The Regulatory Challenges of International Transplant Medicine: Developments in Singapore

I. Introduction

Transplant tourism is spurred by the global shortage of human organs available for transplant and the potential for regulatory arbitrage in seeking to purchase an organ in a jurisdiction that does not prohibit sales, or lacks effective regulatory mechanisms to prevent it.¹ There is broad international condemnation of such transplant tourism and exhortation for nations to prohibit it by implementing effective regulatory oversight to ensure ethical practices in international transplant medicine.² To balance the tension between organ shortages and exploitation of the poor internationally, the current professional strategy promulgated by the Transplantation Society and International Society of Nephrology emphasizes national self-sufficiency from both cadaveric and living donor sources, along with consistent national effort to outlaw transplant commercialism and regulate living donor transplantation.³ This was subsequently endorsed at the Third Global Consultation on Organ Donation and Transplantation.⁴

A positive response has been observed since the Istanbul Declaration. Various nations once identified as transplant tourism hotspots have since enacted legislation prohibiting organ sales and emplaced regulatory frameworks to implement such legislative policy.⁵ However, there have been concerns raised that the regulatory legitimisation of altruistic unrelated living donor transplants (‘LDT’) nevertheless conceals underlying commercialism or unethical practices.⁶ These concerns are potentially heightened when transplant candidates travel across borders in search of international transplant medicine. This article examines the regulatory

² Fifty-Seventh World Health Assembly, Human organ and tissue transplantation, WHA57.18 (22 May 2004), Part I; Sixty-Third World Health Assembly, Human organ and tissue transplantation, WHA 63.22 (21 May 2010), para. 2.
challenges associated with differentiating international transplant medicine from transplant tourism, and various regulatory mechanisms that have been developed to address them from the local perspective – in particular those recently implemented in the Singapore. It seeks to identify the strengths and weaknesses of the Singapore system, and what lessons this has for international standards and practices.

Part II describes the context of international transplant medicine, transplant tourism and the competing interests of stakeholders at play. Part III fleshes out the regulatory challenges involved by examining the available evidence on regulatory failure in respect of transplant tourism. Part IV then examines the recently updated regulatory framework in Singapore and Part V offers suggestions for improvement.

II. Transplant Tourism in the midst of international transplant medicine

Transplant tourism has gained a certain currency as an umbrella term referring to various unethical practices which are a subset of the larger phenomenon of international transplant medicine.7 This latter phrase refers to the practice where organ providers, recipients and transplant professionals travel across borders for the purpose of transplantation. The Declaration of Istanbul uses the term ‘transplant tourism’ to encompass both (a) organ trafficking (where coercive or fraudulent means are used to procure the transfer of organs) and (b) transplant commercialism (where some payment or consideration is offered for the transfer of an organ), in situations where the organ source, recipient and medical service provider are situated in different jurisdictions. In addition, the Declaration includes international transplant medicine that has adverse effect on equitable access for the local population where transplant services are oriented for foreign transplant tourists.8 These various activities have an impact on different ethical and policy concerns. Organ trafficking and transplant commercialism involve the coercion and exploitation of organ providers, and promote the commodification of the human body.9 On the other hand, the commercial nature of international transplant medicine delivery can have an adverse impact on the equitable

8 Supra note 3 at 1228
9 See WHO, Guiding Principles on Human Cell, Tissue and Organ Transplantation, as endorsed by the Sixty-third World Health Assembly Resolution WHA63.22, supra note 2, Commentary on Principle 5, online: <http://www.who.int/transplantation/en/index.html>
access of local patients to transplantation as treatment, which is part of the responsibility of every nation to meet the health needs of its population comprehensively.10

Shimazono provides a more focused definition for the purposes of regulatory intervention in respect of the former set of concerns. Transplant tourism is “overseas transplantation where a patient obtains an organ through the organ trade or other means that contravene the regulatory frameworks of their respective countries of origin.”11 What is crucial in determining legitimacy of international transplant medicine is the circumstances under which an organ is obtained and its conformance with international principles12 and local standards at the point of transplantation.13

The typical scenario of transplant tourism which has attracted the most professional and academic comment occurs where the prospective recipient travels to a jurisdiction to procure an organ transplant by taking advantage of some regulatory arbitrage.14 Given the typical shortage of organs in the recipients’ home jurisdiction, or ineligibility under their national waiting list criteria, such patients are driven overseas in search of alternatives. Historically, these destination jurisdictions either did not prohibit transplant commercialism, or even after enacting legislation in line with international standards, allowed commercial transactions to take place for want of effective enforcement by authorities and unsanctioned non-compliance by medical service providers and organ brokers.15 Typically as well, though not without exception, these countries were not short of ready organ vendors, driven by poverty or financially desperate situations. Nevertheless, transplant tourism can equally occur in jurisdictions where no regulatory advantage is apparent. In these instances, the mode of transplant tourism differs in that the donor and recipient (whether from the same country or not) typically travel to a third jurisdiction for the procedure.16

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10 Madrid Resolution, supra note 4
11 Shimazono, supra note 1 at 956
12 See WHO Guiding Principles, supra note 9
candidates seek both the advantages of travel for transplantation and to overcome the unavailability of a genuinely altruistic donor.

Thus apart from regulatory arbitrage, international transplant medicine has grown in tandem with the rise of medical tourism. The reasons for this are manifold. The increasing availability of more accessible, lower cost or high quality medical services encourages such travel. Medical care and services in the home jurisdiction of such patients travelers are either more costly, less accessible, less developed or simply unavailable. On the supply side, medical tourism has also be an important source of trade revenue for various countries, which have actively promoted the development of their private healthcare sector to service such foreign patients. Thus, under General Agreement on Trade and Services, governments may choose to trade in health services to achieve their national health objectives. More specifically, it may also allow national health systems, such as Singapore’s, to retain medical expertise in public sector healthcare and jurisdiction generally. Attracting medical tourists seeking specialist medical treatment allows the public sector to increase their patient load to match overcapacity and acquire or improve specialized medical skills through admission of foreign medical tourists. It also allows, at least theoretically, for the cross-subsidization of poorer local patients who rely on publicly subsidized health care provided by such institutions. Thus in Singapore, which seeks to position itself as a medical hub in Asia, transplants involving foreign donor-recipient pairs outnumber local candidates by a factor of three to one.

All this does not necessarily run counter to the policy statements within the Istanbul Declaration and Madrid Resolution, which favour national self-sufficiency and equitable

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17 The medical outcomes in jurisdictions where there is a lack of regulation and enforcement are often poor: AE Anker & TH Feeley, “Estimating the risks of acquiring a kidney abroad: a meta-analysis of complications following participation in transplant tourism” (2012) 26(3) Clinical Transplantation E23
19 N Pocock & KH Phua, “Medical tourism and policy implications for health systems: a conceptual framework from a comparative study of Thailand, Singapore and Malaysia” (2011) 7 Globalization and Health 12 at 17-18
20 WHO and WTO, WTO agreements and public health: a joint study by the WHO and WTO secretariat (Geneva: WHO, WTO, 2002) at 111-116
22 Pocock & Phua, supra note 19 at 19
23 Ibid. at 16
24 Sing. Parl. Debates, Vol. 88 Col. 64 (14 Feb 2012) (Gan Kim Yong): Between 1 Nov 2009 and 14 Feb 2012, there were 325 applications for LDT under HOTA, s.15A, of which only 26% were made by Singaporeans and Permanent Residents.
access, and therefore generally frown upon encouraging cross-border travel for transplantation. Istanbul acknowledges that “treatment of patients from outside the country is only acceptable if it does not undermine a country’s ability to provide transplant services for its own population.” Singapore sits squarely within this exception since it seeks to trade on overcapacity within the public sector for LDT, while its reciprocity based cadaveric organ transplant system is accessible to citizens and permanent residents first. Thus the regulatory concerns focus on the protection of the interests of living organ donors and the public interests represented by the criminalization of the organ trade.

In this respect, one can discern two forces that potentially act in tension to one another in the context of international transplant medicine: the promotion of national self-sufficiency in organ transplantation as a strategy to prevent exploitation of vulnerable populations internationally, against the rise of medical tourism, and international transplant medicine in particular. The latter responds to the growing aspirations and means of patients globally and the economic interests of certain nations. Both these interests are at play in designing and working out a suitable regulatory system for jurisdictions, such as Singapore, that have international medical hub aspirations and yet subscribe to international principles in organ transplantation.

III. Regulating international transplant medicine

A. Evidence of fictional altruistic LDT

Epstein and Danovitch have pointed out the real possibility that notwithstanding compliance with a formal regulatory oversight process, a jurisdiction formally criminalizing transplant commercialism could conceal underlying financial transactions. To what extent are these concerns legitimate? Quantitative data on transplant commercialism and tourism in particular are, unsurprisingly, scarce given the commonly clandestine and criminal nature of the activity. There have been a number of anecdotal accounts, particularly out of India, that speak of notional altruistic LDTs that have served as fronts for underlying commercial

\footnotesize{25 Declaration of Istanbul, supra note 3 at 1228 para. 5.b.
26 Human Organ Transplant Act, Cap. 131A, 2005 Rev Ed Sing, s.5 [HOTA]; Chin & Campbell, supra note 21 at 1702
27 See Epstein & Danovitch, supra note 6 at 358
28 Shimazono, supra note 1 at 956}
transactions. More recently, investigations and prosecutions in the US, South Africa and Singapore have revealed that transplant tourism can also occur under the façade of altruism in jurisdictions with regulatory oversight in place. In these reported prosecutions, brokers arranged for foreign vendors to travel to the jurisdiction in question and transplants were presented as being altruistic in nature between related parties. The Singapore cases, involving both local and foreign patients and vendors, are significant in revealing the operation of organ syndicates even in established medical jurisdictions: the parties were coached on how to respond to transplant ethics committee queries and even obtained formal Transplant Ethics Committee (‘TEC’) approval. One transplant was concluded but the other interrupted when the higher authorities intervened.

B. The Tamil Nadu Study

Apart from these anecdotal instances, Muraleedharan et al provide us with what is probably the only qualitative study of the various possible features of regulatory failure in respect of LDT, as perceived by various stakeholders in the organ trade in Tamil Nadu. The authors were able to interview donors, recipients, representatives of hospitals and transplant physicians on the efficacy of the provisions of the Indian Transplantation of Human Organs Act 1994 (‘THOA’). The study is instructive in highlighting a number of practical features in this regulatory dynamic that are likely to be commonly faced irrespective of jurisdictional context.

First, the strong commercial interests driving the black market, represented foremost by the brokers or middlemen that bring vendors and recipients together. As repeat players and

33 Wang Chin Sing v PP [2009] 1 SLR(R) 870 at para. 4-5
36 Act No. 42 of 1994 (8 Jul 1994)
37 Supra note 35 at 47
possibly insiders, they were able to advise and coach applicants on what to say before the
Authorisation Committee (‘AC’), which must grant its approval before any unrelated LDT
can be approved under the THOA.\footnote{THOA, supra note 36, s. 9(3)} Thus, in trying to sort out unethical transplant tourism
cases from legitimate ones, regulatory processes have to acknowledge that self-regulation in
this context is of limited efficacy when there is a collusion of the key interests held by all
stakeholders in the oversight process. It is difficult in transplant tourism to identify any pre-
existing player who will identify themselves as a loser, or whistle-blow, if there is a
regulatory lapse – particularly where the undertaking is profit driven. This suggests that the
formulation of a sufficiently independent and well-funded monitoring agency is critical to the
efficacy of any such system.

Secondly, the discretion afforded to ACs in granting approvals was influenced by what
appears to be emotional pressures attached to such decision making: their commitment to
ensuring compliance with the law was compromised by their sympathy for the plight of
recipients who are seriously ill and require a transplant.\footnote{Supra note 35 at 49} In addition, the lack of clear
medical and evidential standards within THOA framework permitted compromise on medical
eligibility criteria and manipulation in proof of kinship or relational status.\footnote{Ibid. at 47-48} Reliance on
external or top-down compliance and monitoring will thus also have to address the problems
of enforcement integrity highlighted by the Tamil Nadu study, as some regulatory discretion
is an unavoidable feature of the process.

Thirdly, there is an inherent capacity limitation on the part of the regulatory agency created
by THOA. Given the number of applications reviewed and the scale of a country like India, it
is not possible for an AC to investigate information provided by donors and recipients. The
regulatory mechanisms available must thus be able to cope with the frequency of transplant
activity and must be cost effective – the cost burden of which will ultimately fall on the
individual patients, their families or national health care budgets. For example, there are
limits to what hospital ethics committees can effectively do given their limited resources and
expertise.\footnote{See B Dickens, “Ethics Committees, Organ Transplantation and Public Policy” (1992) 20(4) Law, Medicine
and Health Care 300 at 300-301} This is an important consideration where the medical and ethical assessment of a
LDT application involves a detailed factual inquiry into the living donor’s medical and psychosocial circumstances, and the nature of the relationship between donor and recipient. Thus, the growing volume of international transplant medicine (in both organ exporting nations and medical hubs) creates additional problems for any domestic transplant regulatory system tasked with ensuring compliance with legal and ethical norms governing LDT. The evidence concerning such foreign patients and their relationships with organ donors will be far less accessible and far more difficult to assess meaningfully.

IV. Singapore’s current regulatory regime

Living donor organ transplants were not legislatively regulated in Singapore until amendments to the Human Organ Transplant Act 1986 (‘HOTA’) were made in 2004. Prior to this, oversight was rendered by the Ministry of Health (‘MOH’) in the form of professional guidelines which bound medical professionals and hospitals pursuant to its jurisdiction under the Medical Registration Act and Private Hospitals and Medical Clinics Act respectively. The principal requirement of HOTA is that living organ donors should personally consent to the removal of a specified organ (not being mentally disordered or lacking decision making capacity to consent) and such consent must not be given pursuant to a prohibited contract or arrangement involving organ trading, nor by reason of any fraud, duress or undue influence.

Related LDTs were previously handled by the transplant coordinators of the respective hospitals that performed LDT, without the need for prior external approval, although MOH was notified of such cases. It was the responsibility of the respective hospital transplant coordinators to ensure that the medical and ethical criteria for LDT were met. However, for unrelated LDT, specific authorization had to be obtained from the MOH. Under these guidelines, related donors were defined as first and second degree relatives (extending to

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44 Sing. MOH, Guidelines for Living Donor Organ Transplants, Professional Circular 9/2002
45 Cap. 174, Rev. Ed. Sing. 2004, s.70
46 Cap 248, Rev. Ed. Sing. 1999, s.22
47 HOTA, s.15C
48 Professional Circular 9/2002, para. 5
49 Ibid. at paras. 6-7
grandparents, grandchildren and half-siblings), and spouses. Any other persons outside these prescribed bounds are considered unrelated donors.\footnote{Supra note 44 at para. 2}

Post 2004, responsibility for oversight and approval of LDT was devolved to statutory Transplant Ethics Committees (‘TEC’) established under s.15B of the HOTA and constituted in accordance with the HOTA Regulations 2004 (‘HOTAR 2004’).\footnote{Cap 131A, S213/2004} After public consultation, the proposed jurisdiction of TECs was expanded to include related LDT as well on the basis that the potential for undue influence, duress and lack of informed consent could well be greater for related donors.\footnote{MOH, Public Consultation on the Human Organ Transplant (Amendment) Bill – Summary of Feedback Received (15 Sep 2003-31 Oct 2003), online: <http://www.moh.gov.sg/content/moh_web/home/legislation/eConsultation/topics/public_consultationonthehumanorgantransplantamendmentbill-summar.html>}

The laws and regulations in Singapore have, however, never drawn any distinction on the basis of nationality or residence: local and foreign donors and patients are both subject to the same regulatory processes.

TECs are therefore the primary gatekeepers in the Singapore LDT system. Under regulation 4 of the HOTAR 2004, every TEC must comprise a quorum of at least 3 persons, at least one of whom must be an independent medical practitioner not employed or otherwise connected with the hospital and another, a lay person. The third is a medical practitioner associated with or employed by the relevant transplant hospital.\footnote{Reg 4(3); 5(2)} Members forming a quorum were originally drawn from three panels of the respective categories of members appointed by the transplant hospitals themselves (albeit with approval from the MOH). However, presumably because of concerns raised about the sufficiency of independence of hospital appointees and their general competence to discharge the statutory responsibilities of the TEC,\footnote{See Sing. Parl. Debates, Vol. 85 Col. 3524 at Col. 3570-72 (24 Mar 2009) (Hri Kumar)} the system was again overhauled in 2009. It is also probable that the organ trading prosecutions in the previous year and the ensuing investigations by the MOH into the TEC system may have also spurred this review.\footnote{See supra note 34 and accompanying text.} The importance of the efficacy of the regulatory system was increased with the inclusion of reimbursement provisions in the HOTA Amendment Act 2009, which legitimized reimbursement payments for (i) the removal or storage of any organ, (ii) costs or expenses or loss of earnings which are reasonably or directly attributable to the provision of
an organ and (iii) costs related to the medical care and insurance protection required by the donor as a consequence of proving an organ.56

Several critical changes were therefore made in the HOTA Regulations amendments of 2009 (‘HOTAR 2009’): first, the MOH undertook direct responsibility for the composition, training and reappointment of two of the panels – independent medical practitioners and lay persons.57 These ‘national’ panels of TEC members are now appointed by and directly accountable to the Director of Medical Services (DMS), and are an important source of feedback on the ethical challenges and procedural difficulties faced on the ground.58

Secondly, because of the decentralized nature of the oversight system,59 concerns over ‘forum’ shopping by donor-recipient pairs were addressed by requiring explicit approval from the DMS for the appointment of a TEC where a prior application to a TEC had previously been rejected.60 Presumably, very good reasons ought to be given why a rehearing of the transplant application ought to be allowed, for example, because new evidence is available which could not be presented before the previous TEC. In tandem with these amendments, any patient aggrieved by the refusal of a TEC to grant permission for a LDT may now apply for a review of the decision, on the request of the DMS in exercise of her discretion.61

Thirdly, apart from the legislative framework, the MOH has also issued a fresh set of Guidelines for Ethical Living Donor Transplantation, which superseded the 2002 guidelines.62 The only thing clear about their import is that they have introduced a mandatory one-week cooling off period for donors, before which no transplant can take place except in emergency cases.63 Unfortunately, apart from this, the guidelines are classified as confidential and it is not possible to evaluate their regulatory impact further. This detracts from the

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56 HOTA, s.14(3)(c)(i)-(iii)
57 HOTAR 2004, reg. 4(1)
59 TECs are constituted on a case by case basis, albeit from national panels of approved members, and their particular composition therefore varies with each case: HOTAR 2004, reg. 4(3)
60 HOTAR 2004, reg. 4(3A)
61 HOTAR 2004, Reg. 6A
international push towards greater transparency in oversight, and potentially prejudices bona fide local and foreign applicants in incurring unnecessary costs associated with seeking statutory TEC approval when greater transparency of the requirements would have put them on notice of their ineligibility.

Fourthly, the MOH has also invested in more rigorous and continuous training for members of the relevant panels in the medical and ethical aspects of living organ transplantation. This recognizes that prior decentralized training, if any, was inadequate, and the functions of a TEC involve considerably more than an exercise of common sense. Finally, every TEC is required to provide a written assessment of their decision and submit a copy of the report of every decision made to the DMS within 7 days. The MOH therefore appears to be in a position to intervene where a decision is clearly contrary to the evidence or ethical guidelines, and could take direction from such review for future training and discussion of ethical challenges that arise from praxis.

V. Evaluating the Singapore LDT framework vis-à-vis transplant tourism

The critical issue that arises is the efficacy of any regulatory set up in filtering out not only medically unsuitable applications, but also ethically questionable cases – in particular, whether there is in fact an underlying financial transaction involved. This is not merely a function of whether any particular state outlaws organ trafficking and commercial sale, but also how effective the regulatory mechanisms are in detecting transplant applications based on fictional altruistic relationships.

The HOTA has done much to improve the procedural features of the regulatory system – enhancing the independence of the assessors from the commercial interests of the transplant hospital and its health care professionals. Not only are the majority of each panel appointed by the MOH, they also have a direct channel of feedback to the Ministry and there are regular

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64 Istanbul Declaration, supra note 3, Principle 2(b) and Proposal 4; F. Delmonico, “The implications of Istanbul Declaration on organ trafficking and transplant tourism” (2009) 14 Current Opinion in Organ Transplantation 116 at 119
65 See Chin & Campbell, supra note 21 at 1705
66 Sing. Parl. Debates, Vol. 86 Col. 1403 at 1406-7 (14 Sep 2009) (Khaw Boon Wan)
67 HOTAR 2004, reg 5(1)
68 HOTAR 2004, reg 5(5)
69 See comments of the then Minister for Health, Khaw Boon Wan: Sing. Parl. Debates Vol. 85, Col. 3524 at 3586 (24 Mar 2009): “We will conduct regular audits to ensure that that these ethics committees fulfil the legal requirements in evaluating the transplant applications and comply with our guidelines.”
meetings to update members on developments and discuss issues.\(^{71}\) Crucially, each member of a TEC is given an individual veto as the rule is that each committee makes decisions on the basis of consensus.\(^{72}\) This is a hybrid model of regulatory oversight that stops short of a centralized review process for all LDT applications,\(^{73}\) but is less subject to issues related to lack of independence attributed to decentralized systems.\(^{74}\) However, concerns arguably persist notwithstanding these new features of the Singapore regulatory framework especially in respect of foreign donor-recipient pairs.

A. Medical eligibility and the need for live donor follow-up

Foreign transplant patients and donors in Singapore hail principally from South East Asia and South Asia, regions where access to and standards of health care vary considerably.\(^{75}\) A particular medical ethics issue in international transplant medicine relates to the provision of follow-up care to foreign donors post transplant. Adequate long-term follow up post-transplant is stipulated by both Consensus and Ethical Statements of the Amsterdam and Vancouver Forums respectively. In respect of kidney transplants, access to follow-up care is recommended for pre-existing or acquired conditions related to the nephrectomy.\(^{76}\) However, long term follow-up is a pre-requisite for non-renal organ transplantation because of the unknown long term consequences.\(^{77}\) Yet, ensuring this has presented challenges locally where donors are often lost to follow-up for such reasons as distance of travel to transplant centre and the death of the recipient.\(^{78}\) These problems are magnified in international transplant cases where different jurisdictions and healthcare systems make assurances of access to long-term follow-up that much more difficult, unless the donor is a person of adequate means who is able to return to the foreign transplant centre if necessary. In addition, local donor registries would not be able to capture post-discharge information for a living

\(^{71}\) Supra note 66
\(^{72}\) HOTAR 2004, reg 5
\(^{73}\) Cf. the role played by the UK Human Tissue Authority under the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, SI 2006/1659
\(^{74}\) Under the enforced self-regulatory model in the US, authority for oversight of LDT under the authority of the Department of Health and Human Services is conferred on the Organ Procurement and Transplantation Network (OPTN), which is progressively introducing bylaws and policy for OPTN member transplant centres: R.S. Brown et al., “The Evolution and Direction of OPTN Oversight of Live Organ Donation and Transplantation in the United States” (2009) 9 Am. J. of Transplantation 31 at 32-33; Turner, supra note 18 at 393.
\(^{75}\) Pocock & Phua, supra note 19 at 13; Chin & Campbell, supra note 21 at 1706
foreign transplant donor. It therefore remains a real concern whether appropriate risk-benefit assessments can be made by transplant teams supporting and evaluating foreign donor candidates, for want of accurate information on the donor’s access to long term follow-up.

The Minister of Health tacitly acknowledged this problem in Parliament,79 but the regulatory response so far has relied on the informed consent process with specific disclosure on the need for medium to long term follow-up (depending on the type of transplant).80 This is a less than desirable solution to the problem since disclosure on the need for follow-up does not amount to assurance of access – particularly for a foreign donor of limited means. There is now open the possibility of offering defraying or reimbursement for future follow-up medical expenses by reason of the expanded scope of permitted reimbursements under s.14(3)(c) of HOTA; however, such an option is only facilitative and does not oblige the recipient or the transplant centre to facilitate the donor’s access to subsequent follow-up care.

Uncertainty as to access to follow up care also affects the overall ethical assessment of the proposed transplant, as the means to address a medium to long term post-operative risk to the donor must figure in the overall risk-benefit assessment of each transplant.81 It is unclear to what extent such a potential follow-up gap is or should be taken into consideration by TECs in their review of applications. The quality and access to follow-up care may be considered an aspect of the medical assessment of the case, in conjunction with the donor’s transplant risk factors. However, the legislative authority of the TEC expressly relates only to two main criteria – informed consent free of any “fraud, duress or undue influence” and the absence of prohibited consideration for the transplant organ.82 Responsibility for the overall medical and psychosocial assessment presumably still rests with the relevant hospital transplant centres.

It would be difficult for any healthcare professional to make an accurate assessment of opportunity for post-operative follow up beyond the information that the donor or recipient provides about their personal means and the healthcare delivery systems in place in their country of origin. Thus, as a matter of best practice, the regulatory framework and its operative guidelines need to address follow-up care explicitly. One obvious solution would be to mandate up-front reimbursement for follow up care, especially in respect of non-renal

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80 See Chin & Campbell, supra note 21 at 6.
82 HOTA, s.15A(2)(c)(i) and (ii)
transplantation. Correspondingly, the absence of adequate assurance of follow up access should be a counter-indications to suitability for organ donation – the applicable medical criteria for kidney donations between unrelated parties should thus be strictly applied without any allowance for medically complex cases.

B. Independence of medical and psychosocial assessment

Flowing from the foregoing issue, the Singapore regime’s principal reliance on hospital transplant teams for medical and psychosocial assessment is a matter of some concern. First, there appears to be some inconsistency in compliance with the recommendations of the Amsterdam and Vancouver Forums that donor and recipient be assessed by independent medical teams. Secondly, it is not clear what amounts to sufficient professional independence in practice. Unlike the structural features of TECs within their specific statutory remit, there is no equivalent legal protection for hospital transplant centre staff as compared to TEC members, nor specific protection for whistle-blowing.

In the decentralised US system, independent donor advocates are responsible for representing and advising the potential living donor, and promoting her best interests. However, the specific requirements for independence are unclear and the practice varies. It appears that an advocate’s non-involvement in the care of the recipient will suffice, even if employed by the same healthcare institution. In the UK, apart from the specific statutory remit of the independent assessors and Human Tissue Authority (‘HTA’) in respect of the donor’s

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83 The Declaration of Istanbul, for example, makes the provision of donor disability, health and life insurance related to the donation event a necessary requirement: supra note 3 at 1229 para. 5(a). See also M.A. Dew et al., “Guidelines for the Psychosocial Evaluation of Living Unrelated Kidney Donors in the United States” (2007) Am. J. of Transplantation 1047 at 1050.
84 See E Mor, “Kidney Transplantation from Unrelated Donors” (2009) 14 Current Opinion in Organ Transplantation 113 at 114
85 Supra note 76 at 492 and 77 at 1387 respectively.
86 Chin & Campbell, supra note 21 at 1705
87 HOTA, s.15B(4)
88 Cf. Mental Capacity Act, Cap. 177A, Rev. Ed. Sing. 2010, s.43, which offers various forms of protection for health care workers that provide information in relation to a mentally incapacitated person in need of care or protection.
89 42 C.F.R. §482.98(d); US Department of Health and Human Services, Organ Procurement and Transplantation Network Byelaws Attachment I, Criteria for Transplant Program Designation (17 Nov 2009), para. D.(2)(a) (vi), online: <http://optn.transplant.hrsa.gov/policiesAndBylaws/bylaws.asp>
90 42 C.F.R. §482.98(d)(1) simply provides that the living donor advocate or team must not be involved in transplantation activities on a routine basis; see also OPTN Byelaws, ibid.
informed consent and any evidence of an offer of reward,\textsuperscript{92} responsibility for determining the medical suitability of the donor rests with the relevant clinicians and transplant teams. \textsuperscript{93} However, guidance issued by the HTA recommends that the donor and recipient should be assessed and cared for by different clinicians, although there is no further stipulation as to their fiscal or institutional status. \textsuperscript{94}

A tension exists here if the question of independence is to be addressed internally, since the more independent a clinician is in relation to a transplant donor candidate, the less likely she may be knowledgeable of the evaluative issues involved. \textsuperscript{95} Even if recourse is had to a team of professionals, such that at least one member is sufficiently independent of the recipient’s care, it is questionable if staff of the very institution which stands to profit from performing organ transplant can be truly objective and independent by means of purely internal institutional measures. \textsuperscript{96} The US Department of Health and Human Services Advisory Committee on Organ Transplantation observed in its consensus recommendations on LDT:

ACOT recognizes that there is an acknowledged limitation of objectivity and independence [of the patient advocate], given the realities of the processes that take place within a transplant center among medical colleagues who regularly interact professionally; a modern, practicing physician does not work in a vacuum and cannot perform in a way that is wholly apart from other institutional staff. \textsuperscript{97}

It is arguable that in Singapore private sector medicine, even referrals to institutionally affiliated physicians, who practice independently of the recipient’s own transplant clinicians, are still inadequate by reason of affiliation to the same institutional framework and the reciprocal interest in mutually facilitating transplant revenues. There was some mention in Parliament of establishing an independent donor advocate system under the auspices of the

\textsuperscript{92} Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, regs. 11(8)-(9)


\textsuperscript{94} Ibid. at para. 52


\textsuperscript{96} Turner, \textit{supra} note 18 at 393; Chin & Campbell, \textit{supra} note 21 at 1705. For recommendations concerning internal institutional measures to ensure the independence of donor advocate teams, see New York State Committee on Quality Improvement in Living Liver Donation, \textit{A Report to: New York State Transplant Council and New York State Department of Health} (December 2002) at 8, online: <http://www.health.ny.gov/professionals/patients/donation/organ/liver/>

\textsuperscript{97} US Department of Health and Human Services, Advisory Committee on Organ Transplantation, \textit{Full Consensus Recommendations} (November 2002), Recommendation 2, online: <http://organdonor.gov/legislation/acotrecs118.html>.
National Organ Transplant Unit of the MOH, but this proposal does not seem to have materialized.\(^{98}\) Within the geographically compact Singapore healthcare system, it may be more effective to consider referral to public sector hospitals and physicians who have greater independence from the demands of the profit-oriented medical practice.

C. Evidential difficulties in evaluating the ethics of LDT

Difficulties in assessing follow-up care also affect the core question posed to TECs in discharging their functions: whether genetically unrelated donor-recipient pairs are sufficiently emotionally related in order to render an altruistic motivation plausible and the existence of undisclosed payments unlikely. In an unrelated donor-recipient case, evidence concerning the nature of the relationship typical comes exclusively from the statements and interviews of both parties. It is of course entirely possible for a TEC to insist on independent evidence from third parties, or circumstantial evidence, on the existence and nature of such an emotional relationship, failing which no approval would be forthcoming.\(^{99}\)

However, one must recognize the realities surrounding most applications. International transplant services are essentially commercial and foreign transplant recipients commit to significant expense in travelling for, seeking medical treatment and assessment for transplant. TEC members would very likely be mindful of the cost implications of insisting on independent third party evidence, e.g., flying in and accommodating other witnesses, and weigh these against the burdens already suffered by the gravely ill recipient – who typically has to foot all the medical and ancillary expenses for donor and herself. This concern could act as an inhibition on TEC members in asking for further evidence of relationship.

Secondly, the nature of a particular emotional relationship and whether it explains the desire and interests of the donor in making the personal sacrifice involved is also dependent on the social and cultural context of the donor-recipient pair.\(^{100}\) This is a difficult task for a local TEC to undertake if members are unfamiliar with the social and cultural norms that operate within the society of a foreign donor-recipient pair. Regulation 6 of the HOTAR 2009 directs TECs to “have regard to considerations of public interest and community values” when assessing applications. This is potentially very confusing – which set of community values is

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\(^{99}\) See Chin & Campbell, supra note 21 at 1705: TECs can ask for better information or further checks by the hospital transplant centre.

\(^{100}\) See N Schroder et al., “Consideration of psychosocial factors in the evaluation of living donors” (2008) 18 Progress in Transplantation 41 at 46
the TEC to apply? It would seem improper for TECs to apply Singaporean cultural norms to relationships developed and forged in different social and cultural contexts. The regulatory authority conferred under HOTA ultimately rests on a determination of the likelihood of unlawful payments and compliance with informed consent requirements under HOTA, not a conformance of relationships to Singapore social and cultural norms. Nonetheless, the assessment of the nature of an emotional relationship between unrelated foreign donor-recipient pairs requires TEC members to move into potentially difficult factual and ethical territory unless TEC members themselves are familiar with these.

For the most part, related LDTs pose less of an evidential challenge in determining the validity of the relationship. Related donor-recipient pairs, defined by the 2002 MOH guidelines as relatives of the first or second degree and spouses, are often used as an evaluative heuristic by TEC members in filtering ethical from unethical cases on the basis of likelihood of underlying financial motivations – although inducement and coercion could also be of concern in related living organ transplants.\(^\text{101}\) However, in this author’s experience, even the proof of family relationships is not necessarily straightforward matter. There are instances where countries in the region have lost national birth and marriage records by reason of war, or a country may lack reliable birth and nationality records.\(^\text{102}\) What TECs are offered in the alternative are documents signed off by unknown officials from unknown regional districts, with unknown legal authority to make such declarations of kinship. Fortunately, these evidential difficulties may be mitigated by consular officials from the relevant countries who have offered some assistance in evaluating the weight of the documentary evidence proffered, but they are not always in the position to do so. Apart from this, unless that is some irregularity on the face of the documents, TECs do not play an investigative role\(^\text{103}\) and are again likely mindful of the practical and cost implications on the recipient if they insist on further proof or a formal legal opinion.

To address these inherent limits on a local TEC’s competence, means must be found to buttress the expertise available to them. In the oversight of international transplant medicine,

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\(^{102}\) For instance, India currently does not have a comprehensive national identity card system, and the existing plethora of non-comprehensive, non-standardized ID systems increases the opportunities for fraud: see R. Dass & R.K. Bajaj, “Creation of a Single National ID: Challenges & Opportunities for India” IIMA Working Paper No. 2008-08-04 (August 2008), online: <http://www.iimahd.ernet.in/assets/snippets/workingpaperpdf/2379036312008-08-04.pdf>

\(^{103}\) Chin & Campbell, supra note 21 at 1705
these local limitations point toward the need for greater international cooperation, and not national self-sufficiency.\textsuperscript{104} Collaborations need to be worked out with counterpart governmental, non-governmental and professional organizations within usual medical tourism markets for inputs in evaluating applications under the HOTA – perhaps taking advantage of technological advances in teleconferencing. Some ad hoc arrangements have been worked out with foreign consular officers in Singapore on acceptable documentary proof of kinship, but these could be more systematically addressed and organized. One possibility would be for foreign counterparts of TECs, such as the Indian ACs, to be consulted on particular doubts raised by local TECs where the circumstances of the transplant application permit under the auspices of some international cooperation.

D. The standard of proof and exercise of TEC discretion

(1) A contextual bias in favour of approvals?

In the light of these evidential, social and cultural uncertainties, it becomes practically very important what standard of proof TECs apply as a matter of ethics and law in evaluating them. The HOTA simply requires that the TEC be “satisfied” that the conditions under s.15A(2) apply, without specifying any familiar standard of proof. In the face of such legal ambiguity and evidential uncertainty, what are TECs likely to do?

A rational quorum would weigh the consequences of error in setting an appropriate standard of proof. The exigency of the medical needs of the recipient is likely to evoke a strong Hippocratic ethic, reinforced by the majority physician membership of each TEC. The typical circumstances in each LDT case impress strongly in favour of allowing a voluntarily consenting adult donor (who, even in the absence of genuine altruistic motivations, will only speak positively of a transplant that coincides with his financial self-interest) to proceed, in order to help a seriously ill recipient who might otherwise die or be condemned to a disruptive and onerous dialysis regimen. Protocols developed under the HOTAR 2009 can work well procedurally in reiterating the nature of the transplant and the attendant risks to the donor.

In contrast, the countervailing public interest and social values prohibiting organ sales and trafficking are likely to be relatively muted since, (a) it would be nigh impossible to track payments between vendor and recipient overseas beyond the investigative powers of the local

\textsuperscript{104} Cf. Madrid Resolution, supra note 4
authorities – making subsequent discovery of such illegal transactions very unlikely, (b) the TEC is not specifically tasked to investigate wrongdoing, although it is both the ethical and legal gateway to authorized LDTs under the SHOTA,\textsuperscript{105} and (c) s.15B(4) of the HOTA confers legal immunity on TEC members who discharge their functions in good faith. No doubt, all members of a TEC serve as a matter of public service and are only paid an honorarium.\textsuperscript{106} But this also practically limits their capacity and time to thoroughly investigate the circumstances surrounding an LDT application – a majority of whom are medical professionals and not many would have any experience in forensic cross-examination.

Some empirical evidence supporting this type of decision-making calculus emerges from the Tamil Nadu study described above, where AC members may exercise their discretion in favour of approval notwithstanding a known underlying commercial transaction.\textsuperscript{107} However, the argument made here is not one of a tendency towards a dereliction of duty, but rather the implications of decision-making context on the standard of proof. Given the common realities surrounding a foreign LDT application, patient beneficence is likely to impress more strongly than concerns over more abstract moral harms to social justice\textsuperscript{108} and altruistic community.\textsuperscript{109} Thus, it is argued that even an independent TEC is likely when weighing the intangible costs of a false positive against the palpable costs of a false negative, to apply a relatively low threshold of proof in determining if the requirements of HOTA in relation to prohibited consideration are satisfied. This implies a higher rate of error in respect of fictitious altruistic cases, and hence a potential cover for transplant tourism. If unaddressed, it would undermine public trust and breed cynicism in respect of the values underlying an altruistic system of LDT.\textsuperscript{110}

It must be stressed that these observations do not suggest that TEC members are not minded to discharge their obligations in the spirit of HOTA and its altruistic ethos. There have been applications refused since the system was overhauled 2009.\textsuperscript{111} The point here is merely to highlight the practical and functional limits on TECs in protecting both the best interests of

\textsuperscript{105} Chin & Campbell, supra note 21 at 1705
\textsuperscript{106} Sing. Parl. Debates Vol. 86 Col. 1403 at 1405-6 (14 Sep 2009); Chin & Campbell, supra note 21 at 1706
\textsuperscript{107} See supra note 39 and accompanying text.
\textsuperscript{109} See TC Voo, “The social rationale of the gift relationship” (2011) 37 \textit{Journal of Medical Ethics} 663
\textsuperscript{110} See Epstein & Danovitch, supra note 6 at 359
\textsuperscript{111} Sing. Parl. Reports, Vol. 87 Col. 2825 (28 Feb 2011) (Khaw Boon Wan): in 2010, out of a total of 156 LDT applications, 14 were rejected.
genuinely altruistic organ donors and recipients, and the public interest in preventing or impeding organ sales between applicants.\textsuperscript{112}

(2) \textit{Existing constraints on TEC discretion}

To what extent does the existing framework counteract such a tendency? Going back again to Reg. 6 HOTAR 2009, this explicitly requires the TEC to have “regard” to “the public interest and community values”. It is doubtful that such an exhortation can overcome the evidential calculus just described, nor what countervailing effect it is supposed to have. The more important constraint is the oversight by the MOH and its officers rooted in the requirement under reg. 5(1) HOTAR 2009 for each TEC to give a “written assessment” on each application for LDT approval under s.15A(1) of HOTA, and submit a copy of the “report of every decision” authorizing LDT or otherwise to the DMS within 7 days of its decision. The regulations are not explicit on requiring TEC members to document their reasons for the decision, but it would seem strange if reg. 5(1) does not implicitly so require. First, there would not be any other apparent basis for the DMS and the ministry to assess if the respective TECs were substantively discharging their statutory functions in a “satisfactory manner” as required under s.15C(1) HOTA.

Secondly, if TECs were not required to give any reasons for their decision, this would make it very difficult for the DMS to decide on an application under reg. 6A to review a TEC decision to refuse authorization, much less give meaning to his authority to specify “such considerations that the transplant ethics committee shall have regard to…” under reg. 6A(4)(b).\textsuperscript{113} Thus, the recent statements of the current Minister of Health in Parliament are puzzling in asserting that “[e]ach [TEC] member will exercise his or her judgment in each case, taking into consideration many factors. As such, the TECs are not required to provide reasons for their decisions.”\textsuperscript{114} It might be that the MOH confines its oversight to ensuring \textit{procedural} compliance, and declines to adopt any substantive views on the issues outlined above. If this is indeed the position taken by the MOH towards TEC obligations under HOTA, then it reinforces the discretionary gray space where emphasis on patient beneficence may likely be given inordinate weight to the detriment of the public interest in ensuring truly

\textsuperscript{112} See Muraleedharan \textit{et al.}, \textit{supra} note 35 at 52
\textsuperscript{113} HOTAR 2009
\textsuperscript{114} Sing. Parl. Reports, Vol. 88 Col. 64 (14 Feb 2012) (Gan Kim Yong)
altruistic LDTs. It also runs counter to recent experience with organ trading and syndicate activity in Singapore pointing to the need for substantive oversight of TECs.\textsuperscript{115}

(3) Recourse to exclusionary rules, supporting evidence or standards of proof?

The HOTA and its regulations do not adopt proscriptive rules to constrain discretion, as was recommended by Muraleedharan \textit{et al} in response to the findings of the Tamil Nadu study.\textsuperscript{116} Some jurisdictions such as Lebanon adopt a broad-sweep approach that precludes the treatment of foreign patients, thus ruling out international transplant medicine altogether.\textsuperscript{117} This makes some sense from the perspective of a jurisdiction that has a potential to be a net organ ‘exporter’, without any medical hub ambitions – it removes the complexities of discretion in decision making vis-à-vis transplant tourism altogether. A more accommodative approach advocated by Budiani-Saberi & Delmonico would confine ethical international transplant medicine to family members and spouses.\textsuperscript{118} This is also reflected in the laws of some jurisdictions that specifically limit LDT to relatives of a particular degree, irrespective of their nationality.\textsuperscript{119}

These broad exclusionary approaches are questionable as a matter of ethics. Altruistically motivated donations are not logically tied to genetic or familial relationships; in fact some such relationships bear the possibility of equally coercive conditions from societal, cultural or religious expectations.\textsuperscript{120} There has been no significant difference in graft survival rates between genetically related and unrelated kidney transplants.\textsuperscript{121} Thus, it is difficult to see why travel per se should change the ethical complexion of a proposed transplant between two persons outside the bounds of familial or genetic ties. It is easier to understand such exclusionary approaches from an enforcement perspective. If unrelated LDTs present a high risk of underlying commercialism and cannot be effectively weeded out from genuine cases, then perhaps these should be excluded completely. This involves a policy trade-off between reduced access to transplantation for foreign patients and the prevention of transplant

\textsuperscript{115} See Part III.A above.
\textsuperscript{116} \textit{Supra} note 35 at 53
\textsuperscript{117} A. Stephan \textit{et al.}, “Ethical Aspects of Organ Donation Activities” (2007) \textit{Experimental and Clinical Transplantation} 633 at 636
\textsuperscript{118} D.A. Budiani-Saberi & F. Delmonico, “Organ Trafficking and Transplant Tourism: A Commentary on the Global Realities” (2008) 8 \textit{Am. J. of Transplantation} 925-929 at 926; See also Delmonico, \textit{supra} note 64 at 117.
\textsuperscript{119} See A. Garwood-Gowers, \textit{Living Donor Organ Transplantation: Key Legal and Ethical Issues} (Aldershot: Ashgate, 1999), c. 4 at 115-119
\textsuperscript{120} See S Choudhry \textit{et al.}, “Unrelated living organ donation: ULTRA needs to go” (2003) 29 \textit{Journal of Medical Ethics} 169 at 170
tourism, which is unavoidable. The question is whether such broad exclusionary rules represent an appropriate balance between ethical concerns over transplant commercialism, donor-recipient welfare and national policy in promoting international transplant medicine.

An alternative strategy to address this problem would be to impose a requirement of independent supporting evidence of an emotional relationship between the donor-recipient pair. Such a requirement would need to be clear on the nature and source of such supporting source of evidence. For example, this might be a person whose relationship with the donor is verifiable by documentary evidence and who is not financially dependent on the donor. In general, supporting evidence should be independently verifiable apart from the credibility of the donor-recipient’s statements before the TEC. Such a requirement would have cost implications when additional persons have to travel in order to be interviewed by the TEC in its deliberations. However, when compared with the more stringent exclusionary approach, this evidential rule – restricted to unrelated donor-recipient pairs – would appear to be a more reasonable regulatory requirement that balances the competing interests.

However, a corroboration-like requirement that is not sufficiently specific would be ineffectual if it is not applied with an appropriate standard of proof, which is the very weakness of the TEC model identified. This might be counteracted by specifying more stringent standards of proof in targeted relational scenarios where a heightened risk of transplant commercialism exists. For example, some TECs in Singapore have flagged certain situations or relationships where there is either a significant social and economic disparity or some financial dependency (e.g., employer and employee relationships) for careful scrutiny. Unfortunately, how exactly such an apparently enhanced standard of proof should be formulated admits of no ready answer. The criminal legal analogue of ‘beyond a reasonable doubt’ might be adapted for such high risk relationships or donor circumstances, but recourse to elevated standards of proof still leaves the same regulatory challenge: burdens of proof are imprecise standards that are difficult for a state regulator to monitor compliance without reviewing each application in detail. Furthermore, non-legal professional and lay membership on TECs would make consistent application difficult.

Therefore, instead of resorting to broad exclusionary rules or altered standards of proof, the better approach would be to formulate more targeted rules excluding high risk relational scenarios altogether. The clearest example would be to exclude unrelated donors in a

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122 Chin & Campbell, supra note 21 at 1704-5
subordinate or financially dependent relationship. In addition, the regulations could also exclude foreign donors who do not have the independent financial means to manage the risks of donation, on the basis that the risks of commercialism are higher and the regulatory means to exclude or reduce these risks in relation to foreign applicants are limited. More targeted exclusionary rules provide a better balance between the competing interest highlighted, while reducing the decision-making burdens of individual TEC members and oversight responsibilities of the MOH. This is provided that substantive oversight as mentioned by the Ministry in respect of reasoned written decisions of TECs is in fact undertaken.

VI. Conclusion

In summary, international transplant medicine continues to grow in tandem with concerns over transplant tourism. Although there is an overlap between both activities, the regulatory responses cannot focus on national self sufficiency to the exclusion of travel for transplantation altogether. Singapore’s recent legislative and regulatory measures highlight several key features of any evolving set of international standards for a sufficiently transparent LDT oversight system: (i) sufficient institutional independence of regulatory gatekeepers, (ii) a well developed set of ethical and regulatory guidelines that address important substantive issues such as the provision of medical follow-up, a general requirement of independent supporting evidence for emotionally related transplant candidates and clear, targeted exclusionary rules for high risk donor candidates, and (iii) robust regulatory audit of the regime’s appointed gatekeepers. In addition, the effective oversight of international transplant medicine ideally requires transnational or bilateral solutions which institute greater regulatory collaboration between jurisdictions that does not currently exist. In the former respect, significant improvements have been made to the Singapore LDT regime, although there is a need for clearer regulatory standards and more rigorous external monitoring of TECs.

124 Epstein & Danovitch, supra note 6 at 360
125 See Mor, supra note 84