

Bioethics Links

Volume 1, Issue 3 (December 2005)

Familiar Battles for Bioethics: Facing off over Transplantation

Paul A. Lombardo, PhD, JD *

Technologies for organ transplant and the moral controversies they engender provided critical signposts in a timeframe that marks the beginning of the field we now know as "Bioethics." The first live donor kidney transplant occurred in 1954, the same year Joseph Fletcher's *Morals and Medicine* was published. Fletcher's book is widely recognized as one of the earliest systematic analyses of topics in bioethics.

When the first cadaveric kidney was transplanted in 1962, news of a Seattle, Washington committee charged with deciding who would receive kidney dialysis filled the news. That committee's controversial practice of weighing the "social worth" of potential dialysis patients sparked a serious debate on the proper criteria to employ when scarce technologies must be rationed.

Some consider that debate the "birth of bioethics."

Transplants of other organs led to even more soul-searching. Doctor Christian Barnard's first heart transplant in 1967 was followed in 1968 by the dissemination of "brain death criteria" by a committee at Harvard University. The criteria were necessary, many commentators suggested, to allow what would in the past have been considered a premature declaration of death, so that organs could be taken from the newly deceased for transplantation to other patients more quickly, before the organs began to deteriorate. And it was the need to secure useable organs that led to an ultimately unsuccessful lawsuit that same year against a Richmond, Virginia surgeon charged with taking the heart from a not-quite-dead accident victim for

transplant to a patient in cardiac failure. For a time the legal action cast a cloud over the prospect of "donations from the dead."

More recently, attempts to perfect a mechanical, "artificial" heart have pointed ethical questions toward the ubiquitous topic of informed consent. Can a patient on the threshold of death ever consent freely to experimental procedures with only a small chance of

success? Is the "therapeutic misconception" conflating the benefits of proven medical interventions with the merely speculative impact of a new technique-always a factor when desperate people invest more hope than is reasonable in cutting-edge research? How much attention should we pay to the mental health of those who choose to participate in high-stakes procedures? All

these questions have resurfaced recently, and the international news has been filled with accounts some including pictures of what is apparently the world's first case of a facial transplant. Bioethicists have leapt into the fray, and descriptions of the transplant recipient rarely appear without some reference to "ethical concerns" that appear as roadblocks in the way of more widespread acceptance of the novel procedure.

The story of 38 year old Isabelle Dinoire is far from ordinary, and discussion of the events that led to her facial disfigurement, along with the similarly troubling account of the demise of her donor/benefactor, provide more than enough controversy to muddy the ethical waters. The consensus from media reports, though

continued on page 2

Announcement

cbec_{SIUT} Postgraduate Diploma in Biomedical Ethics

Starting: January 23, 2006

- One year modular program for healthcare related professionals; national and international faculty
- Four one week long contact sessions over the year
- Accredited by Karachi University. Credits to accrue to an MA in Bioethics when initiated
- Tuition fee waived by CBEC, SIUT
- For details please see our website: <http://www.siut.org/bioethics>

Familiar Battles for Bioethics: Facing Off over Transplantation

continued from page 1

disputed by at least one of her doctors, is that Madame Dinoire suffered from depression and took an overdose of sleeping pills last spring in an unsuccessful attempt to kill her self. Her black Labrador dog, perhaps in an attempt to awaken his mistress, bit off her nose, chin and lips. The injuries impaired her speech and limited her ability to keep food in her mouth; they also left a section of her jawbone exposed. Distress at her appearance led Mme. Dinoire to remove all mirrors from her home.

In a precedent-setting operation on November 27, 2005, Dinoire received the nose, chin and lips of a woman who had been declared brain dead. Immediately, the ethical debate began and the difficulty of obtaining informed consent for such radical surgery quickly took over as a focus of dispute. This desperate patient, said the critics, could hardly comprehend just how risky the new procedure was. It was questionable whether the engrafted tissue would be rejected and the operation could be a complete failure, leaving the patient in even worse condition. They argued that no patient, most certainly one who had suffered mental illness, could appreciate the long term psychological impact of an "altered identity" that would result from a facial transplant. Those who endorsed the surgery declared that injury had already altered Dinoire's identity to the point that she feared looking into a mirror, and a new face could only improve her life prospects.

Yet, if the procedure was a success, Dinoire would probably have a life-long need to take immunosuppressant drugs to prevent rejection of her engrafted features, and such drugs are potentially carcinogenic. To merely improve the quality of a patient's life (rather than to save it) did not justify undertaking a life-threatening course of therapy, other critics said. In contrast, an essay in the *British Medical Journal* by a surgeon who endorsed the operation concluded that the ethical issue now was not how facial transplants could be justified, but given their potential benefits to recipients, how physicians could deny the imperative to provide this surgery.

In the midst of this controversy, the Dinoire case was further complicated by claims that the facial donor had killed her self by hanging, that her family had not given consent for the transplant to take place, and by the

apparently illegal publication of her name in the press. As if those contentions were not enough to enrage the opponents of facial transplantation surgery, *The Times* of London reported that Ms. Dinoire and her doctors signed a contract for her story to be told in a movie some three months before the surgery, and other reports mentioned commercial arrangements for the sale of photographs and video of the surgery itself.

It has been less than a month since the pioneering surgery took place, and though teams in Britain, the U.S. and China have all announced their desire to breach this newest surgical frontier, only two points seem settled. The operation, like most new medical technologies, will probably not be abandoned. Despite the protests, ethical and otherwise, it will certainly be repeated, expanded and enhanced. And commentary on outer limits of speculation will continue, with some wondering whether total face transplant could become just another cosmetic option of the rich, and whether commodification of one's entire identity is possible. These musings leave us finally with yet another reminder of the scandalously disparate levels of access in most parts of the world to much more mundane health interventions.

*University of Virginia, Center of Biomedical Ethics, USA

International Association of Bioethics World Congress

August 6-9, 2006
Beijing, China

- CBEC is organizing a Special Session entitled "Muslim Voices from the Eastern Mediterranean Region" in collaborations with EMRO-WHO.
- The session will consist of 4 to 5 invited talks followed by a panel discussion
- For details visit:
<http://www.chinamed.com.cn/IAB2006/>

Kidney Trade and Transplant Tourism: Pakistan, the Emerging Leader

Farhat Moazam, MD, PhD *

Kidney transplantation, with organs from cadaveric or living donors, has saved many lives since its initiation in the 1950s. Voluntary donation of a kidney by a living person to another is heralded as an altruistic gesture, a selfless act by one human to give a new lease of life to a suffering fellow human being. Unfortunately, over the years live donation is being converted into a commercial transaction with kidneys (and other organs) perceived as commodities to be purchased in an international marketplace. Kidneys are being bought from the disadvantaged in society, for transplantation into the affluent, and Pakistan is rapidly acquiring the reputation of the emerging leader involved in a practice that has come to be called organ trade or “transplant tourism.” Transplant physicians working in the private sector in Punjab are now using the internet to offer “transplant packages” to people all over the world; this includes kidneys bought from poor villagers, directly or through middlemen. (See <http://www.masoodhospital.com> and also <http://aadilhospital.com/renal.html>)

The worldwide increase in international organ trade was a major focus of discussions in the WHO Regional Consultation Meeting on Cell and Organ Transplantation held in Karachi on November 26-28. The World Health Assembly in 1991 endorsed “guiding principles” (Resolution WHA 44.25) which member states are expected to follow in formulating policies on organ transplantation. One of the principles states that “the human body and its parts cannot be the subject of commercial transactions,” and that “advertising the need for or availability of organs with a view to seeking payment should be prohibited.” Almost all countries have complied and formulated laws that criminalize organ trade. Pakistan remains the only Muslim country that has failed to pass an organ and tissue transplant law, as well as one dealing with brain death (a prerequisite for instituting cadaveric organ transplantation programs and decreasing the reliance on live donors). No legal deterrent exists in the country currently to stop the proliferation of a burgeoning business of buying and selling of kidneys.

In the year 1991, 75% of kidneys transplanted in Pakistan were donated by family members. In contrast,

in 2003 80% of transplanted kidneys were obtained from unrelated donors. Over half of the 2023 transplantations performed that year (more than 1400 of which were done in private hospitals in Lahore and Islamabad) were undertaken in citizens of other countries, especially from the Middle East. It is common knowledge through advertisements (that include names of physicians in the transplant team and their qualifications) posted on the internet by these hospitals that foreigners are charged from US\$1300 to \$25,000 for a transplant including what is labeled euphemistically as “donor cost.” It is estimated that this results in a lucrative business of about \$15 million annually for transplant physicians and surgeons, and their hospitals.

The fact that Pakistan is becoming a transplant tourism haven for the ME is supported by data from Oman presented in the Karachi WHO meeting by Dr. Nabil Mohsin, a nephrologist of the Royal Hospital in Muscat. Although Oman instituted a kidney transplant program in 1988, a majority of transplants (700 out of a total of 900) are taking place outside the country using non-related live donors. According to Dr. Mohsin, in the early 1990s, citizens of Oman traveled to India to get kidneys but this trend decreased dramatically after 1994 following passage of the Indian Transplant Law that criminalized such activities. The flow of transplants from kidneys bought from non-related donors then shifted to Iraq which was curtailed with the onset of war in that country. From 2002 onwards Omanis have been traveling in increasing numbers to Pakistan for this purpose (graph 1.) Hospitals in Lahore and Islamabad are also becoming the hub for such transplants for citizens from other Arab countries in which such activity is prohibited by national law. A Pakistani transplant surgeon I spoke with, who admits to transplanting kidneys from non-related donors, believes that to prevent people from selling their Kidneys is paternalism as it robs them of their autonomy to make choices. In his opinion, it is a “win-win” situation as both donor and recipient benefit, one with money he or she needs and the other with a chance to survive renal failure. This is a fallacious argument. There is evidence that it is

continued on page 4

Cadaveric Organ Donation and the Role of Family

Alireza Bagheri M.D., Ph.D *

The important role of the family in organ procurement policy has been stressed by many commentators. The question remains what can be an appropriate role of the family in making decisions on the determination of death and organ donation. Organ transplantation laws have adopted different roles for the family, from one extreme of ignoring the assertion of any legitimate role for the family in organ donation to another extreme of giving the family a veto power to ignore individual willingness. This paper examines the degree of importance of the family consent in organ donation, especially in organ removal from dead brain cases.

Ignorance and Excessive Power

There is no doubt that any transplant-related legislation should be concerned with inclusion of the

family's opinion in the decision-making process. This forms a basis for social acceptance of the legislation. But to what extent is the family's opinion to be taken into consideration? Organ transplantation laws in different countries address this issue in different ways and take different position towards the role of the family.

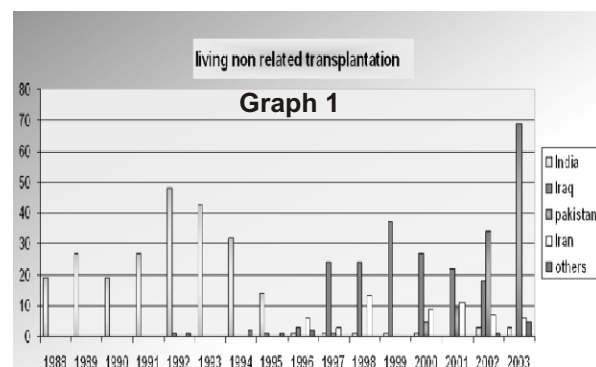
There are two extreme approaches; one ignores the role of family and another gives an excessive role to the family in decision making for organ donation. In some countries which adopted "presumed consent policy", like Spain and Singapore, there is no need to obtain either donor consent or family consent and in fact, the law ignores not only family consent but also individual consent.

continued on page 5

Kidney Trade and Transplant Tourism

continued from page 3

those who have the least control over their lives due to poverty, debts or social inequities, non-autonomous individuals in the true sense of the word, who are forced by circumstances to sell a kidney. It is also a myth that by selling a kidney, such individuals improve their lives. In a study done in India by Goyal and his associates, about 86% reported a deterioration in their health post-



*From Mohsin's presentation, WHO meeting, Karachi Nov 26, 05.

donation, three fourths were still in debt, and the number of donors living below the poverty line actually increased over the years. Most importantly, 79% of the donors said that they would not recommend others to sell a kidney. ⁽¹⁾

Organ trade is an unethical practice which exploits the powerless of this world, and reflects deplorable societal apathy towards the disadvantaged among us.

Moreover, it is an affront to the moral values of a country which professes to follow the tenets of Islam, a religion that emphasizes norms of social justice and obligations towards those less fortunate in life. Muslim *ulema* have repeatedly given *fatawa* that buying and selling of organs is prohibited by *Shari'a*. Yet the commercialization of kidneys as commodities to be bought and sold in the marketplace continues openly in Pakistan. This offensive practice, that is now well known to the international community, is a challenge which the Pakistani government, its medical community and public can no longer afford to ignore if they wish to prevent becoming pariahs of this world. Transplantation tourism, on the rise in Pakistan, should be acknowledged as a serious problem. It must be criminalized by expediting passage of the Transplant Bill that has been shelved by lawmakers for 15 years under the influence of lobbying by those who are benefitting from this practice.

1. M. Goyal, R. L. Mehta et al. "Economic and Health Consequences of Selling a Kidney in India," JAMA, October 2, 2002, vol. 288, no. 13: 1589-1593.

* Center of Biomedical Ethics and Culture, SIUT, Pakistan

Cadaveric Organ Donation and the Role of Family

continued from page 4

For instance Singapore has applied an “opting out” system. According to the Human Organ Transplant Act (HOTA) the designated medical doctor can authorize in writing the removal of any organ from the body of a person who has died in the hospital, for the purpose of the transplantation. An exception to this law is an individual who has during his lifetime registered his objection to the removal of organs from his body after his death. But still there is no need to ask permission from the family.

The other extreme approach can be seen in Japanese organ transplantation law. According to the law, family consent is considered an absolute necessary condition for organ procurement as well as for death declaration in case of brain death. Family members have the authority to override a person's decision if they oppose organ donation. In other words, the family has the power to veto an individual's expressed wish for donation.

In Japan, the donor card has to be signed by the family as well as the individual who wishes to be an organ donor after his death. If the family refuses to sign, the donor card has no validity and legal diagnosis of “brain death” and subsequent organ procurement is not possible. Therefore according to the law, the authority of the family is able to prevent an individual from holding a donor card and, in extreme case, to breach the patients previous agreement and violate his prior written consent to organ donation. Transplant surgeons and patient groups have expressed great concern that this restriction will severely limit organ procurement from “brain dead” sources in Japan. Cultural background has been cited as the reasons behind such a position. For example, the process of dying is regarded not as an individual but a family event in the Japanese culture.

This current law therefore does not respect individual's autonomy in the face of family authority. In Japanese society, the role of family is inevitable and may exert more influence on an individual's actions than in other societies, but the current transplant law gives the family complete control over the individual's action, which makes individuals vulnerable to their families' demands.

The suggestion here is not to ignore the role of family. Even in individualistic societies where the principle of respect for autonomy is quite dominant and the law does not require family consent, family agreement before organ removal is emphasized. Attention is focused on how to reach family agreement.

Other Scenarios

In many other countries, like Iran, Saudi Arabia, India and Turkey, organs can be removed based on either donor's prior declaration or family consent. In these countries, in the absence of any document to show deceased's opinion on organ donation either willingness or objection, family is given authority to act as a surrogate decision maker on behalf of their loved ones.

For instance, according to the 2002 organ transplantation law in Iran, organ removal is legalized for the purpose of transplantation with either: a) Donor's prior declaration as well as family agreement. Donor declaration can be in a written statement or oral consent. Later it must be confirmed in writing by one of the family members, and b) In the lack of donor declaration, the family has a right to make a decision on behalf of their loved ones in the best of his/ her interest. In India also surrogate decision making by the family when an individual has neither expressed willingness for organ donation after death nor any objection, has been recognized.

In Saudi Arabia, consent for organ donation is valid if the deceased has expressed his desire to donate organs during his life. Otherwise consent should be obtained from the heirs of the brain-death case. In Turkey too, if a testament is not present, the relatives of deceased can give permission for organ donation.

In Korea donor consent is required for organ removal but the family has a very strong voice to not allow organ donation if they oppose organ donation.

Conclusion:

The suggestion here is not to ignore the role of family or ignore individual autonomy in favor of family authority. In a morally sound organ procurement policy, neither the individual autonomy nor the role of family should be ignored, and an individual's autonomy and family authority both should be respected.

* Kyoto University, Japan.

Fundamentals of Research Ethics: International and Regional Perspectives

International Conference and Workshop on Research Ethics
November 28 and 29, 2005

Aamir M. Jafarey, FCPS, FRCS *

The third educational event by CBEC in 2005 was an International Conference and Workshop “Fundamentals of Research Ethics: International and Regional Perspectives.” The aim of the conference was to bring together experts from Western countries with those from regional countries that share many values and problems with Pakistan.

The conference was inaugurated by Dr. Pirzada Qasim, Vice Chancellor of University of Karachi. Professor Adib Rizvi, Director of SIUT welcomed the guests. In her talk entitled “Research Unchained: Hopes and Hypes,” Dr. Farhat Moazam, Chairperson of CBEC spoke about different areas of major concern in human subject research. She gave the example of proliferation of commercial companies presenting preliminary research untested for long term safety, including that related to stem cells, as successful treatment to unsuspecting patients.

In his keynote address, Confucian philosopher Dr. Qiu Renzong from Beijing and President of the 8th World Congress of Bioethics, elaborated on “A Search for Moral Diversity in Bioethics.” This is important he said, as the world population draws its sense of right and wrong from many sources which include cultural norms and religious values. Dr. Daniel Wikler from the Harvard School of Public Health spoke on the importance of focusing on the “Ethics of Population Health,” an area that has received insufficient attention. The challenges that research ethics poses to countries in the EMRO region was dealt with by Dr. Al-Khayat, Senior Policy Adviser at the WHO-EMRO office in Cairo. Who stated that Islam gives great importance to dignity of all human beings.

A major component of the conference was dedicated to regional perspectives. Dr. Aamir Jafarey presented the results of his survey undertaken to explore the understanding of “Informed Consent” among laypeople in Karachi, and the ways in which this differs from the

experience in Western countries.

Invited speakers from Pakistan and other South Asian countries referred to the difficulties in protecting populations made vulnerable by poverty, illiteracy, and strong hierarchical societal systems. Such communities are especially at risk when unethical researchers and physicians focus on personal gains while collaborating in studies, especially drug trials, sponsored by multinational pharmaceutical companies.

cbec_{SIUT} - UNESCO Joint Conference and Workshop “Bioethics and Education”

January 21-22, 2006

- Plenary sessions and workshops focusing on bioethics education in high school, medical colleges, and postgraduate training.
- Round table discussion on the Universal Declaration on Bioethics and Human Rights (adopted October 2005, 33rd session, General Conference of UNESCO).
- Details from CBEC office or website.

In this regard, Mr. Latif Shaikh, Director of Pharmacy Services in the Aga Khan University highlighted the challenges and dilemmas connected to pharmaceutical research in Pakistan.

Dr. Nandini Kumar, Deputy Director of the Indian Council of Medical Research gave a talk entitled “Vulnerability in the Developing World Context,” and Dr. Athula Sumitapala, Director of the Forum for Research and Development in Sri Lanka, spoke on “Standards of Care.” Dr. Richard Cash, Senior Lecturer at the Harvard School of Public Health, conducted a dialogue on “What is owed to the community following a research study?” A report of the status of research ethics in Bangladesh was provided by Dr. Harun-Ar-Rashid, Director Medical Research Council in that country; Dr. Huma Qureshi, Director of Pakistan Medical Research Council, did the same for Pakistan.

The two day event ended with a workshop for 31 pre-registered participants. The large number of applicants for the workshop reflected the interest in research ethics among professionals in developing countries. International participants for the workshop included people from Korea, Vietnam, Iran, Sri Lanka, UK, Germany and Nigeria.

* Center of Biomedical Ethics and Culture, SIUT, Pakistan Page 6

Information

Centre of Biomedical Ethics and Culture (CBEC), SIUT
5th Floor, M. A. Jinnah Road, Karachi, Pakistan
Phone: (9221) 2726338 (Direct), 9215718 Ext 2193
Fax: (9221) 2726338
Email: bioethics@siut.org; Website: www.siut.org/bioethics