Ministry of Defence has the main responsibility for the operation of blood transfusion services (blood collection and distribution centres). There are 14 blood transfusion centres spread over the country. In addition to those centres, there are blood banks in the University, military, and Ministry of Health (MOM) hospitals. There are no private blood centres or blood banks in the country.
A national blood transfusion advisory committee has been established by the Ministry of Health to coordinate the activities of all blood transfusion services and blood banks, and to support the further development of safe and effective blood transfusion services. The committee comprises of representatives of the national blood bank and representatives of ministries and organizations involved in the blood collection process; the committee is presided over by the Minister of Health. The number of units collected annually in the country varies between 175 000-200 000 (66 000-76 000 in the capital city). Collections are done in locally manufactured plastic bags. In the capital city, multiple blood bags are used for component production.

The donor system is based on voluntary donation and on circumstantial obligations. There are also unpaid family replacement and emergency donors. A well-motivated, voluntary, non-remunerated blood donor system will be created as soon as possible. There is also a need to organize an autologous blood donation programme.

Donor selection includes history-taking, and physical examination. Pre-donation anaemia screening is usually performed in most centres. There is an adequate record system of donors who have donated blood in all collection centres.

The serum reverse grouping is included in the techniques used for ABO grouping in the national blood bank and in some centres. All blood donations are tested for Rh-D antigen, but irregular antibodies screening is not carried out on blood units. All blood units are screened for HBsAg, anti-HIV 1/2, anti-HCV and syphilis, and 15% of units collected are screened for IgM anti-CMV. EIA techniques are used for the screening of HBsAg, anti-HIV 1/2, and anti-HCV. Screening for syphilis is carried out by flocculation tests, and doubtful results are confirmed TPHA. Positive samples for HIV 1/2 are retested, and repeat positive samples are tested by Western Blot. The seroprevalence of HBsAg is 4.5% and anti-HCV 1.2%. Since 1988, 103 HIV seropositive cases have been detected. Seropositive units for transmissible diseases are discarded by incineration.

Availability and use of blood and blood components

Ten per cent of the blood collected in the main blood transfusion centre in the capital city is converted to components. The components produced include red cell concentrates, leucocyte-depleted red cell concentrates, washed red cell concentrates, platelet concentrates, fresh frozen plasma and cryoprecipitate. Factor VIII and IX concentrates, albumin, streptokinase, gammaglobulines, anti-D immunoglobulins are imported.

Whole blood and packed red cells are stored at between 2 and 6°C in specially designed blood bank refrigerators provided with an alarm system. Monitored refrigerators are not available in all satellite centres. FFP is stored at -35°C. Platelets are stored at between 20-24°C with constant agitation by special rotators. Blood and blood products are often not transported under temperature controlled conditions.

The use of blood products is limited to the capital city. Physicians and surgeons need to be educated in the use of blood components.
ABO blood grouping reagents, Rh-D typing reagents, anti-human globulin reagents are not produced locally. Plasma substitutes for hospital use are not available.

Hereditary haematological disorders

The disorders for which whole blood and/or red cells are used most often include: haemorrhage (pregnancy-related 40%, traumatic 50%, surgical 10%) hereditary anaemia 3%, anaemia complicating pregnancy 2%.

There are a significant number of thalassaemia patients, haemophilia A and B, as well as von Willebrand's disease patients. Official statistics are not available.

Training

There is no specialized training programme in blood banking or transfusion medicine. There is a need to strengthen training for those who are directly or indirectly related to blood transfusion, for donor clinic staff and laboratory technicians, and to promote a continuing education programme for the updating and upgrading of all staff.

Quality assurance

There are no standard operating procedures and there is no participation in external quality assessment or proficiency schemes.

Problem areas

The problems encountered include: lack of a national blood programme based purely on voluntary, non-remunerated donations, and lack of public awareness about the importance of safe blood. Insufficient attention is given to the appropriate use of blood and blood products, increasing costs for the screening of blood, lack of continuing education in transfusion medicine, and shortage of appropriately qualified trainers.

Future plans

There are several plans to establish new blood banks and develop blood component preparation facilities, to organize a long-term national programme for blood donor recruitment on a purely voluntary basis, to create a continuing education system and train BTS staff at all levels, and to develop an effective quality assurance programme.

2.18 Tunisia

Introduction

In Tunisia, there are 8.5 million inhabitants, with 150 hospitals; 16 000 beds; 4 schools of medicine; 1 school of pharmacy; 1 school of dentistry; 4 500 medical doctors; 2 000 pharmacists; 900 dentists.

The number of donations per year is 100,000, 50% of which are voluntary, and 50% family replacement.
Organization of blood transfusion services

The Blood Transfusion Services are under the Ministry of Health. There is a national committee, and a central unit of transfusion. There is a national blood transfusion centre which is the reference centre and which coordinates 4 regional transfusion centres. There are also 34 hospital blood banks. There is no separate budget for blood transfusion services. The Director of Blood Transfusion Services is assisted by the National Blood Transfusion Committee.

National screening policy

Ministry of Health circulars of 1989 and 1994 defined obligatory investigations which are related to: blood transfusion problems (pre-donation screening, blood-typing) virus serology (hepatitis B, C, HIV), syphilis, pre-transfusion testing, and blood transfusion registers. The prevalence of serologic markers is as follows:

- Syphilis: 0.7%
- HBSAg: 5.0%
- Anti-HCV: 0.64%
- Anti-HIV 1/2: 5.5%

Training

This activity is coordinated through the National Blood Transfusion Centre of Tunis, which is a WHO Collaborating Centre. There are a continuous education programme and a diploma course in transfusion.

Use of blood and blood products

The Ministry of Health circular of 26 July 1993 recommends the national use of blood and blood derivatives.

Between 1991 and 1994, there has been an increase in the production of fresh frozen plasma (52.7%), platelet concentrates (47.95%), and cryoprecipitate (22.5%)

Quality assurance

The National Blood Transfusion Centre organization is under discussion with the Ministry of Health.

Standard operating procedures concerning laboratory and blood collection are implemented.

Data on hereditary haematological disorders

There are about 2000 patients suffering from haemoglobinopathies, and 60% of them are supported by the National Blood Transfusion Centre, which provides them with matched blood for Rh and Kell, screening for irregular antibodies; and screening for virus markers (2/year).

There are about 400 haemophilia patients. The National Blood Transfusion Centre and the regional transfusion centres provide 90% of the needs of these patients (cryoprecipitate).
Achievements of the regional targets in 1992-1995

Six targets have been fixed by the country's economic plan between 1992 and 1995. These targets are:

- Self-sufficiency in blood and blood derivatives (200,000 donations/year).
- National use of plastic bags.
- Establishment of a new National Blood Transfusion Centre and bone marrow transplantation unit.
- Establishment of five regional centres controlled by the National Blood Transfusion Centre.
- Setting up of a national diploma course in transfusion.
- Find the best solution for the bulk processing of plasma.

The majority of these targets were achieved or will be achieved next year.

Problem areas and future plans

- Increase in the number of voluntary donors and replacement of family donors by voluntary donors
- Implementation of quality assurance system
- Implementation of haemovigilance
- Implementation of distance learning programmes.

2.19 United Arab Emirates

Transfusion medicine is concerned with all aspects of collection, testing and supply of safe blood and products, and also provides for follow-up and care of donors when needed.

Organization and management

All these services are coordinated nationally through the Government (MOH). The Central Blood Bank in the Capital (Abu Dhabi) is the reference centre for the other 10 blood banks of which 9 are hospital-based, and one is a centre for the northern emirates.

All these blood banks are run by the National Director. His responsibilities include:

- Development of a national blood transfusion policy.
- Coordination through the National Blood Transfusion Committee, with other departments such as military hospitals, Faculty of Medicine, and the Red Crescent.
- The setting up, along with the cooperation of the Hospital Blood Transfusion Committee, of appropriate regulations and legislation in order to safeguard a well monitored and regulated collection procedure with the sole object of achieving the safest transfusion practice possible.

Blood donor system

The country has been self-sufficient in blood and its components since the end of 1993, largely as a result of an intensive programme of
motivation and recruitment through the use of such media as TV, newspapers, magazines and sports clubs.

Gifts to donors in the way of T-shirts with printed slogans, such as "Your precious blood is life", or "A drop of blood could save a life", or "Giving blood is giving hope", gave encouraging response.

Being a Muslim country, the UAE has managed to enlist and secure the very useful contributions of the imams of mosques who directly address worshippers encouraging them to come forward to donate their blood. This particular campaign, according to a survey of one of the most populous cities of UAE (Sharjah), showed a very significant increase in the number of voluntary donors.

Most of the blood banks are linked with a central computer system, and the statistics show that 62 nationalities have donated in the country. The population is 2 million and 21,200 units of blood were collected during the year ending 1994.

Most of the blood donations are collected from voluntary non-remunerated donors; there are a few autologous transfusion programmes which have started in four hospitals. Donations from unpaid relatives are common, and it is intended to eliminate paid donations as soon as possible.

Selection of blood donors is one of the important jobs of the blood bank. In UAE, with 113 nationalities, those in high-risk behaviour categories are to be identified. A computer programme has been developed in such a way that donors are allocated a grade--A, B, C, or D--in a descending order according to parameters such as high-risk behaviour, and remunerated/non-remunerated donation, etc.

National screening policy

A strict policy exists for the screening of blood donations. This policy is established through the annual meeting in the Ministry with the Minister and the Under-Secretary for Health, and the heads of all departments concerned. All blood donations are screened for anti-HIV 1&2, Anti-HCV, HBsAg, anti-HTLV I & II, and syphilis.

Confirmatory tests are available for HIV 1&2, anti-HCV, and HBsAg and HTLV, if needed. In certain medical situations some of the units are tested additionally for CMV and ALT.

Quality assurance/quality control

Quality assurance and quality control have been introduced in order to safeguard and monitor the proper use of reagents, precision, accuracy, and the reproducability of results, and the proper and efficient use of equipment for the proper preservation of blood and its components.

Also, there are certain committees for QA/QC (MOH and the Faculty of Medicine). Each committee is specialized in certain subjects, such as Committee for Blood Banking and Blood Transfusion, Committee for Biochemistry.
Availability and appropriate use of blood

About 40% of donations are processed into various components, and the 11 centres are all using these components: concentrated red cells, platelets concentrates, fresh frozen plasma, cryoprecipitate, and frozen red cells (small quantities).

A committee selected from the blood bank administration staff and headed by the director of blood banks visits the various hospitals regularly in order to check on the use of blood or its components.

Staff training

A continuous education programme has been introduced in 1990 for staff in both technical and administrative aspects. These courses are run by the Higher Technology College, Faculty of Medicine. Also, a special course is available to physicians in the proper use of blood and its components.

Hereditary haematological disorders

In the UAE, hereditary red blood cell abnormalities that lead to the occurrence of a haemolytic type of anaemia are known to exist. Examples are thalassaemia, sickle cell anaemia and glucose-6-phosphate dehydrogenase (G6PD) deficiency.

Until curative therapies become available, the main stay of the therapeutic management of patients is blood transfusion, particularly in the case of β-thalassemia variant cases. Now a major centre has been established in Dubai for the diagnostic and therapeutic management of hereditary haemoglobinopathies.

Implementation of the regional plan of action

Most of the targets of the plans of action of 1991 and 1993 have been achieved.

Future plans

The goal is to achieve 100% voluntary non-remunerated donations by the year 2000. The new active system which has been implemented recently to motivate and recruit donors has been successful in encouraging voluntary donation, especially through the mobile blood bank, and as a result, it is hoped to reach the goal by the year 2000.

2.20 Republic of Yemen

The Republic of Yemen has a population of 15,799,000. The number of hospitals is 75, hospital beds are 8,940, blood banks number 37 (one central blood bank, and 36 hospital-based blood banks). The number of units collected per year is 85,000 units.

Organization and management

The blood transfusion services are managed by the Ministry of Public Health under the General Directorate of the Central Health Laboratory. Most of the blood bank units operate independently.
Since the reunification of the Yemen in 1990, the Ministry of Public Health strongly supports the idea to restructure the blood transfusion services and to enhance the proposed law for the setting up of a National Blood Transfusion Service as an autonomous body having an independent budget. Unfortunately, the political crisis followed by the breakaway war delayed the declaration of the national blood transfusion legislation.

**Organization of blood donor services**

The blood donor services in the whole country depend mostly on unpaid relative replacement donations which represent 90%, while voluntary non-remunerated donations represent 10% only.

Donor motivation and recruitment: there is no increase in the number of voluntary donations due to lack of public awareness.

Donor selection criteria: WHO guidelines are followed.

Blood donor medical check up.

Education and encouragement of the donor for self-deferral.

Blood is collected in CPDA blood bags of 350/450 ml.

**National screening policy**

There is no national screening policy, since the legislation has not been approved. The screening tests applied are: HBsAg, HIV 1&2, VDRL, malaria film (in endemic areas).

**Staff training**

During 1994-95, no refresher courses were conducted at the national level due to political crisis and breakaway war and transfer of WHO budget for staff training. Inservice training is continued at the central level.

**Use of blood and blood products**

Most of the blood is used as whole blood, and packed cells and fresh frozen plasma are rarely requested. The percentage of blood use has not changed much.

- surgical
  - anaemia (pregnancy complication) 40%
  - haemorrhage (pregnancy related) 25%
- internal
  - traumatic 15%
  - anaemia (hereditary, sickle cell and thalassaemia) 10%

There has been an increase in the annual needs of blood due to the following factors:

- Increase in the population size(approximately 16 million)
- Increase in the number of hospitals and hospital beds.
- Opening of centres for specialized care, such as obstetrics and open heart surgery.

Taking the current population of Yemen as 16 million, the actual procurement is far below this target at present.

**Training**

The training of technologists (B.Sc.) is continued, in collaboration with faculties of medicine, and the training of technicians (diploma) with health manpower institutes.

**Quality assurance**

To achieve good quality and safe blood and to reduce the risk of transmission of diseases, the standard in transfusion service is followed at the central level and efforts are being made to maintain it at all levels.

**Data on hereditary haematological disorders**

The most common hereditary disorder is sickle cell anaemia which present more in Taiz and Tbb regions. The total number of cases referred to CHL during the period from 1 January to 30 August 1995 is 334; of these 90 are positive (27%) (AS=42 [12.6%] SS= 48 [14.4%]).

G6PD deficiency is significantly seen in Taiz and Tbb region too. During the period from 1 January to 31 May 1995, 120 cases were referred to CHL, of which 20 cases (24%) were G6PD deficient.

β-thalassaemia major is less frequent than sickle cell anaemia; it is a major problem in childhood as it is blood transfusion-dependent.

**Evaluation of the implementation of the regional plan of action**

**Organization and management**

Although the organization of national blood transfusion services has not been finalized and the proposed legislation is still pending, the following have been achieved:

1) The General Director for Central Health Laboratory and Blood Bank has been appointed in 1992. A director for Blood Bank at the Central Health Laboratory has been appointed in 1995.

2) A national policy for blood transfusion services has been prepared and submitted for approval (1993).

3) The proposal of establishment of a National Reference Blood Transfusion Centre has been prepared and submitted to UNDP through the Ministry of Planning and Development for funds.

**Blood donor system**

1) A coordinator for the blood donor programme has been named.

2) Some motivation and recruitment of voluntary non-remunerated has been done in collaboration with Yemen Red Crescent Society.
Screening policies

Screening policy for HIV testing for all units of blood before transfusion has been enforced by a ministerial decree.

HIV 1&2 screening kits are used in blood transfusion units, any positive sample is to be sent to the Central Health Laboratory for further testing using ELISA method, any positive sample is to be sent to Cairo (NAMRU 3) for confirmation.

All units of blood are tested for HBsAg before transfusion.

In coordination with NAMRU 3 in Cairo, a study of HCV in Yemen has been conducted in different areas in the country.

Appropriate use of blood

1) A survey in Sana'a city has been done to ascertain the trend of blood use (it appeared that about 60% is single unit & 90% whole blood).
2) Several meetings with clinicians were held to exchange the information on this subject, but could not be done at the national level.

Availability of blood and blood products

1) Blood and blood products are not always available due to large demand of blood and increase of the size of the population, for example, the minimum projected requirement is about 160,000 units and the actual quantity of blood collected is 85,000 units which makes the shortage at about 50%.
2) No production of blood components, due to shortage of blood, and lack of qualified persons to repair the equipment (refrigerated centrifuge)

Training

1) Training in general does not reflect the need and is not subjected to plans to meet the need due to many factors:
   - Lack of sufficient information about the needs;
   - Lack of collaboration and coordination during planning and training; and
   - Poor management in employment and distribution.
2) A plan for staff training was developed for both the central and regional levels for postgraduates, but could not be implemented due to shortage of funds.

Quality assurance

1) Quality policy has been developed at central and regional levels.
2) Quality assurance manager has been nominated for central health laboratory and bank. The implementation is poor mainly at regional and district levels.
**Problem areas**

1) Blood transfusion services are part of laboratory services and the separation could not be finalized till now.
2) No separate budget for laboratory services (including blood transfusion services) since five years.
3) Running costs allocated from the government side or WHO side is very small in addition to the constrains in getting and spending it.
4) Lack of reagents, screening kits and antisera.
5) Low staff salary in general and rapid increase in prices make the implementation very difficult.
6) No secretary (English/Arabic) could be maintained.

**Future plans**

1) Continue blood transfusion services and upgrade them according to funds available.
2) Follow up on the proposed legislation of National Blood Transfusion Services.
3) Follow up on the proposal of National Blood Transfusion Centre with Ministry of Planning and Development and with UNDP.
4) Formulation of the Nation Committee.
5) Concentrate more on blood safety at different levels.
6) Concentrate on preparation of blood components at the central level.
7) Exert more effort towards voluntary blood donation, in collaboration with the Yemen Red Crescent Society and universities and institutes in Sana'a and Aden.

**2.21 Algeria**

The population in Algeria is about 30 million, 90% of whom are in the north and 70% are under 30 years of age. Consanguinity is about 28%.

Health care has been free since 1976. There are currently 600 haemophiliacs and 2000 people with thalassaemia major. Thalassaemia trait is about 3%, and haemoglobin S/A is 3%.

Blood donor prevalence figures are as follows:

- HBsAg 2.5%
- Anti-HIV 1/2 <0.1%
- Anti-HCV 2.0%

Prevalence of anti-HCV in thalassaemias is: 30-60%

HIV infection in population:

- Seropositives 480
- AIDS 180 (100 patients are now dead)

Confirmation is performed at the National Reference Laboratory using Western Blot. Up to 1988 transmission by blood transfusion occurred, and since that date sexual transmission accounts for the majority of cases.
Organization of blood transfusion services

The turning point with regards to the organization of the blood transfusion services was in 1988. Before 1988, there was no organization, and there was one blood transfusion centre/hospital, no relationship existed between centres, and there was no political action. In 1988, the "HIV Era", an ad hoc committee consisting of four members was established. A National Committee for Blood Transfusion, a National AIDS Committee, and a Commission on Blood Transfusion were also established. In 1990 workshops on blood transfusion services started, and produced a plan of action. Inspections of blood transfusion services were subsequently carried out. At that time there were 159 blood transfusion centres, of which 20 centres were autonomous, and the rest were part of the general hospital laboratory and restricted to one room. There was no coordination between the different blood transfusion centres and no National Blood Transfusion Centre.

Blood donation

The Algerian Red Crescent and the Blood Donors Association are in charge of blood donations. However, they are actually inactive. Family replacement donation is 70%. There is no remuneration. Blood donation is carried out within the blood transfusion centre and mobile units.

1989: 190,000 blood units/population 27 million = 7.0%
1994: 162,000 blood units/population 30 million = 5.4%

Blood screening

Before 1988, 60% of the blood was screened for HIV, HBsAg, and syphilis. In 1991, training of laboratory staff at the Pasteur Institute of Algeria started. ELISA equipment for 60 blood transfusion centres were made available.

In December 1991, legislation and organization of blood transfusion services were introduced. This included mandatory screening of all donations for syphilis, HBsAg, and anti-HIV. For HIV there was a total of 159 centres, 69 centres screened by ELISA, and 60 by agglutination. By January 1993, 75% of the blood was screened, and, by August 1995, 95% of the blood was screened. For HCV, there are plans to obtain equipment and reagents, and start training to implement anti-HCV screening soon.

Blood products

Blood is collected into plastic bags:

Single plastic bags +++
Double bags
Triple bags: 5 centres

Blood component production

Fresh frozen plasma is produced in five centres, and platelet concentrates in five centres. Cytapheresis is performed, but there is no plasmapheresis. Products such as albumin, Factors VIII and IX, and fibrinogen are used, but have to be imported.
Blood agency

In April 1995 by Official Journal Decree, this agency was formed. It is an organization and administrative body, part of the Ministry of Health, and comprises an executive board (multidisciplinary), and a scientific (technical) board.

Its priorities are:

- Reorganization of blood transfusion centres (criteria to close some blood transfusion centres)

- Blood donor recruiting programme
  Total whole blood
  Plasma
  Buffy coat (cells)

- Appropriate use of blood and blood components. Indications for blood transfusion

- Screening for transfusion transmitted diseases
  100% achievement of goal.

3. SUMMARIES OF PRESENTATIONS

3.1 Transfusion Medicine: Fact and Fiction

Dr Cees Th. Smit Sibinga made the presentation.

WHO defined, in 1991, Transfusion Medicine as that part of the health care system which undertakes the appropriate provision and use of human blood resources. If a working assumption is made that transfusion practice is that collective activity which links the donor with the patient, then it follows that Transfusion Medicine occupies those areas in which it is deemed important or even essential that a medical practitioner contributes to this bridging process. It also follows that the Blood Bank serves as the bridge between the healthy community and the bedside.

There are three distinct operational supports to this bridge:

- the blood collection process (donor motivation and management, medical selection and collection, donor counselling),
- donation testing and processing (QC, processing and preservation, quarantine release and storage),
- the clinical interface (distribution, clinical decision taking, consultative services, compatibility testing and administration).

It should not be forgotten that successful transfusion practice is dependent on many other skills that are made available from professionals other than medical practitioners, such as pharmacists, biochemists, administrators, computer specialists, nursing staff and medical technologists. Nonetheless it follows that Transfusion Medicine can best be described as those functions within this bridging exercise which it is believed should be undertaken by medical practitioners.
Looking across the world, it must be concluded that there are very few blood centres in which this vision of Transfusion Medicine is a reality. Many are dominated by blood collection and donation processing and testing, and have no operational locus at the clinical interface. Others claiming to practice Transfusion Medicine acquire their blood supplies from external sources and direct all their professional energies to the clinical interface. The nature of this interface can vary substantially between different institutions, there are some in which the medical practitioners are familiar, because they are actively involved each day, with the clinical use of all blood components and plasma derivatives and are frequently to be seen in the clinical environments. In other institutions, plasma derivatives are not acquired by clinicians through the hospital blood bank or transfusion service but from the hospital pharmacy, and in many such institutions the primary tool used by the Transfusion Medicine specialist is the telephone.

3.2 Guidelines for a National Blood Policy

Dr J. Emmanuel made the presentation.

It is recognized that governments are responsible for ensuring a safe and adequate supply of blood and blood products for all those in need. These principles are supported by the World Health Organization (WHO), in WHA28.72, 1975, and have been covered in detail in Organization and Management of Blood Transfusion Services (WHO, Geneva, 1990). However, this responsibility may be delegated to a nongovernmental organization (NGO) with an appropriate management committee.

The authority responsible for the national blood programme (NBP) should manage and coordinate activities in the area of blood safety within the framework of the national health care infrastructure. In order for the NBP to function efficiently and cost-effectively, it will be necessary to develop a NBP structure, a national blood policy appoint a responsible authority (Ministry of Health/NGO), appoint a responsible National Blood Transfusion Service (NBTS) with appropriate leadership (National Transfusion Director, etc.) and to ensure adequate funding and support for the NBP as a whole.

The NBP should state the commitment and support of the Government to the National Blood Programme to achieve the following:

- to ensure that authority is given to enforce national guidelines;
- to ensure that adequate funding is made available;
- to ensure the development of a National Blood Transfusion Service (NBTS) which will adequately provide service to the country;
- to appoint a dedicated National Transfusion Director (NTD) with specific responsibility for the National Blood Programme, with the authority to organize, manage, coordinate and collaborate, to ensure the fulfillment and development of the NBP (for effective national control, administration and accountability, the national blood transfusion service may need to be regionalized into regional blood transfusion centres). Suitably trained medical officers should be identified as regional transfusion directors, with the authority to be responsible for blood transfusion in their region, directly responsible and accountable to the NTD. For the purposes of blood
transfusion all provincial transfusion services, within each region
would be responsible and accountable to their regional transfusion
director, and all district hospitals would be responsible and
accountable to the head of blood transfusion at their provincial
hospital.

- to ensure that blood is collected from voluntary, non-remunerated
  safe donors;
- to ensure that donated blood is appropriately screened before
  transfusion;
- to ensure that safe blood and blood products are available for
  transfusion to all who need it; and
- to ensure the appropriate use of blood and blood products.

The above would provide a simple framework to consolidate blood
transfusion within a country, allow for immediate implementation and
future development. The policy should also include:

- the formation of a National Blood Transfusion Committee chaired by
  the National Transfusion Director, comprising the regional
  transfusion directors, and representatives of the national
government (Ministries of Health, Information and Finance), relevant
NGOs, and the medical association;
- the separation, at least at national and regional levels, of blood
  transfusion from general laboratory, and the recognition of blood
  transfusion as a separate specialization that requires separate
  funding and trained staff;
- the funding of blood transfusion directly or indirectly from the
  national government, i.e., direct annual budget or indirect cost-
  recovery from hospitals and the health care institutions where blood
  is transfused and/or which are supplied with blood products;
- the identification of one or two centres of excellence, i.e., one in
  the north and one in the south of the country, accountable to their
  regional transfusion director and the national transfusion director,
to act as: national reference, reagent production, training and
development centres, liaising with external expertise to continue
the growth and development of blood transfusion.

Within the framework of the national blood policy, the National
Blood Transfusion Service should develop and maintain the services
required to provide safe blood and products through:

- developing and moving towards blood donation from voluntary,
  non-remunerated donors, who are at lowest risk of transmitting
  infectious agents through blood donation and who donate regularly.
  (It is acknowledged that this will take time to develop and,
  therefore, should be started as soon as possible.) In addition,
donor education/deferral procedures, counselling and referral for
follow-up where necessary, should also be developed (initially in
stages);
- the screening of all donated blood for infectious agents, ensuring
  donor confidentiality at all times;
- good laboratory practice and quality assurance (QA) in the
  laboratory, screening of donations, blood grouping, and
cross-matching;
- Good Manufacturing Practice (GMP) and QA in the collection,
  component production, fractionation, storage and distribution of
  blood and blood products;
good clinical practice in the appropriate use of blood and blood products and the subsequent monitoring of transfusion recipients;
- continual monitoring and evaluation of all procedures with a comprehensive QA programme;
- training of staff in all areas of the work of the NBTS, as well as the training of staff at district hospital level who may have multidisciplinary laboratory responsibilities;
- cost-effective management, use of resources, continuing staff development and updating;
- developing strong community based links to ensure support for the BTS.

3.3 Current Developments in Screening for Transfusion-Transmitted Diseases

Dr A.D. Kitchen made the presentation.

Transfusion medicine is an ever-changing field, and within that field the screening of blood for infectious agents remains a high profile, and needs to respond continuously to both developments in the production of screening assays and systems, as well as increasing knowledge of the characteristics of transmissible infectious agents.

Currently, there are a number of aspects of the screening of blood for infectious agents that are generating interest. These issues include the range of infectious agents screened for, the range of test types used, testing procedures, quality and theoretical aspects - screening algorithms.

Although viruses have been, and still are, the agents causing most transmitted infection and are the most commonly screened for, other organisms, such as bacteria and protozoa, are also transmitted by transfusion. Whilst post-transfusion sepsis due to bacterially contaminated blood has always been recognized and accepted as a generally fatal complication, reported cases are relatively rare, especially considering the number of transfusions performed. Bacterial contamination and its prevention are becoming a bigger issue now than it has been for many years. The increasing use of room temperature storage and increase in pack manipulation may result in a significant increase in cases of post-transfusion sepsis, and will require transfusion services to look far more closely at the actual cleanliness of their work areas and the consequent risks to their pack handling.

The recent identification of HIV 1 subtype O, and hepatitis B virus mutants have provided challenges to both transfusion microbiologists and the assays that they use. In addition, the recent announcement in the U.S.A. by the Food and Drug Administration, requiring eventual HIV Ag screening of all donations may have an impact far wider than the Americas. Protozoan infections, such as malaria and Chagas' disease, currently screened for by donor selection may eventually be screened for using diagnostic assays. There is also concern that diseases caused by the recently identified agents, prions, may also be transmitted by transfusion, although this is not yet clear.

Major developments are currently occurring in the automation of blood screening. The use of automation has many attractions, especially
for quality issues, although systems currently available still need considerable manual supervision.

The design and use of screening algorithms, especially confirmatory and reinstatement algorithms, are now more common, and such algorithms are particularly effective in minimizing wastage and maximizing available resources, including providing a means of identifying and reinstating donors who have been confirmed not to be infected with an infectious agent, but who have given false positive results with the screening tests used.

To some extent, developments in assays and screening procedures are continuous. Some developments give clear advantages whilst others may not be immediately effective. However, as the awareness of the importance of quality and consistency increases, transfusion microbiologists need to be aware of changes and development, but be clear as to what is essential, what is appropriate and what would be useful to improve the safety of donated blood.

3.4 Quality in Transfusion Microbiology

This item was introduced by Dr A.D. Kitchen.

Quality is a very broad topic which can, at the same time, be very simple in concept, but very complex in its application. This is especially so in the field of transfusion microbiology and the provision of safe blood and products. Under the overall heading of quality assurance come the individual areas of quality control, quality monitoring, quality systems and quality audit; all of which have important roles to play in assuring quality.

The complexity of transfusion microbiology together with the importance of ensuring a safe blood supply produce many problems in developing, implementing and maintaining an appropriate quality system. However, a central part of any such system is in the control of assay performance, specifically ensuring consistent and reliable results. In-process control is a means of achieving this, and importantly is relatively straightforward in application; it can also have the additional benefit of reducing unnecessary waste of resources—donations, test kits and time.

The assays used to screen donations for markers of infectious diseases are generally reliable and perform well when handled properly. However, all such biological assays are subject to variability, arising from minor differences at manufacture—lot variation, conditions of transport and storage, and assay performance—sample quality, operator experience, laboratory conditions. Clearly, gross errors in performance, for example missing reagent or wash step, would generally lead to assay failure; however, minor errors, such as incorrect volumes, could still produce apparently acceptable results but lead to the failure to detect samples with low levels of marker. In-process control involves identifying all the individual steps in the performance of an assay, providing a means to monitor the performance of each step, and identifying the critical/weakest area. A number of tools are available to enable such in-process control; these include the use of automation, and the inclusion by manufacturers of control features in their assays.
Such features include: requiring sample volumes that can be handled manually or by automation, sample addition monitors, coloured reagents and common reagents.

The final results can themselves be used to look back on performance using a statistical tool such as Statistical Process Control (SPC). SPC can be used to analyse assay results over a period of time and establish expected and acceptable ranges for the assay. The use of specific standard sera is very valuable, and SPC can use the data generated by such sera to monitor very closely overall assay performance and thus highlight the start of a potential problem before it becomes critical.

Whatever quality systems are used to monitor assay performance, the key to success is simplicity, whenever possible. Complex systems may provide a lot of information but sometimes too much data could be produced so that the key piece of information which may herald the start of a problem may simply be lost in a mass of other data from other control points that may not yet detect the potential problem.

3.5 Quality Assurance in Blood Donor Selection and Blood Collection

Dr Koistinen introduced the item.

The purpose of the quality assurance (QA) systems in donor selection and blood collection is to ensure that blood collection does not harm the blood donors and the products made from the donations do not harm the patients. This can be achieved by planning carefully all the procedures and by performing them right and repeatedly in as standardized fashion as possible.

The general QA criteria, as described in ISO9000 or any other available general QA instructions, are valid also in creation of the quality assurance system for blood donor selection and blood collection. Instructions for this are given, for example, in the American Association of Blood Banks' (AABB) Quality Programme books (Part I - Quality Plan Manual, and Part II - Self-Assessment Manual), the steps of which are followed in this presentation, as well as in the British "Guidelines on Quality System Elements for the Collection and Processing of Blood and Blood Products".

The categories of a quality plan are: (a) Organizational issues; (b) personnel selection, training and education; (c) validation, calibration, preventive maintenance and proficiency testing; (d) supplier qualification; (e) process control; (f) documentation, record-keeping and record review; (g) label control; (h) incident, error and accident review; (i) internal assessment; (j) process improvement. These categories must be covered in all operational systems in blood transfusion service, which are: (a) quality programme; (b) donor suitability; (c) blood collection; (d) component processing; (e) testing; (f) review and labeling; (g) storage and distribution; (h) compatibility testing; (i) blood administration; (j) investigation of adverse effects; and (k) information management.

After the establishment of a quality programme, the first specific operational quality issue is justification of the donor suitability, in which the first steps are the events prior to blood donation proper.
General information and education of the donors on the criteria of one's suitability to become a donor are especially important in avoiding those with risk behaviour from offering to become blood donors. Pre-screening of potential blood donors can also be performed, but is not practical, for example, in respect of infections with low prevalence in the population.

At donor registration, the blood donors should read information about donor suitability, complete demographic information and health history questions, after which the donor identity must be reliably confirmed. The information given by the donor must be verified by the personnel and risks should be reviewed. Donor signature in the health questionnaire form adds to the reliability of given information. With the signature the donor also accepts the potential risks of the blood donation, which should be clearly stated in the form.

All donor deferrals should be registered. This is necessary for identification of potential risky future donations by the same donors and for verification of prior information in case of donor reentry into active donor registry, for which algorithms must exist. A system for notification of donors of their deferral as well as for donor counselling and education must exist as well.

At the blood collection proper, the donor must be identified again and the donor records (including the health questionnaire) reviewed. Often the numbers to bags and test tubes are applied first immediately before the blood donation.

The critical points in the blood collection are: selection and preparation of the venipuncture site, starting and completing the venipuncture, filling the test tubes and completion of the necessary recording.

Records of donor reactions should be kept, and incomplete bleeds, evidence for contamination, overweight of the blood unit, slow bleeds, complications with the puncture (for example, arterial puncture) as well as material defects should also be recorded. After the collection the donor should be observed for fainting or other complications and the collected blood unit, test tubes and paperwork should be appropriately prepared and transferred to the laboratory and component separation.

The practical setting up of the quality system is often easiest to start from the writing of the standard operation procedures (SOPs). This is important also in donor selection and blood collection. Training records of all employees and training programmes of new employees are other practical matters for which it is fairly easy to create a system and documentation. At the end of each individual training programme document, there should also be a statement, in which it is expressed that the employee is, upon completion of the programme, eligible to perform his/her work independently. The statement should be signed by the supervisor.

Often the more general QA documents, such as the description of the appropriate operational unit and definition of the aims of the unit, may seem more difficult for the operational personnel to draft. However, the operational units should write the documentation, but the QA unit may
give guidance on how to do it and act as a catalyst to keep the QA process going.

Internal audits should be performed in blood donor selection and blood collection by the QA unit of the blood transfusion service. Inspections of the blood transfusion services by the regulatory authorities are done in most industrialized countries and are now required also by the regulations on all blood collection centers, which send plasma to be fractionated into pharmaceutical products.

3.6 Distance Learning in Blood Safety - Experiences from three Regional Workshops

Dr J. Emmanuel made the presentation.

In April 1994, WHO published a series of distance learning materials, Safe Blood and Blood Products, as part of a strategy to improve the safety and adequacy of the blood supply. The materials were produced for use in the professional updating and upgrading of staff working in blood transfusion services, public health laboratories and hospital blood banks, particularly those with limited access to conventional training programmes.

The distance learning materials provide a comprehensive resource that has been developed for self-directed learning to enable staff to undertake a structured training course without leaving their workplace. However, although developed for independent study, the materials have been specifically designed for use within a structured programme of guidance, counselling and support. This is essential to help students to maintain their motivation, resolve any problems they may encounter and apply what they have learned in their professional practice. The effectiveness of the materials will therefore depend to a considerable extent on the quality of the distance learning programmes that are established to support their use.

Regional workshops have been organized by the WHO Regional Offices for the Eastern Mediterranean, Africa and South-East Asia to provide orientation for directors and other senior personnel from blood transfusion services in 40 countries on establishing national distance learning programmes in blood safety.

In most countries, the basic training of laboratory technical staff and nurses has been strengthened greatly in recent years and is generally adequate. The common priorities are to provide specialized training in donor recruitment and selection and to upgrade the skills of existing laboratory technical staff, particularly whose training is inadequate or who have had no opportunities for updating. While the scale of the need for further training varies according to the size of each country and the number of staff involved in blood banking, most countries are facing the following constraints in providing training by conventional means:

- staff are spread out over a large geographical area and have limited access to training institutions
- shortage of funding
- shortage of suitably qualified and experienced trainers
difficulty in releasing staff from their posts to attend residential training courses
- too many staff require training
- shortage of appropriate training facilities
- many trainers themselves require updating and further training
- lack of time to provide adequate training
- shortage of resource materials for training
- lack of stability in employment with many staff transferring after training
- lack of incentives to stay in blood banking or undertake further training.

In each of the workshops, the participants developed a generic action plan to provide a basis for the establishment of a distance learning programme in blood safety at national level. Although the plans developed in each region differ slightly, they contain the following common elements:

1) Report back to Ministry of Health and other relevant government departments.

2) Sensitization of relevant authorities through briefing meetings.

3) Organization of a national meeting to orient relevant organizations and institutions on the use of distance learning in the area of blood safety.

4) Formation of a steering committee.

5) Appointment of programme coordinator(s).

6) Preparation of plan and budget for a pilot project and submission to funding agencies.

7) Selection of centres to participate in the pilot project.

8) Selection of programme personnel: trainers and supporters/mentors.

9) National training workshop for programme personnel.

10) Implementation of the pilot project.

11) Evaluation, replanning and expansion of the programme.

Distance learning has not previously been used in the field of blood transfusion, although it is widely used in professional and vocational education throughout the world. Only 4 of the 49 participants and 13 observers in the regional workshops had any prior knowledge or experience of this approach. Whilst responding positively to distance learning, they unanimously identified a need for further technical assistance and support to follow up on the workshops. The need for further training and ongoing support is likely to be higher in countries where the role of programme coordination is undertaken by personnel who have not attended one of the regional workshops or where there is no open university or similar institution that can provide technical assistance in the use of distance learning.
The principal areas of support requested by participants from WRs, WHO Regional Offices and WHO headquarters are:

1) Advocacy to support the development of national distance learning programmes in blood safety.

2) Funding for pilot projects and activities, such as national workshops.

3) Provision of, or assistance in the procurement of, additional copies of the distance learning materials and other resource materials.

4) Translation of distance learning material into other major languages.

5) Technical assistance and support in the planning, implementation and evaluation of distance learning programmes.

6) Preparation of a manual on establishing a national distance learning programme in blood safety.

7) Distribution of regional newsletters produced by workshops' participants.

8) Organization of a follow-up regional workshop in 1997.

9) Further training in distance education, where required, including training fellowships.

10) Feedback on evaluation reports from Member States.

11) Advocacy to promote the development of blood transfusion services as separate, identifiable and sustainable programmes.

12) Updating, revision and improvement of the distance learning materials, as required.

The following issues emerged in discussion in each of the three regional workshops.

**Advocacy**

Official recognition and support from government is a prerequisite for the establishment of a national distance learning programme in blood safety. WRs and WHO Regional Offices can play a key role in promoting government recognition of the need for additional training in blood safety and support for the establishment of national distance learning programmes.

**Coordination**

Responsibility for the national distance learning programme in blood safety should be retained by the National Blood Transfusion Service or the unit appointed as being responsible for the national blood programme. In some countries, however, it may be appropriate to delegate the coordination role to another agency, such as a recognized training institution.
Comparability

The materials should be used to complement existing training provision, rather than being seen as an alternative. National distance learning programmes should therefore be integrated into existing training structures, wherever possible, with comparable systems of assessment and recognition.

Programme structure

The structure established to deliver training by distance learning should build on the existing service and training infrastructure to make best use of limited financial and staff resources. The most appropriate structure for each country's programme will depend on:

- the size of the country
- the structure of the national blood programme
- the nature and location of existing training facilities.

There are three basic models for the structure of a distance learning programme, each of which can be modified to suit a country's individual requirements. Each provides for the following key functions:

- programme coordination and management at national level
- student support at a distance through correspondence and telephone and in group meetings and short practical courses
- student support within the workplace.

Steering committee

The participants were aware of the importance of drawing on all possible sources of support. The establishment of a steering committee at national level will assist in building awareness and support for the programme and securing funding. It will play an important role in advising on and approving the development and management of the programme, and monitoring progress and standards. Its membership should include:

- the National Blood Transfusion Service, or the unit appointed to be responsible for the national blood programme;
- state or provincial blood transfusion services, where appropriate;
- the Ministry of Health, the National AIDS Control Programme and other appropriate ministries;
- universities and technical training institutions involved in the basic training and continuing education of blood transfusion service personnel;
- professional associations, for example, the Institute of Medical Laboratory Technology;
- nongovernmental organizations, such as the Red Cross or the Red Crescent Society;
open university or other distance education institution or department; and

representatives of programme trainers, supporters and students.

Resource and support requirements

The participants identified the following support requirements in establishing a distance learning programme.

1) Approval and institutional support from the Government, including Ministries of Health, Defence, Education and Finance and relevant authorities, such as the National AIDS Control Programme.

2) Financial support:

- staff salaries or honoraria
- orientation and training of trainers and supporters/mentors
- purchase, translation or reproduction of the distance learning materials and other resource material
- administrative and secretarial support
- communication: postage, fax, telex
- travel and subsistence
- meetings, short courses and workshops
- facilities, equipment and reagents.

3) Institutional support from education and training institutions and open universities and technical assistance in such areas as distance learning, assessment and evaluation.

4) Suitable programme personnel:

- coordinators
- trainers
- supporters
- resource people
- administrative support.

5) Support and commitment from directors, supervisors and colleagues of individual students to:

- create an environment that promotes effective learning, and
- provide encouragement and opportunities for evaluation, innovation and change.

6) Validation and accreditation of the programme by an appropriate, approved institution.

7) Support from international donors and technical assistance agencies.

8. Resource materials:

- adequate supplies of the distance learning materials in appropriate languages
- policy guidelines and updates
- additional reference and resource materials.
Potential sources of financial and technical support

The following sources of support were identified:

1) The Ministry of Health and other relevant government departments.

2) National AIDS Control Programme or WHO/Government joint programmes.

3) Education and training institutions, including universities, technical institutions and distance education institutions or adult education departments.

4) International agencies, such as WHO Regional Offices and headquarters, the International Federation of Red Cross and Red Crescent Societies, DANIDA, FINIDA, UNDP.

5) National professional associations for laboratory technical staff and nurses.

6) National nongovernment organizations, such as the Red Cross and Red Crescent Societies, the National Association of Blood Donors.

7) International professional associations, such as the International Society of Blood Transfusion, the World Federation of Hemophilia, the International Association for Medical Laboratory Technology.

8) National service organizations, such as Rotary Club, Lions Club.

Distance learning material

The number of staff who are able to participate in the programme will depend on the availability of funding to purchase sufficient quantities of the distance learning materials. WHO headquarters had already distributed copies of the material to Member States through the regional offices, but is unable to supply large quantities free of cost. The options for the wider distribution of the materials include:

- purchase from WHO headquarters at cost price
- reproduction of the materials by WHO regional offices, consortia of countries or individual countries. The WHO Regional Office for South-East Asia (SEARO) has already printed additional copies for use within the Region
- distribution of the material in diskette form for local reproduction: few blood transfusion services have appropriate software and this method is unlikely to be cost-effective.

Translations

Various language editions of the distance learning materials will be required for use in countries where English is not the medium of instruction. Priorities include:

French
Spanish
Arabic
Russian
Chinese
Portuguese.
The preparation of French and Russian editions has already commenced and other language editions will be produced when funding has been secured. The translation of the materials into national languages, where required, will need to be undertaken at country level.

Student motivation

Undertaking a course by distance learning often requires a higher level of motivation than in conventional training, because individuals have to take greater responsibility for organizing their own study. Factors that are likely to motivate them to enter and successfully complete the programme include:

- awareness of their need for further training and of its benefits in terms of their professional growth, increased self-esteem and self-confidence
- awareness of limited opportunities for further training by traditional means
- careful selection to ensure that they have the capacity to benefit from training
- encouragement and support from their director and supervisor
- adequate orientation about the programme and how it will work
- study support at local level from their supervisor or other appropriate senior member of staff and regular programme meetings
- an effective student support system in which they have regular contact with their designated trainer
- allocation of time for study
- recognition of their achievement in terms of:
  - a certificate or letter of satisfactory completion
  - enhanced opportunities for promotion and/or salary increase
  - improved job security
- an opportunity to act as a peer educator/supporter for other staff member subsequently undertaking the programme.

Higher dropout rates are likely in countries where the prospects of advancement as a result of further training are limited because there is no clear career structure or staff have no control over their being moved out of blood banking.

Improved quality in service

The provision of uniformly high quality training through the distance learning materials will lead to improved quality in service and help to set and maintain national standards in all parts of the national blood programme. The structure of the distance learning programme will
also open up new channels of communication between the different levels of the national blood programme, bottom-up as well as top-down, that will promote the sharing of ideas and experience, including innovative approaches developed by students in the action plans that they prepare as part of their work on the materials.

3.7 Functions of the Hospital Transfusion Laboratory

The item was introduced by Dr F.A. Ala.

For nearly 60 years, the fundamental role of most hospital transfusion laboratories has been the delivery of adequate, compatible red cells for transfusion to patients in a timely manner, to meet both routine, elective and emergency requirements.

This seemingly straightforward function nevertheless demands well planned and maintained infrastructural resources, such as: good inventory control, an appropriate blood group mix, the judicious selection of blood compatibility testing policies which are neither too onerous, nor too sketchy. These policies will include a Maximum Surgical Blood Ordering Schedule (MSBOS), fully agreed with local surgeons and anaesthetists, together with a "Screen and Save" policy to avoid unnecessary cross-matching and sequestration of red cell units which are unlikely to be utilized.

Well-established quality assurance systems must underpin these functions, in order to avoid the all-too-frequent occurrence of errors, whether in the laboratory or hospital wards and surgical theatres. This will involve well-designed request and compatibility forms and labels, and meticulous record-keeping.

Reporting of adverse post-transfusion events (febrile reactions, acute or delayed haemolysis, toxic shock or anaphylactic reactions, as well as less common events such as transfusional GvHD and transfusion-associated lung injury) must be actively fostered and they must be seen to be promptly investigated and reported in an open, non-defensive manner.

Finally, among the traditional tasks of the hospital transfusion laboratory, is the resolution of serological problems and the identification of red cell allo-antibodies, either in-house, or with the support of a reference centre equipped with a broader spectrum of reagent red cells with rare combinations of specificities.

More recently, numerous other clinical requirements have arisen to provide hospital transfusion laboratories with the opportunity for exercising leadership in a more direct relationship with the clinical sector.

1) Antenatal serology may comprise both routine ABO/Rhesus and allo-antibody screening, as well as the development of laboratory indices for predicting the destructive potential of red cell antibodies. These, together with clinical parameters, will serve as important guides to the management of difficult pregnancies.
2) Transfusion policies for transfusion-dependent patients suffering from thalassaemias, sickle cell disease or aplasia: selected phenotyped blood, leucocyte-depleted components, etc.

3) Establishment of an autologous blood pre-deposit programme for elective surgery cases.

4) Other special services, such as a Therapeutic Plasma Exchange Programme for selected clinical conditions; a platelet immunology service; gamma-irradiation of blood components for immunodeficient or immunosuppressed patients, peripheral stem cell harvesting and storage.

5) The creation of a day-care centre for ambulant patients requiring transfusion of blood components, coagulant factors, or immunoglobulins.

6) The formation of a hospital transfusion committee is arguably one of the most significant means for establishing appropriate transfusion guidelines and criteria, for auditing transfusion practice against these guidelines, and for discussing adverse events and shortcomings, together with the means for overcoming them and ultimately improving the quality of patient care.

3.8 New Developments in Transfusion Medicine

Dr Sibinga introduced the item.

The reality of future trends and developments in blood transfusion are largely determined by the introduction and acceptance of the concept of Transfusion Medicine. There can be distinguished five major fields of attention:

- community aspects
- component/derivative production and preservation aspects
- laboratory and quality control aspects
- clinical aspects
- GMP and total quality management aspects.

Each of these fields of attention play a specific role in the way these developments take place and effect the evolutionary process of the blood supply system.

Community aspects relate to the introduction of a sustainable system of voluntary, non-remunerated community support of the blood supply. Equally important is the gathering and evaluation of the demography of the community and the health statistics. Through these informations better mechanisms to create public awareness become available on a dynamic basis.

Blood component and plasma derivative production and preservation aspects relate to the developments in separation and purification technology and the introduction of biotechnology, and cryopreservation and ultimately vitrification technologies. Another aspect is in the developments in the preservation of cell and protein function and potency, and the assurance of safety through polymer technology for
storage containers, specific preservation media for red cell and platelets, lyophilization technology and virus inactivation or elimination technology.

Laboratory and quality control aspects relate to the possibilities to increase efficiency and accuracy of testing procedures, the minimization of reagent consumption and increase in sensitivity and specificity of reagents and test systems. Equally important is the introduction of automation of both equipment and the administrative and documentation processes through computer controlled systems.

Clinical aspects relate to improving the transfusion efficacy or outcome, reducing the morbidity and mortality of transfusion practice at the bedside and the introduction and further development of preoperative blood salvage technologies and autologous (predon) transfusions on medical indications. Also, the exploration and development of nontoxic alternatives to human blood, such as haemoglobin analogues, recombinant growth factors and recombinant clotting factors, are of increasing importance.

GMP and total quality management aspects are based on the introduction of these valuable concepts focused on the assurance of a day-to-day standard quality practice from donor to patient. The essence is in adequate motivation, teaching and training of personnel on an ongoing basis. Tools and guidelines are in documentation, SOPs and critical evaluation through error policy, statistics and self-inspection.

Evidently developments and future trends in Transfusion Medicine need the introduction and establishment of adequate and focused education in the field at all levels of staff on a permanent up-to-date and multidisciplinary basis. Full recognition of the concept of Transfusion Medicine within the totality of the medical profession is a prerequisite.

3.9 Quality Assurance of Component Separation

This item was introduced by Dr Koistinen.

The same general rules of quality assurance systems apply in component separation as in donor selection and blood collection, with the exception that there are more quality control measures performed in the laboratory.

The important elements in QA of blood components intended for transfusion are: (1) Observation of temperature; (2) segregation of exception units; (3) recording the beginning of the bleeding process; (4) recording of the volume of platelet rich plasma; and (5) recording of the volume of platelets. For components intended for further manufacturing, in addition to the ones mentioned, the time in freezer must be recorded and the fresh frozen plasma must be designated either for transfusion or for further manufacturing.

If the blood components are modified the SOPs must be followed when irradiated, leucocyte-reduced, CMV-negative, frozen, washed or rejuvenated units and pooled components are made. The expiration dates
and times must be changed accordingly, labels must be rewritten according to SOPs and the blood return or reissue SOPs must be followed.

Quality requirements and rules for quality control samples and measures must be documented and followed. The Council of Europe has given detailed minimum requirements for quality assurance systems of blood and blood components. Because there is no batchwise production of the cellular components, the QC is based on the statistics of the QC measurements on a sampling of products. The taking of the QC samples should not follow a predictable pattern and should be decided by a supervisor, who is not directly involved with the component separation process.

On all units of whole blood the following tests are required: ABO and Rh grouping, HBsAg, anti-HIV, anti-HCV and anti-HTLV/II. Syphilis test is required in most countries, anti-HBC in some and anti-CMV of some blood units. A standard volume of the donation should be 450 ml±10% and 1% of all units should be weighed.

In addition to the requirements mentioned above, the red blood cells units should have a volume of 280±60 ml and 1% of units should weighed. The EVF should be 0.65-0.75 and at least 4 units/month should be controlled. Haemolysis at the end of storage should be less than 0.8% of the red cell mass and should be measured at least on 4 units/month. If the buffy coats are removed from the red cells, the leucocyte count should be less than 1.2 x 10^9/unit, and in washed red cells the protein content should be less than 0.5 g/unit. In leucocyte-depleted red cells, the leucocyte count should be less than 5 x 10^6/unit, which can be reliably done by visual counting only, and the loss of red cells in the process should be less than 10% of the original red cell mass.

Single unit platelet concentrates should have a volume of over 50 ml and all units should be controlled. The platelet count must be done on 1% of all units or at least on 4 units/month and should be over 60 x 10^9/unit. There should be less than 0.2 x 10^9/unit residual leucocytes and less than 1 x 10^6 leucocytes per unit, if the platelet concentrate is to be called leucocyte-depleted. The pH of the platelet concentrate should be 6.0-7.4 at the end of recommended shelf-life, and this should also be controlled on 1% of units or at least on 4 units/month.

Some of the cellular components, for example, washed, leucocyte-depleted platelet concentrate for intrauterine use, are extremely complicated to make and thus it may be useful to write the SOP in the form of a check-list, in which every production step is signed by the person who makes the component.

Complications leading to slight deviations in the storage or transportation conditions of blood components may sometimes not render them completely unusable. In such a case a system should be in place for the judgement of the situation and for eventual clearance and definition of release conditions. This can be done, for instance, by consulting the QA director in each individual case, who then takes the responsibility of the release or destruction of the component.

Sterile connection devices are nowadays used in modern component separation, which has abolished open systems and thus virtually
eliminated the possibility for bacterial contamination. If there are any open steps in the component separation, they should be done in a laminar flow cabinet and there should be a systematic sterility and particle control in the rooms and laminar cabinets where the separation is done. Particles of the rooms and sterility of the surfaces and centrifuge cups should be checked even if the separation procedures are done in closed systems.

Special emphasis should be given to all documentation in the component separation, because there are additional risks of clerical errors due to the complicated production process and transfer of the products through several different bags and sets of bags.

3.10 White Cell Depletion and the Use of Filters

Dr Ala made the presentation.

Blood transfusion can exert profound, often long-lasting effects upon the host immune system. Most of these harmful effects are mediated by "passenger" leucocytes.

1) Allo-immunization to HLA antigens is reported in 30% to 70% of multitransfused patients, and the incidence of these lymphocytotoxic antibodies correlates well with unresponsiveness to random platelet transfusion.

The results of the many reported clinical trials on leucocyte-depletion of blood components do suggest that when the number of leucocytes per transfusion is below one million, allo-immunization is either abolished or greatly reduced. The secondary anamnestic response in patients already sensitized by previous pregnancy or transfusion is very difficult to prevent, however.

Providing HLA Class I matched platelet donors for transfusion-dependent patients who have become refractory to random platelets is expensive and labour-intensive. Therefore, there is much to be said for preventing primary immunization in these specific cases.

2) Non-haemolytic febrile transfusion reactions were traditionally attributed to leucocyte antibodies. Current evidence suggests that many of these adverse effects are due to cytokines secreted by passenger leucocytes during storage of blood components.

3) It is well established that transmission of cell-associated viruses, such as CMV, HTLV, and EBV, can be prevented by leucocyte-depletion of blood components.

4) Transfusion-associated Graft-versus-Host Disease cannot currently be prevented by even the most exhaustive leucocyte-depletion, and gamma-irradiation of components remains as the method of choice.

5) A number of other in vivo effects attributed to leucocytes, such as immune modulation causing increased post-operative infection or cancer recurrence, have yet to be corroborated.

Adverse in vitro effects of leucocytes upon both red cells and platelets have also been documented by a number of workers in the field.
In contrast, passenger leucocytes may possess a number of redeeming features, such as protection against bacterial contamination of blood components, and a beneficial immune-modulatory, or "tolerogenic" effect.

The foremost approach to leuco-depletion is by filtration through increasingly efficient devices, although modern cell-separators can also deliver platelet concentrates with very low leucocyte contamination.

At the very low residual leucocyte levels currently achieved by filtration and apheresis, new techniques have had to be devised for reliably counting remaining white cells in blood components. The best of these methods employ large counting chambers (Nageotte), or flow cytometry.

Although there is still considerable debate regarding the cost-benefit of routine leuco-depletion, a number of recent clinical outcome studies do suggest that, in selected cases, long-term health benefits can be achieved which justify this added expenditure.

3.11 Trigger Factors in Transfusion Medicine

Dr Sibinga made the presentation.

In Transfusion Medicine the practice is defined by the bedside. In preparation of the clinical transfusion practice the blood bank is actively involved in the provision (the blood collection process, the donation testing and the processing) of the blood components needed. An important trigger for an optimal use at the bedside should be a customer-oriented approach, rather than to focus on a self-oriented quality policy.

As the community as well as the blood bank testing and processing laboratories are needed to guarantee adequate and sustainable quantities and qualities of blood components, developments at the bedside need communication between the responsible clinician and Transfusion Medicine specialist. Team approach and mutual respect are needed to trigger anticipation of developments and allow adequate and optimal haemotherapy support. However, the clinical transfusion demands seem to depend on many predictable and unpredictable variables. These do affect the decision (trigger) to transfuse, urging the medical practitioner to a rational rather than an emotional approach in the clinical transfusion practice.

Blood transfusion as a clinical practice has many benefits, but also some risks. Therefore, before transfusion is given the question arises whether there is any clinical need and if so what the need actually is. Given the variability from donor to donor and the changes in biological function of cells over the storage time ex vivo, the clinical need seems to depend more on the desired clinical outcome or efficacy than on the pharmaceutical characteristics of the component offered. To achieve an optimal outcome, many factors do have an effect. These range from day to day aspects of safety, purity and potency of the various components, to factors defined by the indication, the clinical condition of the patient, the transfusion policy and bedside practices. Regarding the risks, the public seems to have developed a perception of these risks, triggered by the AIDS epidemic. This perception has grown out of
proportion, where fear has become the leading factor triggering even more risky transfusion practices.

Like any other intervention in medicine, blood transfusion is based on setting the indication and taking the decision to practice. Transfusion policies, therefore, should be based on general (consensus) principles: assessing the need (triggers), setting indications and defining desired clinical efficacies. Besides, there are tailor-made policies necessary for a variety of clinical situations. Following these processes, evaluation of the transfusion regime is needed to determine whether the clinical outcome meets the desired efficacy, whether the calculated benefits (justification of the trigger) have indeed outweighed the anticipated risks. Clinical transfusion practices are often based on historically grown customs and traditions. To evaluate these practices, consensus protocols are needed. Audits, in a peer review setting to monitor and evaluate accepted standards and protocols, could serve as an important trigger mechanism to optimize clinical transfusion practice. Here, national and international legislation and regulations focused on Transfusion Practice might provide defined limitations to the practice of blood transfusion and trigger important mechanisms related to safety, self-sufficiency, standardization, inspection and accreditation, optimal use of human blood and blood resources, etc. in Transfusion Medicine.

3.12 Regulatory Aspects in Blood Collection and Component Separation

Dr J. Kolatinen made the presentation.

Different legal traditions in different countries lead to differences also in regulations concerning blood transfusion service activities. While in some countries there are detailed regulations on most of the steps of blood collection and component separation, some others may have no regulations given by government authorities. Only when complications occur, the case is taken into court and the court decisions serve as a precedent and rule in the future. In some countries, parliamentary acts dictate the overall policy and more or less detailed additional regulations are given either by the ministry of health or by some other regulatory agency.

It is important that blood transfusion experts become involved in drafting the national regulations. This can be done through professional societies, national or regional blood transfusion committees or through direct contact with the regulatory agency. If the regulatory agency is not active in initiating the design of regulations, it is recommended that the blood or plasma collecting organizations draft sensible rules and eventually discuss the need of official regulations with the government or other regulatory agency on the basis of the existing internal rules.

The guidelines and documents of international organizations, such as WHO and the Council of Europe, although not binding, are usually taken into consideration when national regulations are drafted. The Directives of the European Union, however, are binding on the Member Countries and must be followed also in the national regulations.

The regulations should define the general policy of blood transfusion service activities, such as defining the organization(s)
responsible for the activity and telling whether the donation is nonremunerated or not. The agency having the responsibility of the inspections should be defined. The obligatory laboratory tests as well as the tests and other criteria of blood donors are given. Rules of documentation and keeping of donor registers are also defined. The objective of the regulations is to protect the patient from harmful effects of blood transfusion, as well as to protect the blood donor from harmful effects of the donation. The regulations should, however, take into consideration the fact that some risks of blood transfusion are unavoidable.

The era of regulated blood collection and component separation has undoubtedly brought the blood transfusion service activities closer to pharmaceutical manufacturing from pure practice of medicine and clinical pathology, where it was before the emergence of concern for all the transfusion-transmissible infections of today. The resulting systematic approach to all the procedures has helped the blood transfusion services to identify and correct many weak points in the processes and practices.

The steps in the process of blood collection and component separation, where regulations can improve the quality of the process are: (1) acceptance of the donor; (2) collection of blood or plasma; (3) cooling, transportation and storage of blood; (4) testing the blood units for transmissible infections; (5) centrifugation and separation of plasma and cellular components; (6) additional production steps of the cellular components (washing, leucocyte depletion, etc.); and (7) freezing of plasma and approval of the frozen plasma units on the basis of the screening test results. Regulations on the design and validation of the information chain, usually including rather sophisticated computer systems, are important and helpful.

The regulatory agencies perform inspections of blood transfusion services and in those the emphasis is on: (1) organization and lines of responsibility; (2) adequacy and training of the personnel; (3) SOPs; (4) GMP principles; (5) information flow (traceability of blood units and donors); and (6) safety measures in donor selection, blood or plasma collection, testing, processing and storage.

3.13 Facilities for Training in the Regional Training Centre in Tunisia

The presentation was done by Professor K. Boukef.

Training is an important step in the development of transfusion and identification of a regional training centre will contribute to the achievement of this goal.

The National Blood Transfusion Centre in Tunis is a government institution under the authority of the Ministry of Health, and is recognized as a hospital institution and also as a university institution. The National Blood Transfusion Centre has a variety of activities.

A training centre needs staff, training facilities, and equipment, as well as training programmes. All technical staff of the National Blood Transfusion Centre are trained well and have good experience in blood banking and blood transfusion (one professor, one MCA, one AHV,
two pharmacist biologists, and 10 medical doctors). A lecture room for 30 persons, a library, and equipment for teaching are available. The National Blood Transfusion Centre of Tunis is well equipped with haemopheresis machines, refrigerator centrifuges, deep freezers (-30°C, -80°C), laminar flow cabinets, autoanalyzer (virology testing and immunohaematology).

A training programme covering all the aspects of transfusion is available. A continuing education programme is provided for medical doctors, pharmacists, nurses, and laboratory technicians (seminars and short courses 2/year). A diploma course in transfusion for physicians and pharmacists is also provided. It is recognized by the university as a highly specialized diploma in haemobiology transfusion, and the Training Centre would be very happy to welcome trainers to Tunis.

4. AMENDMENTS TO THE PLAN OF ACTION

After consideration of the individual country reports, it was recognized that, within a relatively brief time lapse of four years, highly significant progress has been achieved in the realization of many of the interrelated targets identified at the EMRO Meeting on Blood Safety and Development of Blood Transfusion Services held in Nicosia, April 1991. Indeed, evidence from the Regional Meeting of Directors of Blood Transfusion Services in September 1993 suggests that this progress has been sustained.

Nevertheless, the participants acknowledged that even though the plan of action adopted in 1991 (document WHO-EM/272-E, Item 4.1, page 48) remained relevant and basically sound, it was appropriate, at this stage, to focus particular attention upon certain areas of priority where further emphasis and reinforcement is required.

In order of importance and urgency, these specific areas of concern are:

- Organization and management
- Blood donor motivation and recruitment
- Quality management.

4.1 Organization and Management

It is essential that the National Director of Blood Transfusion Services is enabled to acquire and develop specific management skills. A management team should be created to assist and support the director in the task of preparing and implementing a national plan of action comprising administrative, financial, social, as well as technical issues (mid-1997).

4.2 Blood Donor System

Where this has not already occurred, the appointment of a designated blood donor programme coordinator, carefully selected and trained to undertake the task, is of fundamental importance (mid-1997). This individual must be suitably supported by a dedicated staff in order to address donor management issues, such as identifying and establishing
links with prominent segments of society; fostering an effective, continuous campaign for voluntary, non-remunerated donor recruitment; donor retention and counselling policies, as well as systems for the management of a registry of established donors.

The acquisition of local information regarding epidemiology and risk factors will assist in developing appropriate donor selection criteria, against the background of WHO recommendations.

4.3 Quality Assurance

The appointment of a suitably selected and trained national quality manager with the authority to develop and progressively implement a national quality management system by mid-1997 is of crucial importance.

4.4 Other Items Requiring Clarification or Emphasis

The essential function of a national committee (where it exists) is to act in a consultative capacity and to provide the director with political and community support. Its tasks are therefore quite distinct from those of technical or medical advisory committees whose advice may also be required by the director.

4.5 Screening Policies

1) Review screening policy for transmissible infectious agents to ensure that all screening performed is appropriate and reflects those agents present in the donor population.

2) To ensure that all blood collected is screened and to the same standard of quality across the whole of the country.

3) Review screening methodology in order to adopt the most appropriate and cost-effective technology for screening and confirmatory procedures.

4) Establish and review policies for the counselling and care of donors confirmed positive for any transmissible agents with due attention to confidentiality and care.

Further progress in documenting trends and emerging needs for blood and blood products is required.

It is also essential to develop guidelines for the appropriate use of blood and blood products, in close collaboration with clinical users by a variety of means, such as the organization of local consensus meetings and workshops. The progressive establishment of hospital transfusion committees and clinical audit will further support this task and serve to monitor its successful implementation.

Among the key potential functions of a national reference centre are the following: a problem-solving function; initiation of training programmes; establishment of standards; provision of reagents and reference materials; introduction of new developments; fostering research. The establishment of a reference centre by mid-1997.
5. RECOMMENDATIONS TO WHO

The participants recommended that the WHO Regional Office should:

1. conduct a workshop on donor motivation and recruitment;

2. conduct a workshop for quality assurance managers; and

3. continue regular biennial meetings of Directors of Transfusion Services.
Annex 1

AGENDA

1. Opening session
2. Election of officers
3. Adoption of agenda
4. Regional overview of blood transfusion services
5. Transfusion medicine: facts and fiction
6. National blood transfusion policies, and coordination of blood transfusion services
7. A review of current developments in screening for transfusion-transmitted infections
8. Country reports
9. Quality assurance in microbiological screening
10. Quality assurance in blood donor selection and blood collection
11. Distance learning - experience of workshops in three Regions
12. Functions of hospital transfusion laboratory
13. New developments in transfusion medicine
14. Quality assurance of component separation
15. White cell depletion and use of filters
16. Trigger factors in transfusion medicine
17. Regulatory aspects in blood collection and component separation
18. Facilities for training in the Regional Training Centre in Tunis
19. Discussions and evaluation of achievements of the plan of action formulated in 1991 and revised in 1993
20. Group discussion - general and specific problems
21. Presentation of group reports
22. Preparation and discussion of final plan of action
23. Closing session
Monday, 25 September 1995

08.30 - 09.30 Registration
09.30 - 10.30 Opening Session
- Opening address by H.E. the Minister of Health
- Message from Dr Hussein A. Gezairy, Regional Director, WHO Eastern Mediterranean Region
11.00 - 11.15 Introduction of speakers and participants
   Election of Chairman and rapporteurs
   Adoption of agenda
11.15 - 12.00 Regional overview of blood transfusion services, by Dr M. El-Nageh
12.15 - 13.00 Transfusion medicine: facts and fiction, by Dr C.Th. Sibinga
13.00 - 13.45 National blood transfusion policies, and coordination of blood transfusion services, by Dr J. Emmanuel
13.45 - 14.30 A review of current developments in screening for transfusion-transmitted infections, by Dr A. Kitchen

Tuesday, 26 September 1995

08.30 - 11.15 Country reports
11.30 - 12.15 Quality assurance in microbiological screening, by Dr Kitchen
12.15 - 13.00 Quality assurance in blood donor selection and blood collection, by Dr J. Koistinen
13.00 - 13.45 Distance learning - experience of workshops in three Regions, by Dr Emmanuel
13.45 - 14.30 Functions of hospital transfusion laboratory, by Dr F.A. Ala
Wednesday, 27 September 1995

08.30 - 09.15  New developments in transfusion medicine, by Dr Sibinga
09.15 - 10.00  Quality assurance of component separation, by Dr Koistinen
10.15 - 11.00  White cell depletion and use of filters, by Dr Ala
11.00 - 11.45  Trigger factors in transfusion medicine, by Dr Sibinga
11.45 - 12.15  Regulatory aspects in blood collection and component separation, by Dr Koistinen
12.30 - 13.15  Facilities for training in the Regional Training Centre in Tunis, Tunisia, by Dr Boukef

Thursday, 28 September 1995

08.30 - 10.30  Discussions and evaluation of achievements and implementation of the plan of action formulated in the Regional Meeting of 1991, and revised in the Regional Meeting of 1993, by Drs El-Nageh and Boukef
10.45 - 12.00  Group discussions: General and specific problems of countries of the Region. How to overcome difficulties to achieve targets?
12.15 - 14.15  Presentation of group reports. Discussion of the plan of action. Is there a need to have more than one plan of action for each group of countries?

Friday, 29 September 1995

08.30 - 10.30  Presentation and discussion of draft plan(s) of action
10.45 - 11.45  Discussion and adoption of the final plan(s) of action
11.45 - 12.15  Closing session
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