

# Tissue Banking in Asia Pacific Region - Ethical, Legal, Religious, Cultural and Other Regulatory Aspects

Aziz Nather, M.B.B.S., F.R.C.S. (Ed), F.R.C.S. (G), M.D

*Department of Orthopaedic Surgery and NUH Tissue Bank  
National University Hospital Singapore*

## ABSTRACT

In Asia Pacific Region development of tissue banking depends on ethical, legal, religious and cultural issues. Where laws exist, they follow the "opting in" framework requiring informed consent - Australia, Singapore, Malaysia, Sri Lanka, India, Philippines and Vietnam. No law exists in several countries China, Japan, Korea, Thailand and Myanmar. Religions play a major role. Whilst no religion forbid tissue donation, interpretations vary and misconceptions exist. Whilst Buddhism supports tissue donation strongly, more support is needed from Muslim communities. Better public and professional awareness programmes are needed to promote tissue donation and transplantation. Support by government is very important and depends on standard of primary health care achieved in each country.

IAEA through its RCA tissue banking programme exerts an important regulatory influence on tissue banking in the region. APASTB will play an important regulatory role in setting the General Standards for the region and in providing accreditation for all tissue banks.

## HISTORICAL DEVELOPMENT

Tissue banking activity started in the region with the establishment of the 'Burma Tissue Bank' by Dr. U Pe Khin in 1984 in 'Burma'. Unfortunately in 1987, Dr. Pe Khin suddenly passed away. With his sudden demise, Thailand became the leader in the region with the inauguration of the Bangkok Biomaterial Centre in Siriraj Hospital in Mahidol University by Dr. Vajaradul in December 1984<sup>1</sup>. In Singapore, the National University Hospital Bone Bank was established in the Department of Orthopaedic Surgery in October 1988 by the author<sup>2</sup>. In China, China Institute for Radiation Protection Tissue Bank was set up in Taiyuan, Shanxi Province in 1988 by Dr. Sun Shiquan whilst in India, the Tata Memorial Hospital Tissue Bank was established in Bombay by Dr. Kavarana in 1988. The Philippines Tissue Bank was started in the Department of Orthopaedics in University of Philippines College of Medicine in May 1990 by Dr Agcaoil<sup>3</sup>. In Jakarta, the Batan Research Tissue Bank

was developed in 1990 by Dr. Hilmy. The Korea Biomaterial Research Institute was established in 1990 by Dr. Chang in Dankook University. In Malaysia, two tissue banks were established in 1991, one in Department of Surgery, University Sains Malaysia by Dr. Hasim Mohamad and the other in Malaysian Institute of Nuclear Technology in Selangor by Dr. Norimah Yusof. A significant development is the inauguration of the Sri Lanka Model Human Tissue Bank in Colombo in May 1996 with Dr. Hudson Silva as its Executive Director.

## ETHICAL ASPECTS

Whilst no formal ethical code has been produced for the Asia Pacific Region similar to Ethical Code of European Association of Tissue Banks, all tissue banks in the region comply with all the principles enunciated in this document. Since tissue donation is an act of humanity to alleviate suffering of fellow human beings, it is unethical to allow any element of profit. Tissue banks should not sell tissues. It is permissible to charge for costs of procurement, processing and distribution ie "processing costs". "Processing costs" have been introduced by some countries including Japan, Singapore, Malaysia, Sri Lanka and India.

## LEGAL ASPECTS

There is no universal law governing tissue procurement and tissue transplantation in various countries of the Asia Pacific Region. While the law exists in some countries in the region namely Australia, Singapore, Malaysia, Sri Lanka and India, these are based on similar "Human Transplantation Acts" in Europe and in the United States of America.

There are two different legal frameworks namely that of informed consent or "opting in" system and the "opting out" system based on presumed consent. In the Asia Pacific Region, in countries where laws exist they invariably follow the "opting in" system requiring consent from the donor or next-of-kin. Tissue procurement in Singapore follows the "Medical (Therapy, Education and Research) Act of 1972" where "any person of sound mind and eighteen years of age or above may give all or any part of his body for education,.....transplantation.....The gift take effect upon death."

In Malaysia, tissue transplantation follows the "Laws of Malaysia, Act 130, 1974" which provides for the use of parts of the human bodies of deceased persons for therapeutic purposes and for purposes of medical education and research. Sri-Lanka follows "The Human Tissue Transplantation Act No48 of 1987" which requires consent from the donor or next of kin. In India, tissue procurement follow "The

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*Correspondence should be sent to:  
Dr Aziz Nather  
Dept of Orthopaedic Surgery  
National University of Singapore  
5 Lower Kent Ridge Road  
Singapore 119074*

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Bombay Anatomy Act 1949” permitting the use of unclaimed or donated dead bodies for therapeutic purposes, or for the purpose of medical education or research. In Philippines, tissue donation follows the “Republic Act 7170, 1991” which authorizes the legacy or donation of all or part of the human body after death for specified purposes. Tissue procurement in Vietnam is provided for by “The Civil Code, Article 32, Chapter 2” where consent is needed from the donor or next-of-kin and by “The People’s Health Protection Code, Chapter 4” which provides for tissue transplantation. Indonesia is unique in the region, in that the legislation is incomplete for tissue procurement. “The Indonesia 1992 Health Regulation” provides for procurement of tissues from living donors only but not for deceased donors. A “Fatwa for Bone, Skin and Amnion” was introduced by the religious council on 29 June 1997 permitting tissue procurement from cadaveric donors.

In contrast, there are several countries in the region where no law is present to provide for tissue procurement and transplantation. Such countries include Thailand, China, Myanmar, Japan and Korea.

In Japan, brain death has not been recognized for several decades. Although legislation in 1997 recognized the concept of brain death, no heart transplantation was performed until recently. On 28 February 1999, a liver, a heart and two kidneys were legally procured from a ‘brain dead’ donor in Kochi and air-flown for transplantation to four recipients in four other cities in Japan<sup>4</sup>. It is hoped that this landmark event will change the legal environment to favor tissue transplantation in Japan. In Korea, the concept of brain death has recently been recognized legally in February 2000.

Whilst it is difficult to change the legal framework in any one country, it is heartening to note that recently in Bangladesh in April 1999, a “Tissue Donation and Transplantation 1999 Act” has been passed permitting donation from living and cadaveric donors.

## RELIGIOUS AND CULTURAL ASPECTS

The major religions in the Asia-Pacific Region include Islam, Buddhism, Christianity and Hinduism.

The attitude of Buddhism is in perfect agreement with tissue donation<sup>5</sup>. In Buddhist scriptures there are stories where donation of tissues have been referred to as acts of charity earning merits. In countries where Buddhism is the predominant religion, there is no shortage of tissue donors. These countries include Sri Lanka, Thailand, Vietnam and Myanmar. The most successful public awareness programmes on tissue donation have been achieved by Thailand, Sri Lanka and Vietnam. The decision of setting up a model Human Tissue Bank in Sri Lanka by the International Atomic Energy Agency is influenced greatly by the world renowned success of the Eye Donation Society led by Dr. Hudson Silva who has reached a target of 40,000 eyes procured by May 1999, coupled with the abundance of tissue donors in this predominantly Buddhist country. Countries where Buddhism is an important factor though less dominant include Korea (30%) and Singapore (30%). The success of the National University Hospital Tissue Bank in Singapore is largely due to the fact that the Buddhist community in Singapore strongly supports the tissue transplantation programme.

Muslims are by far the most controversial group for tissue donation. In the Asia Pacific Region, Islamic States include Pakistan, Bangladesh, Malaysia and Brunei. Islam is also the predominant religion in Indonesia, a secular country which follows the five principles of Pancasila. There are about 200 million Muslims in China, another secular country. Islam has also an important influence in Singapore (20%) and in India, both secular countries. Whilst Muslims are more likely to allow kidney donation, they are less likely to allow tissue donation because the latter is often perceived as not saving life but as improving the quality of life. ‘Fatwas’ are religious rulings made by the Fatwa Committee to make an official stand by the Government on certain issues eg. issue of tissue donation and transplantation. With regards to organ donation, Fatwas have been declared in several countries in the Asia Pacific Region including Malaysia, Brunei and Singapore<sup>6</sup>. With regards to Fatwas specific for tissue donation, the first ‘Fatwa on Bone, Skin and Amnion’ was introduced by the Malaysian Islamic Centre on 4 September 1995. This was followed on 29 June 1997 by a ‘Fatwa on Bone, Skin and Amnion’ introduced in Indonesia permitting tissue procurement from deceased donors. This is a great step forwards for Indonesia, noting that till then the only law present, “The Indonesia 1992 Health Regulation” allowed tissue procurement from living donors only. Another important factor is that Muslims must bury the body as soon as possible after death. Therefore procedures like tissue procurement which may delay the burial is not taken too kindly. Culturally, Muslims accept that God created them whole and they prefer to return to him whole. It is common practice amongst many Muslims to bury amputated limbs, foreskin from circumcision, amnion from delivery.

There is a big shortage of donors for bones in countries where Islam is the predominant religion including Pakistan, Bangladesh, Malaysia and Indonesia. More public education is needed to change these cultural practices and beliefs even when Fatwas are present before more Muslims will come forwards to become tissue donors.

Christianity is the predominant religion in the Philippines and in Australia. Countries in which Christianity is less dominant but exerts an important influence include Korea (30%), Singapore (30%) and Malaysia. Catholicism emphasizes the dignity that belongs to human beings and praises charitable acts of donation. Christianity is compatible with tissue donation and Christian communities in Europe and USA have generously supported tissue transplantation. On June 20, 1991, Pope John Paul II received participants attending the Congress of the Society for Organ Sharing in audience and made a statement in full support of organ and tissue donation and transplantation. Yet, there is still a shortage of donors in the Philippines due to cultural factors. Cultural factors are also responsible for less Christian donors in Korea and in Singapore.

Hinduism is the predominant religion of India, a secular country. Hinduism is parallel to Buddhism in many ways. The religion has no objection to tissue donation and transplantation. In Hinduism as in Buddhism, the body is cremated which is in fact the destruction of the body in front of and with the full knowledge of the relatives.

## **REGULATORY ROLE OF GOVERNMENT IN RELATION TO STANDARD OF PRIMARY HEALTH CARE ACHIEVED**

The support given by the Government is an extremely important factor in the development of tissue banking in the country. This is to a large extent dependent on whether the country has achieved a high standard for primary health care or not. Where a high standard of primary health care has not yet been achieved in countries including Bangladesh, Indonesia, Myanmar, Pakistan, Philippines, Sri Lanka, Thailand and Vietnam, the government is not likely to support the tissue bank with big financial grants. The facilities in these tissue banks are not likely to match those in countries where the health care standards are very high and the Governments are focusing their attention on secondary health care and the introduction of the latest technologies such as minimally invasive surgery. In such countries including Singapore, Hong Kong, Australia and Japan, the tissue banks are more likely to receive bigger grants from their Governments.

The facilities available for procurement and processing therefore vary from country to country. In some countries such as in Vietnam and Philippines few femoral heads could be procured because many patients with fracture neck of femur are treated conservatively as the patients are unable to afford the operation of a hemiarthroplasty.

In some countries with less developed health care, the existing facilities do not permit full laboratory tests to be performed for donor screening. Sri Lanka, Indonesia and Myanmar are not equipped to do Hepatitis C screening. It is only recently in May 1999 that IAEA provided radio-immunoassay kits to Sri Lanka to allow Hepatitis C screening for tissue donors only and not for the whole country.

The rate of utilisation of tissue grafts again vary from country to country. In Sri Lanka, the rate of transplantation of tissues is particularly low and more programmes on professional awareness are needed.

## **REGULATORY ROLE OF INTERNATIONAL ATOMIC ENERGY AGENCY (IAEA)**

IAEA runs a programme through the Regional Co-operative Agreement (RCA) Project RAS 7/008: "Radiation Sterilisation of Tissue Grafts". Through this project, equipment is provided to 12 Member States (Singapore excluded) and 17 tissue banks were established. Each country is represented by a national project co-ordinator, usually the director of a tissue bank nominated by the Government who is responsible for conducting national programmes in that country for tissue banking.

An IAEA/RCA Curriculum on Tissue Banking was completed in September 1995 to be used by all tissue bank operators in the region. It was written by all the national project co-ordinators with Professor Phillips as the co-ordinating editor. By this curriculum, a set of guidelines on all activities of tissue banking from donor screening, procurement, processing to transplantation with recommended quality standards was for the first time agreed upon for use by the whole region. This draft curriculum was later converted into Multi-Media Curriculum by NUH Tissue Bank with funds provided by the Singapore Government<sup>7</sup>.

The IAEA/RCA Programme on tissue banking focuses on achieving good quality control standards. By January 1998 all tissue banks are required to produce their own Procedure Manuals and Quality Control Manuals based on a standard format. All operational procedures in the tissue banks must comply with procedures outlined in detail in these manuals.

To further raise the quality standards of tissue banks an IAEA/NUS Regional Training Centre was established in Singapore in November 1997 to provide centralized training for all tissue bank operators in the Asia Pacific Region<sup>7</sup>. National University of Singapore launched a distance learning, one year NUS Diploma in Tissue Banking –the first of its kind in the world. The first batch convocated in October 1998 with 4 Distinctions, 5 Credits and 3 Passes. The second batch of 16 participants completed their examination on 31 March 2000 and convocated with 2 Distinctions, 5 Credits and 8 Passes. By following the same Diploma Course in the Regional Training Centre, IAEA is able to harmonise the varying quality standards existing in the region. This will facilitate exchange of tissue grafts between member countries in the near future.

## **REGULATORY ROLE OF ASIA PACIFIC ASSOCIATION OF SURGICAL TISSUE BANKING (APASTB)**

APASTB was developed in October 1988 with its secretariat in Bangkok and with Dr. Yongyudh Vajaradul and Dr. Aziz Nather elected as its President and Vice-President respectively<sup>8</sup>.

It has since grown rapidly with a current membership of 161 ordinary members mainly from 15 countries in the region including Australia, Bangladesh, China, India, Indonesia, Japan, Korea, Malaysia, Myanmar, Pakistan, Philippines, Singapore, Sri Lanka, Thailand and Vietnam and some members from 7 other countries in Europe and the United States.

Whilst APASTB has not yet exerted any regulatory influence on tissue banks in the region, it will soon play a very important role in the near future. Whilst the region has developed a Curriculum on Tissue Banking, it has yet to develop its own General Standards to be adopted by all countries in the region. This is a role that APASTB has to play just as EATB and AATB, has set the General Standards for Europe and the United States respectively. The immediate challenge for APASTB is to set the General Standards for the Asia Pacific Region. Its next task is to run audits for all tissue banks in the region and to provide accreditation for tissue banks in all member countries.

## **CONCLUSIONS**

The success of any transplantation programme in a country depends on several key factors including ethical, legal, and religious and cultural considerations. Whilst no religion outrightly forbids tissue donation, interpretations vary and several misconceptions exist. There is therefore a great need to conduct public awareness programmes to dispel such misconceptions and promote tissue procurement. There is also a need to conduct professional awareness programmes to promote tissue transplantation. IAEA and APASTB will both continue to play a very important role in promoting

the development of tissue banking in the Asia Pacific Region.

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