2025 Friday, 10/10

- AM 8:30-PM 15:30
- International Conference Hall, International Agricultural Research Center Building, NCHU｜中興大學國農大樓國際會議廳
- In person and online Webex Conference ｜ 實體加 Webex 線上會議

2025 The International Symposium on Ethical and Legislative Advancements in Organ Trafficking, Xenotransplantation, and Cell Therapy

2025 器官交易、異種移植和細胞治療的倫理和立法進展國際研討會

TIME	ITENERARY
08:50-09:15	**Opening Remarks** Prof. Chao-Chin Chang (張照勤副校長), Vice President of National Chung Hsing University Prof. Yun-Ching Fu (傅雲慶院長), Superintendent of Taichung Veterans General Hospital Prof. Jian-Wei Chen (陳健尉院長), Dean of College of Medicine, National Chung Hsing University Prof. Mai-Szu Wu (吳麥斯校長), President of Taipei Medical University, President of Taiwan Society of Nephrology Prof. Meng-Kun Tsai (蔡孟昆副院長), Deputy Superintendent National Taiwan University Hospital Hsin-Chu Branch, President of Transplantation Society of Taiwan
09:15-10:00	**Unproven Cell-Based Interventions: Current Practices, Regulatory Challenges, and Lessons from Japan** Speaker: Prof. Misao Fujita (藤田みさお教授), Uehiro Research Div. for iPS Cell Ethics, Center for iPS Cell Research and Application, Kyoto Moderator: Prof. Mai-Szu Wu (吳麥斯校長), President of Taipei Medical University, President of Taiwan Society of Nephrology
10:00-10:45	**Battling transplantation tourism through policy and legal reform in Taiwan** Speaker: Prof. Daniel Fu-Chang Tsai (蔡甫昌教授), Department & Research Institute of Medical Education & Bioethics, National Taiwan University College of Medicine, Taiwan Moderator: Prof. Meng-Kun Tsai (蔡孟昆副院長), Deputy Superintendent, National Taiwan University Hospital, Hsin-Chu Branch, President of Transplantation Society of Taiwan
10:45-11:00	BREAK
11:00-11:45	**The Leaky Sieve of Organ Trafficking – How Protective Measures May Be Circumvented** Speaker: Prof. Benita Padilla, National Kidney and Transplant Institute, Philippines Moderator: Prof. Cheng-Hsu Chen (陳呈旭系主任), Director of Post-Baccalaureate Medicine, NCHU, Taiwan
11:45-13:00	Lunch and Free Communication (午餐及自由交流) & Poster session (海報展示)
13:00-13:45	**Kidney Transplantation in The Next Decade: Xenotransplantation** Speaker: Prof. Chih-Yuan Lee(李志元教授), Division of General Surgery, National Taiwan University Hospital, Taiwan Moderator: Prof. Huang-Yu Yang (楊皇煜教授), Kidney Research Center, Department of Nephrology, Chang Gung Memorial Hospital, Taiwan
13:45-14:30	**What Next for Transplant Ethics in the Era of Xenotransplantation?** Speaker: Prof. Dominique Martin, Deakin University, Australia Moderator: Prof. Peih-Ying Lu (呂佩穎教授), College of Humanities and Social Science, Kaohsiung Medical University, Taiwan
14:30-15:00	**Practices and Policies of Organ Transplantation and Organ Trafficking in Taiwan** Speaker: Prof. Ming-Che Lee (李明哲董事長), Chairman of Taiwan Organ Sharing Registry and Patient Autonomy Promotion Center Moderator: Prof. Chien-Sung Tsai (蔡建松教授), Chairman of Taiwan Surgeons Association; Director-General of Medical Affairs Bureau, Ministry of National Defense, Taiwan
15:00-15:30	**Panel Discussion & Closing Remarks** Speaker: Prof. Chien-Sung Tsai (蔡建松教授), Chairman of Taiwan Surgeons Association; Director-General of Medical Affairs Bureau, Ministry of National Defense, Taiwan

All researchers interesting to the symposium are welcome｜所有對本國際會議有興趣的同仁均歡迎參與

Organizers: , College of Medicine, NCHU; Department of Postgraduate Medicine, NCHU; Division of Nephrology, Taichung Veterans General Hospital; Taiwan Society of Nephrology, Transplantation Society of Taiwan｜主辦單位：中興大學醫學院、中興大學學士後醫學系、臺中榮民總醫院腎臟科、台灣腎臟醫學會、台灣移植醫學會

Professor Misao Fujita, MS, MPH, Ph.D.

Current Roles & Affiliations

• Project Professor and Head, Uehiro Research Division for iPS Cell Ethics, Center for iPS Cell Research and Application (CiRA), Kyoto University
• Professor, Institute for the Advanced Study of Human Biology (WPI-ASHBi), Kyoto University

Education & Career Milestones

1992: Graduated, College of Human Sciences, University of Tsukuba
1995: M.A. in Clinical Psychology, University of Idaho; Clinical Psychologist, Obitsusankei Hospital
2003: M.P.H., Graduate School of Medicine, Kyoto University
2006: Ph.D. in Public Health, Graduate School of Medicine, Kyoto University
2004–2009: Researcher → Assistant Professor, Dept. of Biomedical Ethics, University of Tokyo
2013: Project Associate Professor, Uehiro Research Division for iPS Cell Ethics, CiRA
2018–Present: Project Professor, CiRA; Professor, ASHBi

Research Focus & Contributions

Specializes in ethical, legal, and social issues (ELSI) related to human iPS cell applications. Focus areas: regulatory oversight, iPS cells for chimeric animals and human germ cells, public attitudes, and ethics governance frameworks.

Policy Engagement & Advisory Roles

• Member, International Bioethics Committee, UNESCO
• Member, Japanese National Commission for UNESCO
• Advisor to Cabinet Office and MEXT Expert Panels on bioethics and embryo research
• Contributor to ISSCR guidelines and BioBank Japan Advisory Board

Selected Publications

• Cell Stem Cell (2022): “Current status of cell-based interventions in Japan”
• Stem Cell Reports (2024): “Urgent need for clear and concise regulations on exosome-based interventions”

At a Glance

Specialization: Bioethics of regenerative medicine (iPS cell ethics)
Current Positions: Divisional Head (CiRA); Professor (ASHBi)
Policy Impact: Contributor to national and international regulatory frameworks
Scholarly Impact: Influential publications on safety and oversight of cell therapies

Unproven Cell-Based Interventions: Current Practices, Regulatory Challenges, and Lessons from Japan

Misao Fujita

The commercial provision of scientifically unproven stem cell-based interventions is a growing concern around the world. In Japan, a legal framework established in 2014 under the Act on the Safety of Regenerative Medicine (ASRM) requires that any plan to administer cells to humans, whether as part of research or clinical treatment, must first be reviewed by a Certified Committee for Regenerative Medicine (CCRM) or a Certified Special Committee for Regenerative Medicine (CSCRM) and then submitted to the Ministry of Health, Labour and Welfare. Although the ASRM was intended to enhance safety oversight, it has instead legitimized the use of unproven interventions and contributed to the expansion of the issue. This presentation draws on findings from our empirical research to illustrate how a wide range of unproven cell-based interventions are being offered in Japan for various medical conditions. It also highlights structural weaknesses in the current regulatory scheme, including cases where CCRMs or CSCRMs may lack independence or show signs of conflicts of interest. These issues raise fundamental questions about the effectiveness of Japan's regulatory approach and offer important lessons for developing responsible governance frameworks in other countries.

Misao Fujita is Program-Specific Professor and Head of the Uehiro Research Division for iPS Cell Ethics at the Center for iPS Cell Research and Application (CiRA), and also holds a joint appointment at the Institute for the Advanced Study of Human Biology (ASHBi), Kyoto University. She is a member of the UNESCO International Bioethics Committee, the Ethics Committee of the International Society for Stem Cell Research (ISSCR), and the Expert Panel on Bioethics of the Council for Science, Technology and Innovation, Cabinet Office of Japan. She also serves on several expert committees under the Ministry of Education, Culture, Sports, Science and Technology (MEXT). Her research group explores a range of ethical and policy issues related to human iPS cell research, including the creation of human-animal chimeras and germ cells, unproven cell-based interventions, and the ethical governance and regulation of these technologies in both domestic and international contexts. https://www.cira.kyoto-u.ac.jp/e/research/fujita_summary.html

蔡甫昌 教授

學歷 台灣大學醫學系、英國曼徹斯特大學生命倫理學博士

現職

- 台大醫學院醫學教育暨生醫倫理學科暨研究所教授；家庭醫學科、臨床醫學研究所、醫療器材與醫學影像研究所、公共衛生學院健康行為與社區科學研究所合聘教授
- 台大醫院醫學研究部主治醫師、倫理中心主任、研究倫理委員會主任委員、臨床倫理委員會委員兼執行秘書
- 台灣大學人文社會高等研究院特約研究員
- 國家衛生研究院論壇諮議委員會委員
- 德國 MERCK Ethics Advisory Panel 委員
- 國際生命倫理講座國際網絡台灣代表機構主任
- 台灣臨床研究倫理審查學會常務理事
- 中華民國醫師公會全國聯合會醫學倫理暨紀律委員會委員
- 台灣安寧照顧基金會董事
- 中華民國通識教育學會會士

經歷

- 台大醫學院社會醫學科教授兼主任
- 台大醫院家庭醫學部主治醫師
- 臺灣大學生醫倫理中心主任
- 金山鄉衛生暨群體醫療執業中心主任
- 衛生署醫學倫理委員會委員
- 國家衛生研究院論壇生命暨醫療倫理委員會委員
- 科技部人文司醫學教育學門召集人
- 台灣臨床研究倫理審查學會理事長
- 聯合國教科文組織生命倫理講座國際網絡台灣代表機構主任
- 行政院衛福部嚴重特殊傳染性肺炎專家諮詢會委員
- 德國 MERCK Bioethics Advisory Panel 委員

國際榮譽

- Honorary Membership, UNESCO Chair in Bioethics (2015)
- Vice-President, International Association of Bioethics (2016-17)
- Goldman-Berland Lectureship in Palliative Medicine, USA (2019)
- Hastings Center Fellow, USA (2021)

Dr. Daniel Fu-Chang Tsai

academic qualifications

National Taiwan University School of Medicine、PhD in Bioethics, University of Manchester, UK

Present positions

- Professor, Department & Research Institute of Medical Education & Bioethics, National Taiwan University College of Medicine
- Attending Physician, Department of Medical Research; Director, Ethics Center; Chairman, Research Ethics Committee, National Taiwan University Hospital
- Executive Secretary & member, Clinical Ethics Committee, National Taiwan University Hospital
- Director, Center for Biomedical Ethics, National Taiwan University
- Research Fellow, Institute for Advanced Studies in Humanities and Social Sciences (IHS), National Taiwan University
- Merck Ethics Advisory Panel, Germany
- Head of Taiwan Unit, International Chair in Bioethics
- Executive Director, Taiwan Association of IRBs (TAIRB)
- Hastings Center Fellow, USA

Past Positions

- Director, Department of Social Medicine, Department of Medicine, National Taiwan University School of Medicine
- Attending Physician, Department of Family Medicine, National Taiwan University Hospital
- Director of Jinshan Township Health and Group Medical Practice Center
- Member of the Medical Ethics Committee of the Department of Health
- Member of the Life and Medical Ethics Committee of the National Institutes of Health Forum
- Convener of the Department of Medical Education, Department of Humanities, Ministry of Science and Technology
- President, Taiwan Association of IRBs (TAIRB)
- Head of Taiwan Unit, International Network of UNESCO Chair in Bioethics
- Merck Bioethics Advisory Panel, Germany
- Member, Expert Advisory Committee, the Central Epidemic Command Center, Ministry of Health & Welfare

International honor

- Honorary Membership, UNESCO Chair in Bioethics (2015)
- Vice-President, International Association of Bioethics (2016-17)
- Goldman-Berland Lectureship in Palliative Medicine, USA (2019)
- Hastings Center Fellow, USA (2021)
- Special Lecture, Boston Children’s Hospital Neurology Grand Round (2025)

Battling transplantation tourism through policy and legal reform in Taiwan

Daniel Fu-Chang Tsai

Taiwan's history of organ transplantation began in 1968 with the first kidney transplant in Asia and was institutionalized through the 1987 Human Organ Transplant Act. Yet for decades, Taiwan faced an acute imbalance between organ demand and supply. The country's exceptionally high prevalence of end-stage renal disease and hepatitis B, coupled with cultural barriers, severely constrained domestic organ donation. As a result, transplantation tourism flourished. By 2006, Taiwanese patients underwent approximately 400 kidney and 222 liver transplants abroad, primarily in China, a number that at times exceeded domestic transplant procedures. Without mandatory reporting, the government had virtually no oversight, and patients often lacked information about donor sources or surgical risks. Ethical concerns mounted as China admitted to using organs from executed prisoners, while international instruments—including the 2004 World Health Assembly Resolution 57.18 and the 2008 Declaration of Istanbul—condemned such practices as exploitative of vulnerable populations.

Growing international pressure, increasing societal awareness, and advocacy within Taiwan's parliament and medical profession culminated in the landmark 2015 amendment to the Human Organ Transplant Act. The reform introduced four key provisions: (1) mandatory registration of overseas transplants, requiring documentation of organ type, country, hospital, and physicians; (2) explicit bans on commercial transactions and brokerage, with criminal penalties of one to five years' imprisonment and fines up to USD 50,000, including extraterritorial jurisdiction over illegal overseas transplants; (3) authorization of paired exchanges within spouses and up to five degrees of kinship; and (4) a required request system obliging citizens to declare organ donation preferences when renewing identity documents.

While these reforms marked a significant advance, implementation challenges soon emerged. Between 2015 and 2018, only 137 overseas transplants were reported, with a compliance rate of just 22%, reflecting patients' and physicians' reluctance to disclose. Subsequent investigations uncovered continued illegal brokerage, including a physician who facilitated 35 transplants in China between 2016 and 2019. These

cases reveal persistent gaps in monitoring, enforcement, and reporting, despite the existence of a legal framework.

Taiwan's professional efforts and legislation amendments demonstrate a model for combating transplant tourism through incremental reforms. At the same time, ongoing challenges highlight the need for stronger enforcement mechanisms and cultural change. Broader regional collaboration—through policy sharing, coordinated action against illegal brokers, development of cross-border tracking systems, and promotion of transparent donation standards—remains essential to foster ethical transplantation practices in Asia and to construct democratic solutions to the global problem of illicit organ trade.

Benita S. Padilla, M.D.

Professor of Medicine & Nephrology, Philippines

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Profile

Nephrologist with over 30 years of experience in kidney disease and transplantation. Senior consultant at the National Kidney and Transplant Institute (NKTI) since 1994, mentor to generations of nephrologists, and recognized global leader in ethical transplantation, organ donation, and anti-trafficking advocacy. Co-founder of Kidney Friends Foundation, empowering patients with CKD through livelihood and education.

Education & Training

M.D., University of the Philippines, 1983
Residency & Fellowship, UP-PGH (Internal Medicine, Nephrology), 1985–88
Fellowship in Nephrology & Hypertension, University of Cincinnati, 1989–92
M.S. in Clinical Epidemiology, University of the Philippines, 1997–2005

Leadership & Appointments

NKTI: Head, HOPE (Human Organ Preservation Effort) 2016–21; Head, Hemodialysis Unit 2005–09; Head, Emergency Division 2021–present
Philippine Society of Nephrology (PSN): President 2008–09; Chair, Ethics & Teaching Committees 2023–present
Philippine Renal Disease Registry: Co-Chair & Chair, Kidney Biopsy Registry, 1996–2008

International Roles

Declaration of Istanbul Custodian Group (DICG): Member (since 2009), Executive Committee (since 2022)
The Transplantation Society (TTS): Education Committee (since 2020); Country Liaison for Philippines (since 2008)
World Health Organization: Task Force on Organ & Tissue Donation/Transplantation (since 2018)
Asian Society of Transplantation (AST): Co-Chair, Ethics Committee (since 2023)
ISN: Committees on Kidney Health in Disadvantaged Populations (2006–14)

Foundation Work

Founding President, Kidney Friends Foundation (2008–21). Supports CKD and transplant patients via skills training, microloans, partnerships with local enterprises, and scholarships.

Awards (selected)

A-One Award, Philippine Society of Nephrology (2011)
Exemplar for Community Development, Philippine College of Physicians (2014)
Gawad Lagablab for Achievement in Medicine, Philippine Science High School Alumni Association (2011)

Key Publications

Impact of legal measures to prevent transplant tourism. Medicine, Health Care and Philosophy, 2013
Paid donation: a global view. Advances in CKD, 2012
Supporting Financial Neutrality in Organ Donation. Transplantation, 2025
Prevention of Trafficking in Organs, Tissues, and Cells. Transplantation, 2025

Professional Memberships

Philippine College of Physicians (Life Fellow) | Philippine Society of Nephrology (Life Fellow) | International Society of Nephrology | The Transplantation Society | Asian Society of Transplantation | DICG

THE LEAKY SIEVE OF ORGAN TRAFFICKING

Benita S. Padilla, MD

Organ trafficking is a scourge that tarnishes the good that organ transplantation brings to patients' lives. Many countries have put policies in place with the goal of preventing it. But how successful are these policies? They are supposed to sieve the good from the bad, but the sieves are often "leaky". The sieves can generally be classified into two categories: (1) legislation and law enforcement and (2) medical protocols. Here we will present examples of how organ traffickers take advantage of weaknesses or loopholes in the policies and their implementation. The examples are based on published news articles, but this presentation is not comprehensive and we make no claim that these practices or problems are occurring only in those cited in the examples.

Legislation and law enforcement.

1. Legislation may be inadequate. The Kenyan Health Act of 2017 provides for the donation of kidneys to relatives or for scientific purposes, within strict guidelines. But the act doesn't explicitly outlaw the illicit trade in which people agree to sell their organs – a loophole that aids illegal harvesting, storage and transportation of kidneys.
2. Law enforcement may be weak. In Pakistan, an organ trafficking ring leader was arrested in 2023. This individual had been arrested five times previously for the same crime but managed to secure bail each time.
3. Organ trafficking is part of organized crime. In Nepal, the nexus of traffickers is organized and well-connected with traffickers in other countries.
4. Corrupt government officials are involved. In a 2023 incident in Indonesia, police and immigration officers were accused of helping traffickers send 122 Indonesians to a hospital in Cambodia to sell their kidneys. In Bangladesh, corrupt passport officials have been reported to create forged passports showing a blood relationship between the victim and the recipient.
5. Some governments are complicit. In India, the law says no foreigner can donate to an Indian. But foreigners are able to get certificates from their embassies or forged documents showing relationship.

Medical protocols

Medical protocols can act as sieves when (1) doctors perform their role as gatekeepers, (2) some kind of screening process is institutionalized and (3) there are donor advocates who act for the protection of the potential living organ donor. These protocols fail to sieve in these situations:

1. Surgeries are performed outside medical establishments. There have been reported incidents in Pakistan when transplants were carried out in private homes - often without the patient knowing.
2. Medical professionals are inadequately trained to deal with trafficking issues. This has been reported in Bangladesh.

3. There are some medical professionals who are complicit. In a reported incident of a Nepalese man who was trafficked to India, doctors conducted an illegal removal of one of his kidneys. In 2017, four doctors, a Greek businessman, and a local police officer were arrested in Costa Rica for running a trafficking network that recruited kidney donors with promises of hefty payments.
4. Screening processes can be subverted. In the Philippines, agents have been known to coach prospective organ sellers on how to give "correct" answers professing altruistic motives to the Ethics Committees. Forged documents showing a consanguine relationship can be forged.
5. There may be no provision for donor advocates or inconsistent implementation. In the US, UNOS mandated in 2007 that all transplant centers must have an independent living donor advocate but a study has found wide variability in clinical practices. Not all countries have donor advocates.

Fighting organ trafficking can become a never-ending contest between those who are trying to put up barriers and those who are looking for loopholes. The root of the problem is often presented as an issue of supply and demand for transplantable organs, but it is much more complex than that. It is imperative that we continue to look for sustainable solutions that address not just medical issues but also al the accompanying cultural, social, economic and legal complexities.

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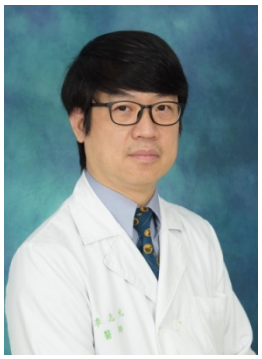

Education

M.D. (1997), National Taiwan University

M.Sc. (2007), Clinical Medicine, NTU

Ph.D. (2017), Molecular Medicine, NTU

Professional Experience

• Resident, Dept. of Surgery, NTU Hospital (1999–2004)
• Staff Surgeon, NTU Hospital (2004–present)
• Research Fellow, Johns Hopkins (2004–2006)
• Associate Professor, Surgery, NTU Hospital (2022–present)

Awards

Tien Te Lee Biomedical Technology Award | 2018 Young Investigator, Taiwan Surgical Society | 2019 Outstanding Research Award, NTU Hospital

Research & Publications

Author of 70+ peer-reviewed papers in transplantation, hepatobiliary surgery, immunology, and infectious disease. Key work on kidney transplantation (desensitization, antibody-mediated rejection, pediatric/robotic techniques), liver & pancreas surgery, immunosuppressive regimens, TB/vaccine in dialysis & transplant patients, and molecular studies on caveolin-1, ZNRF1, and regenerative therapies. Publications in *Nat Immunol, Nat Commun, Diabetes, Diabetologia, Clin Infect Dis, Am J Transplant, Transplantation, Br J Cancer,* and others.

Leadership & Contributions

Expanded donor kidney pools with ECMO, advanced desensitization protocols, bridged basic and clinical science in transplantation and immunology, and mentored future surgeons at NTU.

Abstract

Xenotransplantation:

The transplantation of kidneys from non-human species (e.g., genetically modified pigs) into humans to address organ shortage.

Key Advances:

1. **Genetic Engineering**: Pigs are genetically modified to:
   - Knock out nature antigens (reduce hyperacute rejection).
   - Insert human genes encoding immune regulators (e.g., CD46, CD55), complement inhibitors, and coagulation-modulating proteins.
2. **Immunosuppression**: Requires tailored regimens to prevent rejection.
3. **Recent Milestones**:
   - 2021–2024: FDA-authorized pig-to-human kidney xenotransplants.
   - Limited survival (weeks to months) but demonstrated immediate function.

Challenges:

- **Immunologic**: Coagulation dysregulation, chronic rejection.
- **Infection Risk**: Zoonotic pathogens (e.g., porcine endogenous retroviruses).
- **Ethical**: Animal welfare, public acceptance.

Future Directions:

- Longer-term survival in living humans.
- Development in Taiwan.

Professor Dominique E. Martin, MBBS, PhD

Professor in Health Ethics & Professionalism, School of Medicine, Deakin University
Adjunct Professor in Health Ethics, Australian Centre for Health Law Research, QUT

Email: Dominique.martin@deakin.edu.au | Phone: +61 403 087 141 | LinkedIn: https://au.linkedin.com/in/dominique-martin-9489528 | X: @DrDEMartin

Education

• PhD (Applied Ethics), University of Melbourne
• MBBS, BA, University of Melbourne
• BA (Hons, Philosophy), University of Melbourne
• Grad. Cert. University Teaching, University of Melbourne

Academic & Professional Roles

• Professor in Health Ethics & Professionalism, Deakin University (2023–present)
• Adjunct Professor, QUT (2024–present)
• Associate Professor & Senior Lecturer, Deakin University (2016–2022)
• Lecturer, University of Melbourne (2012–2016)

Leadership & Service

• Councillor, The Transplantation Society; Co-Chair, Education Committee
• Co-Chair, Declaration of Istanbul Custodian Group Council (2017–2018)
• Ethics Lead, ISN Education Academy (2017–present)
• Member, ESOT AI & Advanced Therapies Working Groups (2024–present)
• Steering roles in international ethics, donation, and transplant policy initiatives

Research Interests

• Ethical frameworks in organ donation & transplantation
• Organ trafficking, transplant tourism, and global governance
• Ethics of kidney care & innovative therapies
• Development of international curricula for kidney ethics

Selected Publications

• Over 100 peer-reviewed works in Transplantation, Kidney International, The Lancet, Nature Reviews Nephrology, Seminars in Nephrology, etc.
• Co-author, Declaration of Istanbul (2008, 2018, 2019 editions)
• Recent (2025): MJA on legal barriers in donation; Transplantation on global equity in SoHO-based therapies

Invited Talks (Recent)

• 2025: Ethical Challenges of Xenotransplantation, World Congress of Nephrology, New Delhi
• 2024: Transplantation Society Congress, Istanbul – Ethics of xenotransplantation, Organ trafficking
• 2023: ISODP Congress, Las Vegas – Ethical complexities of donor research

Key Recognitions

• International leader in health ethics, with consultancy to WHO, Australian Organ & Tissue Authority, and global organ donation agencies
• Multilingual: English (native), French (professional fluency)

What Next for Transplant Ethics in the Era of Xenotransplantation?

Professor Dominique E. Martin

The recent, rapid development of xenotransplantation research conjures visions of a new era in transplantation. Hopeful patients may wonder if the oft-cited and ever-increasing "gap" between supply and demand for organs will disappear with the advent of a steady stream of organs from pigs. While infectious diseases specialists might worry about the unpredictable risks of novel diseases emerging, transplant surgeons may be excited at the possibility of working more regular hours with a reliable supply of standardised grafts available on request. As for transplant ethicists, the emergence of clinical trials in xenotransplantation promises respite from perennial ethical debates about markets in human organs and equity in allocation of scarce deceased donor organs. The field of transplant ethics appears set to engage with relatively new topics such as ethical considerations in the selection of participants for trials and the treatment of non-human donors, and questions regarding the potential restrictions of individual liberty that might be necessary to ensure adequate infectious disease surveillance.

In this talk, I outline some of the important ethical questions that have been and will continue to be explored as xenotransplantation evolves from a hypothetical proposition to an established clinical therapy. While some of these questions reflect a substantive shift from the longstanding ethical concerns of human allotransplantation, I contend that others reflect the core challenges of transplantation, irrespective of the donor species involved. While some commentators have suggested that the success of xenotransplantation may eliminate some of the ethical challenges associated with allotransplantation, I argue that this is a dim possibility. If the era of xenotransplantation is to be truly successful, I conclude that we must continue to focus on and strive to uphold the fundamental ethical values that have grounded donation and transplantation since the mid 1900s.

Ming-Che Lee, M.D.

Superintendent
Shuang Ho Hospital, Taipei Medical University, New Taipei City, Taiwan.
Professor
Department of Surgery, School of Medicine, College of Medicine, Taipei Medical University, Taipei City, Taiwan.
Member of the Council
Transplantation Society of Taiwan, Taipei City, Taiwan
Chairman
Taiwan Organ Sharing Registry and Patient Autonomy Promotion Center, Taipei City, Taiwan

Dr. Lee graduated from School of Medicine, Taipei Medical University (Former Taipei Medical College), Taipei, Taiwan in 1991. He completed his surgical residency training in Hualien Tzu Chi Hospital and worked as a full-time general surgeon since 1996 at Department of Surgery, Hualien Tzu Chi Hospital, Hualien, Taiwan. He had visited Thomas E. Starzl Transplantation Institute, University of Pittsburgh Medical Center, Pennsylvania, USA as a visiting research fellow in liver transplantation program between September 1997 and December 1998. He was also a short-term visiting research fellow of Department of Urology, Tokyo Women's University Hospital, Tokyo, Japan in July 2008. In August 2021, he relocated to Wan Fang Hospital, an affiliated hospital of Taipei Medical University, to restart his carrier in organ transplantation. Currently, he moves to Shuang Ho Hospital, Taipei Medical University, New Taipei City, Taiwan since December 2023. Now he is the Superintendent of Shuang Ho Hospital and the Professor of Surgery, School of Medicine, College of Medicine, Taipei Medical University, Taipei City, Taiwan. As the Member of the Council of Transplantation Society of Taiwan and the Chairman of Taiwan Organ Sharing Registry and Patient Autonomy Promotion Center, Professor Lee actively involves in the field of liver and kidney transplantation surgery, deceased organ recovery and organ donation education. He is also the Immediate Past President of Organ Donation Association, R.O.C., which is a non-profit organization to promote organ donation and donor family counseling in Taiwan. His major interests include hepatobiliary and pancreatic surgery, organ transplantation including deceased and live donor liver and kidney transplantation, and pathogenesis of liver cancer metastasis. Professor Lee has published more than 100 scientific articles in field of organ transplantation, gastrointestinal motility, and surgical oncology in relevant scientific journals.

Practice and policies of organ transplantation and organ trafficking in Taiwan

Ming-Che Lee, M.D.

Division of General Surgery, Department of Surgery, Shuang Ho Hospital, Taipei Medical University, New Taipei City, Taiwan

Department of Surgery, School of Medicine, College of Medicine, Taipei Medical University, Taipei City, Taiwan

TMU Research Center of Organ Transplantation, Taipei Medical University, Taipei City, Taiwan

Taiwan Organ Sharing Registry and Patient Autonomy Promotion Center, Taipei City, Taiwan

Abstract

"Human Organ Transplantation Act" was firstly promulgated in 1987, and was amended in 2011. Meanwhile, Ministry of Health and Welfare funded and established the "Taiwan Organ Registry and Sharing Center" (TORSC) to in charge the registration of organ donation and transplantation in June 2002. With the establishment of infrastructure for organ donation and transplantation, all the process for organ recovery and procurement was standardized through the country, and the organ allocation was computerized according to the policies since 2005. However, regarding to cultural and religious barrier of organ donation from the deceased, there was no significant increase in the number of organ donation rate during past two decades. More than 10,000 people each year are waiting for an organ transplantation, and only 140 organ donors were found and a thousand of organ transplantation were done each year, with an estimated organ donation rate of 5.7 per million population. Although the government approved the process of donation after cardiac death (DCD) in 2017, the organ donors did not increase so many. In 2021, TORSC was reorganized to be a new center called "Taiwan Organ Sharing Registry and Patient Autonomy Promotion Center", to integrate the practice of organ donation and transplantation, palliative care and patient autonomy in one center to promote end-of-life (EOL) care in clinical setting. We respect that all EOL patients have the right to choose their way to death. Through education and clinical practice, we can emphasize the importance of EOL care and help the EOLs to make the decision of organ donation possible in a proper time.

As a part of national responsibility to meet the health needs, it is equal importance to invest the prevention programs through intervention in the risk factors for end-stage organ failure and the development of health systems able to meet the challenges of chronic diseases. The nationwide hepatitis B

vaccination program started in 1984, and not only the risk of hepatitis B viral infection declined but also the development of liver cancer in childhood decreased. In 2011, the National Health Insurance Bureau reimbursed the “Multidisciplinary Care Program”, established by the Taiwan Society of Nephrology in 2003, for the standardized pre-dialysis care of chronic kidney disease patients. The propagation of the program has stabilized the increase of incidence in end-stage renal disease patients in Taiwan.

Transplant tourism is still a worldwide existing problem. According to the “Human Organ Transplantation Act”, all the person not only the brokers but also the medical personnel who introduce patients for transplant tourism will be penalized. In Taiwan, all the recipients must be registered no matter where the transplant surgery was done. The outcome of transplantation will also be traced and reported.

In conclusion, organ transplantation is now a well-established medical procedure with great success in Taiwan. Although the organ shortage is still a challenging issue, the education and promotion programs for organ donation are still active to change the society. Through a transparent and fair allocation system, all the donated organs will be transplanted to suitable recipients. Since transplant tourism is still a hidden story in Taiwan, government should forcefully prohibit such a practice and establish several strategies, such as DCD, to increase the organ donor pool. The most important things, however, are to promote general healthcare and prevent chronic diseases toward organ failure, and to maintain the sustainability in organ donation and transplantation system in the country.