

Report on the

**Regional consultation on cell, tissue and  
organ transplantation**

Karachi, Pakistan  
26–28 November 2005



Regional Office for the Eastern Mediterranean

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## **1. INTRODUCTION**

The World Health Organization (WHO) Regional Office for the Eastern Mediterranean held a regional consultation on cell, tissue and organ transplantation from 26 to 28 November 2005, in Karachi, Pakistan. The meeting was attended by representatives from Bahrain, Bangladesh, Bhutan, People's Democratic Republic of Korea, Egypt, India, Islamic Republic of Iran, Kuwait, Libyan Arab Jamahiriya, Maldives, Myanmar, Nepal, Oman, Pakistan, Saudi Arabia and Thailand. The objectives of the meeting were to:

- share countries' experiences of cell, tissue and organ transplantation;
- create a regional network for cell, tissue and organ transplantation; and
- encourage interaction between focal points in respective countries.

Dr Nabila Metwalli, Regional Adviser, Blood Safety Laboratory and Imaging, delivered the message of Dr Hussein A. Gezairy, WHO Regional Director for the Eastern Mediterranean. Dr Gezairy said that cell, tissue and organ transplantation had raised many ethical, legal, cultural and clinical issues. The World Health Assembly endorsed Guiding Principles on Human Organ Transplantation, which were developed following the resolutions of 1987 and 1989 and the primary concern was trafficking in organs. In May 2004, the World Health Assembly endorsed a resolution (WHA57.18) which stressed the effective oversight by national health authorities of allogeneic and xenogeneic transplantation. The resolution also requested the WHO Director General to update the Guiding Principles on Human Organ Transplantation and to promote international cooperation.

Dr Gezairy said that in response to this, WHO had organized a number of consultations globally to ensure the Guiding Principles on Human Organ Transplantation remained appropriate. The present consultation would provide a review from the Eastern Mediterranean and South-East Asian Regions and would facilitate networking and collaboration between respective national health authorities.

The Chairmanship was shared between Professor Rizvi (Pakistan) and Dr Jain (India). Professor Dev Bhatta (Nepal) and Professor Anwar Naqvi (Pakistan) were elected as Rapporteurs for the meeting. The programme and list of participant are included as Annexes 1 and 2, respectively.

## **2. TECHNICAL PRESENTATIONS**

### **2.1 Objectives of WHA Resolution 57.18**

WHA Resolution 57.18 emphasized the need for: oversight by health authorities of allogeneic and xenogeneic transplantation; collection and analysis of data; update of the guiding principles on cell, tissue and organ transplantation; improvement of access to suitable cell, tissue and organ transplantation; global harmonization of practices (safety, quality, efficacy and ethics); and to prevent exploitation of the poor and vulnerable.

The big challenge is to practise organ donation ethically by providing incentives and preventing commercialism and organ trafficking. The other challenge is to meet the patients'

needs and to ensure essential transplantation in developing countries and to provide safety, quality and efficacy of human material for transplantation.

The second component of the resolution was animal transplantation to humans which was of concern for the World Health Assembly. There are risks involved and this practice should develop in a very controlled environment. The first request is for Member States to ensure that xenotransplantation takes place under strong government controls. With effective control and surveillance by health authorities, Member States are urged to cooperate in global harmonization of practices, including protective measures. They should be equipped to face these dangers, especially across national borders. WHO is requested to facilitate communication and to collect global data. WHO will inform Member States of risks of infections arising from xenogeneic transplantation and is requested to provide technical support to strengthen expertise whenever Member States request it to properly control xenogeneic transplantation activities.

## 2.2 WHO guiding principles

*Dr Farahat Moazam*

The first of the WHO guiding principles is the stated preference for using organs from the deceased, rather than living donors, to avoid risks and harm to the latter. However, experience over the last decade has shown that better results are obtained with transplanted organs taken from living donors. In many countries in the west, whereas the number of kidneys obtained from cadavers has reached a plateau there has been a steady increase in the number of living donors. In fact, in developing countries the vast majority of kidney transplantations are being performed using live donors. There are factors contributing to insufficient cadaveric organs, including the absence of the costly and labour-intensive infrastructure needed to identify and obtain cadaveric organs, as well as cultural and religious beliefs about what constitutes proper behaviour towards dead bodies. Of considerable concern was the lack in some countries of legislation supporting whole brain death criteria.

The second relevant guiding principle is the recommendation that when living donors are used, except in the case of regenerative tissue such as bone marrow, preference should be given to genetically-related adult donors. Minors should not be used as organ donors except for bone marrow. An objection by the minor should be given due consideration.

Another recommendation of the 1991 principles is that no part of the human body must be "commercialized," to be bought and sold as a commodity. Advertising the need or availability of organs should be prohibited and transplant physicians and surgeons must not use organs obtained through such transactions. Despite this recommendation, the last decade has seen a proliferation of the international organ trade with physicians and hospitals openly advertising their readiness to transplant organs obtained through payment to living donors.

There are other ethical concerns connected to another area in transplantation, that of cell and tissue transplantation. There is a steady increase in the number of private and commercial companies advertising stem cell transplantation as a panacea for all manner of ills. Stem cell therapy is being offered as a treatment to desperate patients for diseases ranging from

thalassaemia to cancer, Parkinsonism, heart disease and all manner of neurological disorders, including stroke and paraplegia. Such enterprises are beginning to proliferate in developing countries, including Pakistan. These profit-making schemes, as well as the commercialization of human genetic and cellular material, are occurring largely in countries that have none or poor oversight mechanisms.

### **2.3 WHO achievements and strategy**

*Dr Luc Noël, Coordinator, Clinical Procedures, WHO headquarters*

There is a need to create and maintain a global network of focal points in charge of transplantation at national health authority level. Health authorities should strengthen their interactions with WHO. The objectives are to facilitate access to information and exchanges between health authorities, to encourage transparency, to ensure access to reliable data and to promote international cooperation. To acquire a global consensus on transplantation, experts, health authorities and all stakeholders as patients, donors and industry have to be brought together. The WHO Director General has been requested to gather information on allogeneic and xenogeneic transplantation, especially the global data on evaluation practices and infectious events related to the latter. This will provide ensure, trust in patients, donors and the public and a factual basis for priority-setting and policy-making.

The global knowledge base on transplantation, which is an overriding tool for WHO programme has four components: activities and practice; legal framework and organizational structures; adverse event risks, threats and safety measures; and xenotransplantation.

It is necessary to have access to the basic quantitative data on the number of transplants, the qualitative data on the safety and outcome of transplants and qualitative analysis through scientific societies. The global knowledge base on transplantation has a legal framework for deceased donor donation consent, protection of live donors and recipients, products of human origin for transplantation, authorization of centres for each activity, allocation, importation, exportation, inventory and analysis.

The organizational structure is composed of a national transplantation authority and national transplantation committee, national organization for procurement, allocation and traceability, transplantation centres, cells and tissue banks, registries for recipient and donor outcomes and a regulatory authority. Threats and safety measures are necessary and for this practice, surveillance and vigilance are employed. Adverse events of public health significance and risk of infections are evaluated and ethical risks noted to prevent exploitation. Risks for transmissible infections have to be focused upon. Practices not acceptable by any society for transplantation include: exploitation, coercion of living donors and transplant tourism. Information will be gathered from publications, communications and the Internet and from confirmed reports volunteered by professionals. Enquiries will be carried out where required.

The objectives of resources for xenogeneic transplantation are to provide Member States with updated and complete guidance on xenotransplantation trials and surveillance of adverse events. Support through collaboration with centres of excellence and an inventory of

xenogeneic trials will be available. WHO will provide surveillance through its infectious disease surveillance network.

## **2.4 Overview of the global knowledge base on transplantation**

*Dr Mar Carmona*

Previously, there were no accurate data available on transplantation activities throughout the world. Documentation was required for an estimation of the extent of unethical practices and the relative efficacy and safety of transplantation in different conditions and settings. A questionnaire was prepared to determine donation and transplantation activities of each country and the legal aspects. The questionnaire was sent to the western Pacific countries and a response was provided in relation to kidney, cornea, vascular tissue and valves transplantation.

The National Organization of Transplantation in Spain is a large multidisciplinary group which has been functional for more than 15 years and which has accumulated experience due to working with European institutions and which has now been extended to cover Latin America. In 1996, the organization started to publish a newsletter which provides results of data collected on organ donation and transplantation, waiting lists, family refusals, tissue and haematopoietic stem cell transplant activity. Europe, Australia, Canada, New Zealand and the United States of America (USA) have been collaborating in this activity since 1996 and Latin America since 2004. All data are stored in a specific database and are published with recommendations and guidelines approved by the Council of Europe Transplant Committee during the same year.

### *Discussion*

There is no demarcation between primary and tertiary care. The benefits of transplantation should be calculated by the cost-benefit ratio and cell, tissue and xenotransplantations should be used only if the patient does not have living related donors. Kidney transplantations could be cheaper than haemodialysis.

## **3. COUNTRY PRESENTATIONS**

### **3.1 Bahrain**

Bahrain has a population of 707 160, including 550 nephrologists. There is one nephrologist per 100 000 population. The number of beds per 10 000 population is 287. The Government of Bahrain spends more than 8% of their gross domestic product on health. The per capita annual budget of the Ministry of Health is US\$ 232. The Government spent US\$ 12 million on the care of end stage renal failure treated by dialysis or renal transplantation.

In 1998, the Amiri Degree of Organ Transplant was passed. The Bahraini law on organ transplantation requires the donor to be in sound mental health, to be aware of all complications involved and not to be under any kind of pressure to donate his/her organs. The donor has full rights to withdraw consent at any time before surgery. Trade in organs is

prohibited in Bahrain. Organs from a cadaver can be transplanted with the approval of relatives and/or Ministry of Health officials if the deceased has not specifically denied consent to donate in his/her lifetime or, if after his/her death, his/her relatives refuse to donate his/her organs.

Renal transplantation in Bahrain was initiated in 1985 and to date 60 related donor transplants and 17 cadaver transplants have been performed. The success rate is 95% in the first year and 85% over five years. Other transplants performed in Bahrain include corneal (400), cochlear prosthesis (37) and bone (5). The plan is to start liver transplants and stem cell transplants in the near future.

### **3.2 Bangladesh**

According to estimates, 12 million people in Bangladesh suffer from chronic kidney disease (CKD) and 15000–20 000 reach end stage renal failure each year. Out of these only 2%–4% patients receive renal replacement therapy. To date, 700 transplants have been performed in government centres, 322 in Bangladesh and 398 outside the country. The former is usually from live related donors and the latter from live unrelated donors. The one-year graft survival rate is 96%, and the five-year graft survival rate is 86%. For patients on haemodialysis, the survival rate for one year is 80%, for three years 70% and for five years 50%.

The major obstacles in renal transplantation in Bangladesh are: 80% of patients cannot afford the cost of transplantation, while 20% face donor crisis as according to the Organ Transplant Act 1999 only living related donor transplants are allowed, for which only first degree relatives and spouses are acceptable as donors. A cadaveric organ donation law has been approved but there is no clear cut definition of brain death. Living unrelated organ donations are prohibited by law and are a punishable offence for parties, the centre and doctors involved. This includes fines, imprisonment and cancellation of registration. Apart from this, there are inadequate transplant centres and trained manpower. Special investigative facilities are few.

To overcome these obstacles it is suggested that the cost of cyclosporine be minimized, so that more patients are able to afford transplantation. Also, special investigative facilities such as PCR tissue typing, drug level measurement machines and dopplers should be made available at government level. The training of manpower and availability of more machines for intensive care units is also necessary. An active cadaveric donation programme should also be implemented by increasing awareness, encouraging cadaveric donations and improving the literacy rate. At present, the cadaver programme has not started due to lack of facilities and infrastructure. As the organ transplantation law allows only first degree relative donations, there is a shortage of organs. Now, doctors are trying to obtain permission to include second and third degree relatives in the programme.

### *Discussion*

There are no guidelines from WHO for primary prevention of kidney disease. A question was asked about who bears the cost of transplantation. For tests that are unavailable in government hospitals, the patient has to bear the cost. In the private sector, the patient pays for all expenses.

### **3.3 Bhutan**

Surgical services are available at seven hospitals. There are nine surgeons, of whom four are nationals of Bhutan. In other district hospitals only minor surgery is performed. Patients are referred to India for kidney and bone marrow transplants. Haemodialysis treatment is carried out in Bhutan. The only transplants performed are corneal transplants at eye camps, and skin grafts. Kidney transplantations, though very few, are done only if the donor is genetically related and all the costs are borne by the Government. There are no nephrologists in Bhutan.

Constraints and challenges faced include: difficulty in accessing health care due to the difficult terrain; a double burden of disease: increase in health care expenditure; shortage of health workers and the rising incidence of HIV. Improvements in the economic structure and the incidence of certain noncommunicable diseases is increasing, i.e. diabetes, hypertension, cancers and renal diseases.

### **3.4 Democratic People's Republic of Korea**

The scope of transplantation surgery in Korea includes bone (started in 1950), skin, cornea (allograft, 1960), lens (1980), blood vessels, heart valves, pacemaker, total hip replacement (1980), bone marrow (1990) and kidney (2005). The pre-testing of donors includes histocompatibility. Secondly, immunosuppression levels are performed. For rejection reaction interleukin-2, biopsy and clinical laboratory tests are conducted. Organ transplantation in the country is performed under the guidance of the Ministry of Public Health and, at present, studies on organ transplantation are being conducted by Pyongyang Medical University Hospital.

### **3.5 Egypt**

Transplantation started in Egypt in ancient times with the replacement of damaged limbs. Corneal transplants have been performed successfully in Egypt for 50 years and there are two corneal banks. Bone marrow transplants are also being performed successfully at many centres. In term of renal transplantation, living related transplants are performed at more than 15 centres with excellent results. Earlier transplant tourism was common until the medical syndicate and health authority intervened and prohibited the activity. Liver transplantation in Egypt started in 2001 in collaboration with foreign centres. It is only done with living related donors. Now, liver transplants are being performed at eight centres (Government and private) and about 900 liver transplants have been performed.

The incidence of hepatitis C in Egypt is approximately 12%, so 1500 patients need liver transplants every year, which requires a large budget. The Government of Egypt spends US\$ 80 million on dialyses annually and also shares the expenses of liver transplantation and pays post-operative immunosuppression expenses. This large budget has motivated the Government to pay more attention to the prevention of kidney and liver disease and surveillance of risk factors.

In Egypt, the concept of donation has changed completely in the last 10 years. However, the concept of brain death is still under discussion. There is no cadaveric organ donation law. Research is being conducted on hepatocyte and stem cell transplantation at the National Hepatology and Tropical Medicine Research Institute on animals with some early success. Egypt also looks forward to collaborating with other centres in the fields of hepatocyte transplantation and monocyte isolation and its reverse subscription.

In 2005, the Government supported 100 liver, 135 kidney, 2000 cornea, 130 bone marrow, 5 cochleae, 150 post liver and 840 kidney transplants. It is suggested that liver and kidney diseases could be prevented by media awareness campaigns, education and following infection control guidelines. Egypt hopes to work towards minimizing the cost of transplantation, to clarify the definition of brain death, to regulate transplant tourism and prevent transplant trafficking, to increase awareness and to network globally and develop global guidelines to unify thinking in the field of transplantation.

### **3.6 India**

In India the types of transplantations performed include renal, bone marrow, liver, heart, combined kidney and pancreas and stem cell (experimental stage).

The regulatory act for transplantation in India is the Transplantation of Human Organ Act 1994 (THOA). It aims to curb unrelated renal transplants and to prevent organ trafficking. It also provides guidelines for the establishment of brain death to facilitate cadaveric transplantation and also establishes who is eligible to donate, where and for whom. THOA was enacted to curb malpractices, including the sale of organs, insufficient facilities in terms of trained personnel and equipment for organ transplantation. For any centre in India to start a transplant service it has to apply to the appropriate authorities which, after ensuring that all facilities are available, grants permission for five years after which it needs to be revalidated. Malpractice is very strictly monitored and violation of the act is punishable by five years' imprisonment. Also, in hospitals performing transplantation, there is an authorization committee for emotionally-related donors, comprised of three official and three unofficial members. There is also a brain death committee, for the establishment of brain death and the removal of organs. The Organ Retrieval Banking Organization (ORBO) maintains a list of donors and recipients and the retrieval and harvesting of organs from patients who have suffered from brain stem death, 150 organs have been harvested by this organization. Xenotransplantation is not mentioned in the THOA Act as it is completely experimental and requires genetic modification.

The main achievement is that the organ trade has been banned as hospitals are monitored carefully for unrelated transplantation. The major constraints of this act are that it is mainly donor-based rather than recipient-based, it does not address the needs of those who do not have any relatives, there is no mechanism to ensure donor safety, welfare or recognition and an inadequate focus on cadaveric organ donation programme. In India there are more than 60 000 fatal road traffic accidents annually and if unrelated transplantation was allowed these unfortunate deaths could result in the lives of many others being saved.

To improve transplantation activity in India, it is suggested that THOA should be made both donor- and recipient-friendly which would help to curb organ trafficking. The cadaveric transplantation programme should be aggressively promoted to increase the donor pool. A review committee has been formed and has submitted a report. Its main recommendation is that all related donors should also be examined by the review committee. Possible efforts are being made to promote the cadaveric transplant programme. To increase the donor pool, a multipronged approach needs to be adopted, which requires the active involvement of health workers, intensive care unites neurosurgeons and nongovernmental organizations. An incentive could be offered to the family of the potential brain death donor.

It is suggested that the ORBO network be spread all over the country, the cost of immunosuppression be reduced and intensive research carried out into stem cell and xenograft transplants. Cadaveric donations could be improved through campaigning in the mass media, sensitizing the community through religious leaders and introducing certain information in the school curriculum. The terms 'required request' and 'presumed consent' should be introduced. Driving licences should mention 'mandated choice' and institutions, such as ORBO, should be introduced in other large cities.

### 3.7 Islamic Republic of Iran

Transplantation activity in the Islamic Republic of Iran started in 1935 when the first corneal transplant was performed. This was followed by kidney (1968), bone marrow (1991), liver (1993), heart (1993) and lung transplantation (2000). For cadaveric organ donation, a religious statement was made in 1989, legislation was passed and a pilot study was conducted in 2000 resulting in approval of a decree in 2002. Each case of brain death is determined by five doctors in a university hospital performing transplants and is appointed by the Ministry of Health. The tasks of the Iranian Network for Organ Procurement include policy-making, programming, centralized management, supervising, national allocation, scientific protocol compiling, scientific data registry and waiting list management. The transplantation network has 12 organ procurement units, 18 brain death identification units, transplantation centres (kidney (25), liver (1), heart (4), lung (2), bone marrow (2), cornea (58)) and tissue banks (bone marrow (2), bone (1), heart valve (1), cornea (1), amniotic membrane (2), cord blood (2), blood transfusion organization (1)). In the Islamic Republic of Iran, the organs transplanted include kidney, liver, heart and lung, and tissues transplanted include cornea, heart valves, bone marrow, amniotic membrane, bone, cartilage and tendon. By 2004, 17 601 kidney, 169 liver, 88 heart, 9 lung, 24 217 cornea, 1132 bone marrow, 1082 heart valve and 983 bone transplants had been performed in the country.

### 3.8 Kuwait

The population of Kuwait is 2.5 million. There are seven adult and one paediatric ICU per 60 hospital beds. The incidence of end stage renal disease is 120 million per year and 40 million renal transplants are performed. In Kuwait, the number of transplants being performed is much higher than in neighbouring countries and in Europe. Before the transplantation programme started, a large number of kidney failure patients were going abroad to buy kidneys. In order to stop this, kidneys had to be made available in Kuwait. The reason was that when these patients returned, they had many problems such as ureteric leaks, infections and even HIV. In 1996, the Government was asked to provide incentives to donor families. An incentive-based cadaver programme was started in 1996, although this did not stop people from going abroad as there were not enough kidneys available. In 1999, after witnessing the success of the system in the Islamic Republic of Iran, the living unrelated donor programme was started. The decision on accepting a living unrelated donor is taken by an official committee after a psychological assessment of the donor. Cases of coercion and obvious exchange of money and drug addicts are excluded. As part of this programme, from 1999 until September 2004, 414 prospective donors were interviewed, 283 were approved and 148 donated. To date, 180 living unrelated transplants have been performed in Kuwait.

However, there are drawbacks in the programme as it discourages living related donation, creates a market for kidneys and serves the rich. Also, money is exchanged in a majority of cases. Donors and patients are also exploited by each other in the living unrelated donor programme. Ideally, it is suggested that there should be no contact between the donor and the recipient, compensation could be paid by the Government or a charitable organization, kidneys should be distributed fairly amongst the rich and poor, donors and patients should be protected and the black market of organs should be abolished. The first living donor kidney transplant was performed in 1979. In 1981, the first cadaveric kidney was transplanted. A bone marrow transplant was performed for the first time in 1985 and the first cadaveric pancreas was transplanted in 1989, while the first living donor pancreatic transplant was performed in 1996. In 1996, the first transplantation coordinator was appointed. To date 1130 kidney transplants have been performed. The highest number of kidney transplants in Asia and the third largest number of kidney transplants in the world (after the US and Spain) are performed in Kuwait. The living donor transplant survival rate for one year is 97% and for five years 94%. The survival rate for cadaveric renal transplants is 92% for the first year, 89% for five years and 88% for eight years. The overall survival rate is 95% for one year, 93% for five years.

### 3.9 Libyan Arab Jamahiriya

Organ transplantation in the Libyan Arab Jamahiriya was started in 2004. There is only one centre and it has performed a total of 55 transplants. Only living related donation is accepted. No unrelated or cadaveric organs are considered. The donors were between the ages of 18–54 years (median age 31.4 years) and the recipients were between the ages of 7 and 62 years (median age 35.07 years). This shows that renal diseases are prevalent in this young age group. Sixty-nine per cent (69%) of the donors were male and 31% were female. Seventy-

three per cent (73%) recipients were male, 27.3% were female, 98.2% of the donors were blood relatives and 1.8% were emotional relatives.

It is suggested that a national registry for all transplant patients should be developed and immunosuppression should be regulated. To start cadaveric transplantation, cadaver organ donations should be encouraged by educating the masses, establishing a registry of potential donors and highlighting their consent on driving licenses and other documents, including identification cards. Unrelated, living donation is against the country's policy. Before the end of 2005, the national organ transplantation service in the Libyan Arab Jamahiriya will start living related liver transplants. Three female patients have already been chosen, with their relatives as donors, to be transplanted in the first week of December 2005.

### 3.10 Maldives

Annually 50 new cases of chronic renal failure are identified, half of which start haemodialysis the same year. Haemodialysis services were started in 2001, and currently, 35 patients are undergoing regular haemodialysis. Haemodialysis in Maldives is very costly as everything is imported. The cost of this treatment is US\$ 4000 per year (including medication). To date, 20 patients have undergone renal transplantation, four of whom died. In 2004, six patients underwent renal transplantation in India and all are doing well.

Thalassaemia is a very common condition in the Maldives and every fifth person is a carrier. There are approximately 400 registered thalassaemics in the Maldives, 300 of whom receive regular blood transfusions every fortnight. Eight patients have undergone bone marrow transplants (one patient died).

### 3.11 Myanmar

The first renal transplant was performed in May 1997. All 29 transplants carried out in Myanmar were from living related donors. The highest rate of donation was among siblings. The mean age of recipients is 36.8 years (between 28 and 53) and the mean age of donors is 38.3 years (between 19 and 60). Sixty-two per cent (62%) of the recipients were male and 37.9% female; 55% of the donors were male and 44.8% were female. No paediatric renal transplant has been attempted to date.

The Health Minister will be the chairman of the committee related to body organ transplantation. There is a limit to the age of the donor and those younger than 18 are not allowed to donate their organs. Breaking the law is punishable by up to three years imprisonment and a fine. The first liver transplant was performed in August 2004. The donor was a 39-year-old woman with a head injury and the recipient was a 39-year-old man with renal failure. Constraints experienced in organ transplantation in Myanmar relate to tissue typing, immunosuppressants, lack of current global information and the training of personnel. Other organ transplantations, such as heart, lung and stem cell have not been performed, although many corneal transplantations have been performed. Constraints also include very restricted tissue typing facilities. Samples from donors and recipients are sent to neighbouring countries and it takes 3–6 months to obtain the results. Tissue typing laboratories need to be

established. Also, so far, no generic immunosuppression medicines are available in the country. There is a lack of journals on transplantation in the country and obtaining articles from the Internet is expensive. There is a dire need for more trained personnel.

### **3.12 Nepal**

Kidney transplantation started in 2004. Only first degree relatives are permitted to donate. Nepal has only one government hospital where transplantation is performed. The Cadaver Act has not yet been approved. Maintenance haemodialysis is very costly, so renal transplantation becomes mandatory. The problems faced are the high cost of immunosuppressive medicine and the very strict laws. If the donor dies, the entire transplantation team is imprisoned for 18 years. All these factors are barriers to the progress of renal transplantation.

### **3.13 Oman**

In 1983, renal services were started in Oman and between 1983 and 1984 living related transplants were performed in Oxford as part of an official cooperative programme. The Oman transplantation programme was established in 1988 when one living donor and two cadaver donor transplants were performed. However, in Oman the major source of transplantation is living unrelated or "transplant tourism". In 1993, transplantation legislation was established, according to which only living related (by blood or marriage) transplants are permitted. This law prohibits the commercialization of transplantation, allows cadaveric transplantation and outlines the criteria for establishing brain death.

The bone marrow transplantation unit was established in 1994, and to date, 150 bone marrow transplants have been performed. A transplantation coordination unit was established in 2005. This year proved to be the best in terms of living related donor transplants. To date, more than 900 renal transplants have been performed. Approximately 200 of these were living related (120 in Oman) and 11 were cadaveric transplants. An overwhelming number of transplants are commercial transplants performed abroad in India, Pakistan, Islamic Republic of Iran and Iraq. By 2010, Oman plans to perform 50 transplants annually (25 living related and 25 deceased). Currently, major problems being faced include an insufficient number of living related transplants and fewer still cadaveric transplants, the non-availability of life-saving medicines and organs (heart, liver, and pancreas) for transplantation.

### **3.14 Pakistan**

In Pakistan, 20 million people suffer from kidney disease, the most common of which is UTIs, stones and prostate diseases. Fifteen million people suffer from hypertension (15% will have renal involvement) and 12 million people are diabetic (20% will have renal involvement). Each year, 15 000 people develop end-stage renal failure, requiring dialysis and transplantation. In Pakistan, 30 000 dialyses sessions are performed each month, of which two thirds are done in Sindh, 25% in Punjab, 1% in Baluchistan, 6% in North-west Frontier Province 5% in Islamabad and 22% at SIUT. Renal transplantation activity has risen considerably in Pakistan since 1994, when 197 transplants were performed, until 2003, when

2023 transplants were performed. In 2003, 186 transplants were performed in Karachi, 778 in Islamabad, 676 in Lahore, 22 in Peshawar and 4 in Hyderabad.

There has been an exponential rise in living unrelated donor transplantation since 1991, when unrelated donor transplants were 25%, to 2003, when the number of such transplantations increased to 80%. Each year, of all transplants performed, 400 are related donors, 600 unrelated donors and 1000 are foreigners. Transplantation activity at SIUT started in 1986 (11 transplants were performed that year). The number of transplants performed in 2004 was 125. To date, 84 paediatric transplants have been performed at SIUT. Recently, children under 15 kg in weight have also been transplanted, with the youngest weighing 8.5 kg. Three living related transplants are carried out each week at SIUT.

In Pakistan, the major concerns regarding transplantation are lack of legislation, transplant tourism and commercialization. Pakistan has performed 18 cadaveric transplantations with the help of the Eurotransplant Foundation (the kidneys came from Holland). There were four cadaveric transplants from kidneys harvested from local donors.

### **3.15 Saudi Arabia**

Saudi Arabia is a leading country in the area for transplantation activities. Almost all types of transplantations, including kidney, liver, heart, pancreas, lungs, corneas, bone marrow and cardiac valves are performed here.

More than 1400 deceased kidney donor transplants have been performed since 1986. During the last two years 141 transplants from cadaveric donors and 420 living related donors were performed. Nevertheless, during the same period 1200 living unrelated renal transplants were performed outside the country and this trend has risen steadily from 1998 to 2003. In 2004 there were 70 cadaveric and 189 living unrelated renal transplants. A large number of unrelated transplants are performed outside Saudi Arabia.

The liver transplantation programme was initiated in 1999 when 73 transplants were performed. This programme benefits chiefly from cadaveric donations. A total of 270 transplants have been performed to date, of which 263 were cadaver organs.

The heart transplantation programme was started in 1986, and up until 2004, more than a 100 hearts and 311 cardiac valves have been transplanted. In Saudi Arabia, there has been qualitative development in the field of organ transplantation and brain death reporting and the procurement of cadaver organs has been optimized. From January to October 2004, 287 brain death cases were reported, 193 of these were medically documented, 155 families were approached and 48 of them (31%) consented to donation. Saudi Arabia has organ sharing programmes with Oman, Kuwait, Qatar and a transplantation programme with Yemen.

### **3.16 Thailand**

Corneal transplantation was started in 1968 with the support of the Red Cross Society. The tissue bank was started in 1972 at the Siriraj Hospital. The Red Cross kidney

transplantation project was started in 1983. To date, around 3000 kidney, 176 liver, 57 heart, 30 heart and lung, 22 lung, 245 heart valve, 449 eye and 31 950 various procured tissue transplantations have been carried out in Thailand. In 1983, the first series of free style allograft operations was started. Bone marrow transplantation started in 1985. In 1999, a Masters Degree curriculum was developed. In 2001 tissue engineering was started. Thailand is a counterpart of the IAEA. The Thai Association of Tissue Banking was started in 2001. In 1988, the Asia Pacific Association for Surgical Tissue Banking was established. In Thailand there is a lack of organs and deceased donors are not readily accepted. Awareness campaigns are required as, due to religious beliefs, people are not willing to donate. Only the organs of 33% of people with brain death are donated. To increase this figure, nongovernmental organizations, Scouts, Lions and Rotary Clubs are required to campaign for the donation of organs. Now there are 24 centres working for organ transplantation.

#### **4. CURRENT ISSUES**

##### **4.1 Preventing organ trafficking and transplant tourism**

*Dr Luc Noël, Coordinator, Clinical Procedures, WHO, Geneva*

The trade in organs and transplant tourism are issues of concern for Member States and WHO. Patients are desperate and organs can be obtained from induced living donations, executed convicts and through distortion of allocation mechanisms. Donors will accept whatever financial incentives they are offered as they need the money but the middlemen profit the most. Insurance systems are disinterested in the mechanism of transplantation but want to get the patient off dialysis as it is more expensive. Institutions are known to be involved in transplant tourism.

The source of information today is the Internet. Hundreds of offers are seen on the Internet to sell a kidney. A number of institutions advertise from countries where legislation is not present. In the USA an inmate of the jail was willing to sell a kidney for thousands of dollars. In developing countries, the poor sell their kidneys for a couple of hundred dollars. Living kidney donation is a balance and both donor and recipient should be protected, as they have the same value. In organ trade the policy is to discard the donor. There are not many studies on donor issues. Data could be provided by the health authorities, collaborating centres, scientific and professional societies, publicly available material after careful evaluation of scientific reports, lay press reports and web pages. Transparency is necessary to safeguard against exploitation and unethical practices. In Pakistan, there has been an increase in living unrelated donors in the last 15 years and transplant tourism has become an industry. Pakistan has become the first provider of kidneys for Oman.

WHO is planning to promote global transparency through the global knowledge base on transplantation and through the network to spread knowledge and eventually form a forum. The tools developed will be principles, best practices, guidance, communication and assessment tools. This will include policy-making for the protection of donors. Country-based support will involve developing a legal framework and supporting access to deceased donor donations.

#### **4.2 Ethics and safety of living cell or organ donations**

*Dr Frank Delmonico, Temporary Adviser, USA*

The objectives of the meetings in Amsterdam and Vancouver were to obtain data, information and an awareness of the risks associated with live organ donation. Live organ donation has become the predominant practice around the world. In Amsterdam, participants from 40 countries from all the continents were present to develop a reference for guidelines. The focus of this meeting was not on the recipients but on the care of the live kidney donor. The ethics of live organ donation is all about transparency, awareness of the risks and follow-up of donors. The issues of donor safety and medical criteria for selection of donors were discussed as was the long-term follow-up of live donors. The objectives in Amsterdam were to develop a nucleus of professionals who would bring about such a standard of care and produce a position statement regarding the responsibility of live organ donation. There is no donor registry in the USA at present, but they surveyed many transplant centres in the country to try to assess donor deaths. Among 10 000 live kidney donors that they surveyed from 1999 to mid 2001, two donors died, another one was in a persistent vegetative state and subsequently died, giving a rate of live kidney donor death of 1 in 3000.

WHO is showing great interest in xenotransplantation. The organs from pigs will be readily available in the near future for transplantation into humans to obviate the need for live donor organs. There is no data collected about the role of genetic background in the development of hypertension or renal insufficiency in the live donor, but any live donor is susceptible to develop these long-term complications and should be followed up. Both related and unrelated donors are equally susceptible to develop hypertension, particularly if they are overweight and not careful, irrespective of human lymphocyte antigen (HLA) or genetic identity.

#### **4.3 SIUT donor follow-up programme**

*Dr. Fatema Jawad*

The SIUT donor follow-up programme started in the middle of 2000 and so far has registered 1000 donors. Donors are screened by physical examination, biochemical examination and the findings are compared with previous data from pre-transplant files. Most of the donors are related, the majority of them are first degree relatives and a couple of spouses. It was observed that the donors have a special place in society and their families and are given special food. Some therefore develop obesity and its related complications, including diabetes and proteinuria. The SIUT guide them regarding diet and take care of their complaints.. The Institute could conduct yearly follow-ups and donors are advised to come any time if they have any problems.

The number of donors who have developed the original disease of their recipients which lead to chronic renal failure is unknown, as the majority come into the SIUT very late and a biopsy is not performed. Some donors who developed hypertension and diabetes had a family history of these conditions. Only one donor developed end stage renal disease.

*Discussion*

All discussions focused on the importance of having a follow-up programme for the donor's health and for donors with multiple abnormalities to be rejected. Registries for the follow-up of living donors and accurate data from the donor himself are needed to make sure that the health of the donor and the recipient are maintained well. Any follow-up programme should follow the rules and guidelines of the Amsterdam forum in the evaluation of the donors. Medical judgement should take precedence over donor autonomy.

**4.4 Improving access to deceased donors**

*Dr Blanca Miranda, Temporary Adviser, Spain*

In Spain 50–60 kidney transplants per million population are performed against a need for 100 per million population. More than 4000 patients in Spain are on the waiting list for kidney transplantation. The organs can come from live or deceased donors, although the latter is preferred. Deceased donors can be the only source for many tissues and organs, so while waiting for stem cell and xenotransplantation, deceased donations can be used.

Spain has had a legal framework on organ donation since 1979. Spanish legal rules cover all basic legal aspects, including death certification, consent and criteria for living donation, criteria of deceased donation, criteria for authorization and accreditation of both procurement and transplant centres. It also controlled the import and export of organs and organized a coordinating system. The main aim of the organization was to improve procurement of organs. It is stated in Spanish law that the transplant coordinator is the legally responsible person for events related to the organ donation process in the hospital. In 1998, less than 20 transplant coordinating teams in hospitals in Spain existed, now there are 143 coordinating teams one in each authorized organ procurement hospital. 60% of organ donations for organ transplantation come from hospitals with neurosurgery and transplant teams, while 40% come from hospitals without transplant teams. In Spain, the mass media public plays a great part in the motivation of the public in favour of organ donation, 20%–30% of the time of national/regional coordinators is spent talking to the media.

After the organizational system was established in Spain, the number of donors has more than doubled. Most of this increase has occurred from deceased donations. Living donation constituted less than 2% of organ donation activity. In 2005, this is expected to increase to 3%–4%.

*Discussion*

The definition of brain death is taken as the irreversible cessation of the function of brain and brainstem, but an agreement on the mode of diagnosing this is required. In the UK, clinical assessment is needed. Other countries have other methods of confirming this. This necessitates the development of international consensus on a set of diagnostic tests for diagnosing brain death depending on the age of the patient, circumstances of the death and circumstances of the evaluation. In India, they follow brainstem reflexes and functions. If they are lost, they consider the patient to be brain dead as in the British system. If the papillary size

is more than 4mm, it is fixed and dilated, oculocephalic reflexes are lost and cold water irrigation of the ears and no reflex movements of eyes, the person is considered brain dead.

The American system depends on the absence of circulation to the brainstem as the main factor. There is no need for the requirement of an EEG. The irreversible cessation of brain stem function is a unifying concept of brain death. The same system is implemented in Kuwait. Brain death, as defined in the Islamic Republic of Iran, is the irreversible cessation of brain function, of cortical and subcortical areas and brainstem.

WHO can only support countries in their definition of brain death but the countries themselves have to define the criteria of brain death depending on their society, cultural values and current knowledge. The organizational structure in the Islamic Republic of Iran that led to the expansion of the organ donation programme was based on reviewing other systems, (especially the systems in the USA and Spain) then was amended according to social, cultural and religious needs.

#### **4.5 Other tissues recovered from deceased donors**

*Dr Luc Noël, Clinical Procedures, WHO, Geneva*

Other tissues are recovered from deceased donors to allow therapeutic service for patients. These tissues are amenable to banking, they can easily circulate across boundaries and need to meet safety criteria.

Other tissues from deceased donors have distinct advantages for developing countries. They offer alternatives for expensive technologies that are not available in most developing countries. One example is the use of human valves. Human heart valves are more successful than mechanical or bioprosthetic valves in many respects, including no use of anticoagulation. These are suitable for women of childbearing age and children with growth potential.

In the Madrid meeting in 2003, some issues regarding cell and tissue banking were discussed. These included the generally poor level of education, training and research in tissue banking globally. There is an obvious lack of evidence for the efficacy of some tissues. In operations, the traceability of tissues was often lacking. There was also lack of harmonization of regulatory standards delivering high costs for tissue banking. Other issues raised included inconsistent approaches to donor consent, unregulated commercialization, the existence of tissue trafficking on a global basis and also concern about ensuring the self-sustainability of non-profit tissue banks and preventing excessive profits for some profit banks from altruistically-donated material.

WHO initiated the first global consultation on regulatory requirements for cells and tissues for transplantation. Cells and tissues are considered a specific class of health products. The majority of countries, including developed countries, have no data available on the activity of cell and tissue transplantation. There is lack of regulatory framework.

It is the responsibility of health authorities to seek safety, ensure clinical efficacy for the recipient and ensure the protection of the donor. Also, there is a need to build up a regulatory

framework, as this practice has grown into an international business. The benefit of creating a comprehensive regulatory framework outweighs the costs of necessary investment. There is need for a reference document, standards and specifications and these must be designed with the input of professional society and require enforcement. They also need to address public and private activities alike.

Vigilance and surveillance need to be incorporated at an early stage because the cells and tissues carry the risk of transmission of infections and other diseases, including susceptibility to microbial contamination. There is a lack of clinical trials. Surveillance should not only mean adverse event reporting but active, prospective surveillance. Strong communication between clinicians, operators, regulators and policy-makers is an essential prerequisite for the progress in this field, as is international collaboration.

The Ottawa meeting stressed the need for a quality management system as the only way to ensure the consistency of results. It should control all steps from donor selection to clinical outcomes. Another conclusion of the Ottawa meeting was to use the experience of more advanced countries. In advanced countries, many cell and tissue transplant establishments were closed as they did not have the resources to meet the quality and safety requirements. The centralization of cell and tissue banks is essential for improved quality management. A comprehensive oversight mechanism by health authorities is also mandatory.

An action plan was evolved at the Ottawa meeting, which envisaged the involvement of national health authorities, the creation of a global knowledge base on transplantation, guidance for national health authorities and operators and the development of a document.

### *Discussion*

Discussions centred on the importance of access to bone marrow transplant services and haematopoietic stem cells. There was some debate on the issuance of an international treaty for the control of the stem cells. Some participants felt that as WHO was still collecting data for the global knowledge base for transplantation, this should not be issued until all data had been collected.

#### **4.6 Xenotransplantation**

*Dr Carl-Gustav Groth, Temporary Adviser, Sweden*

Transplantation started in 1964, and 10 000 kidney transplantations, both cadaveric and living, have been performed. There is no organ sale. Sweden contacts a very small number of transplants of other organs including liver, lungs, heart and intestine. The favoured animal-to-human transplantation is the pig as pig organs are very similar to human organs.

Xenotransplantation is necessary because transplantation has proved to be a very successful procedure. There are several other advantages to animal organ transplantation. It would cut down the waiting time for patients, all organs will be of optimal quality and living donors would not be required. Availability of pig organs could also widen the indications for organ transplantation. Pig organ transplantation would also save lot of money and commerce

would be eliminated. Protection would be provided by HLA antibodies and auto-antibodies, no organ procurement organizations and patients could be pre-treated transplanted instantaneously without undergoing thousands of dialysis sessions. HLA laboratories would not be required, pig organs could be modified and manipulated to avoid rejection. However, there are some factors which are holding back the practice of xenotransplantation, such as immune barriers, xeno-viruses and the fear factor.

Recently, very interesting developments have taken place in the field of immune barriers. Gal-negative (double knock out) pigs have been produced by cloning and tissues from such pigs are free from Gal epitope, a sugar molecule that induces hyperacute rejection. There have been recent encouraging reports of kidney and heart transplantation from such Gal-negative pigs presented by American researchers at an International Xenotransplantation Association meeting.

The second factor holding back xenotransplantation is the risk of transmitting viruses to humans. One example is the porcine endogenous retroviruses. The viruses could produce disease in the recipient, his next of kin and could infect the community at large, producing an epidemic, although recent reports have shown that the real risk of transmission of pig viruses to humans is extremely low. When transplantation of human organs began in 1960s, there was tremendous fear about transplantation, the same arguments are being raised again about xenotransplantation.

### *Discussion*

The long-term consequences of genetically-modified organs from animals and animal rights were discussed. Concerning slow viral diseases developing in the animals, these can be eliminated by screening the animals and keeping them in a very controlled environment. The endogenous viruses which are part of the genome of the animal cannot be eliminated. Screening could also take place. There have been no reports concerning the changes in human behaviour after xenotransplantation. Xenotransplantation is going to be a highly cost-effective procedure. It will obviate the need for dialysis except in only acute situations. HLA laboratories and organ procurement organizations will not be needed. Animal organs will be cheaper. WHO has advised countries to engage in xenotransplantation only when effective national regulatory control and surveillance mechanisms overseen by national health authorities are in place.

## **5. RECOMMENDATIONS**

### *To Member States*

1. Formulate and effectively implement national legislation on the transplantation of cells, tissues and organs.
2. Address the issue of donations from the deceased and living donors. The law should also address issues of donor selection, care compensation and follow-up. It should also address the infrastructure and technical competencies for transplantation as well as cell,

tissue and organ trade within a country, as well as from abroad. It defines the national regulatory authority for human cell and tissue products for transplantation.

3. Set up a national organization for transplantation.
4. Ensure transparency in transplant practices and contribute regularly to WHO's global knowledge base on transplantation.
5. Envisage awareness of the utility, safety and cost-effectiveness of transplantation to the general public, nongovernmental organizations, professionals and public opinion leaders through all appropriate means of communication.
6. Encourage donation after death. The family of the deceased donor should not bear the cost associated with donation.
7. Foster behavioural changes to increase citizens' understanding of the need and value of donations after death.
8. Recover multiple organs and tissues from deceased donors whenever possible.
9. Consider kidneys for transplantation from living adult donors for patients with kidney failure, genetically- or emotionally-related donors who are found to be medically and psychologically eligible. Donor exchanges under the oversight of a national regulatory authority may be allowed in cases of incompatibility.
10. Ensure that the recommendations of the consensus statement on the care and follow-up of live donors are implemented. This is for live donation for all organs.
11. Compensate the living donor for loss of income, providing that health care benefits and long term follow-up is acceptable.
12. Adopt and implement the legal dispositions to protect poor citizens from the vagaries of organ trafficking.
13. Ensure control of xenotransplantation practices by national health authorities.

*To WHO*

14. Facilitate the creation of a network of national focal points for transplantation, including health authorities in charge, national regulatory authorities and institutions of excellence for transplantation, related professional bodies, as well as promoting communication between members of the network.
15. Facilitate the formation of a global consensus on algorithms for the determination of brain death adapted to various contexts.

**Annex 1**

**PROGRAMME**

**Saturday, 26 November**

- 08.00–08.15 Registration
- 08.15–09.00 Opening ceremony and group photograph
- 09.00–09.15 Message from Dr Hussein A. Gezairy, WHO Regional Director for the Eastern Mediterranean
- 09.45–10.0 Introductions, objectives of consultation, Overview of agenda, adoption of agenda, *Dr N. Metwalli, Dr R. Bhatia, Dr L. Noel*
- 10.00–10.15 Technical presentations
- 10.15–10.45 WHO and transplantation, WHA Resolution WHA57.18, *Dr L. Noel*
- 10.45–11.05 Ethics and the 1991 Guiding Principles on Human Organ Transplantation, *Dr A. Capron*
- 11.05–11.30 WHO achievements and strategy, *Dr L. Noel*
- 11.30–11.45 Overview of the global knowledge base on transplantation (GKT), *Dr M. Carmon*
- 11.45 – 12.00 Clarifications/discussion from participants
- Regional situation*
- 13.30–13.45 Overview of the South East Asia and Eastern Mediterranean Regions from a global perspective
- 13.45–15.30 Country presentations from participants
- 16.00–17.00 Country presentations and plenary discussions continued
- 17.10 Reception

**Sunday, 27 November**

- 08.30–08.45 Summary of previous day
- 08.45–08.55 Current issues: introduction and plenary discussions

- 08.55–09.10 Preventing organ trafficking and transplant tourism, *Dr L. Noel*
- 09.10–09.40 Discussion
- 09.40–09.55 Ethics and safety of living cell or organ donations, *Dr F. Delmonico*
- 09.55–10.30 Discussion
- 10.45–11.00 Improving access to deceased donors, *Dr B. Miranda*
- 11.00–11.30 Discussion
- 11.30–12.00 General discussion
- 13.30–13.45 Cell and tissue products for transplantation, *Dr L. Noel*
- 13.45–14.15 Discussion
- 14.15–14.30 Xenotransplantation, *Dr C. Groth*
- 14.30–15.30 Discussion
- 16.00–7.00 Plenary discussion: access to and oversight of transplantation

**Monday, 28 November**

- 08.30–8.45 Summary of previous day's discussions
- 08.45–10.30 Revisions to 1991 guiding principles
- 11.00–12.00 Plenary discussions on meeting recommendations
- 12.00–12.30 Closing ceremony

**Annex 2**

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