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Living kidney donation in Europe: legal and ethical perspectives – the EUROTOLD Project

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Abstract The demand for organ replacement by transplantation continues to outstrip supply, leading to unnecessary morbidity and health care costs. "Space capacity" (i.e. cadaver organs not currently harvested for transplant) has been tackled within Western Europe in particular by many strategies – medical, social, educational and legal – but with varying degrees of success. Despite this, the use of living donors has not been fully exploided in many European countries to fill this gap. The total picture is, however, one of marked differences between countries and between centres within countries. In Turkey and Greece, living donors generally account for 60–90% of all renal donors. Countries within Scandinavia also have a high rate of living donor use, especially Norway. By contrast the percentage is far more modest, for example in Spain, Ireland, France and Germany. In the United Kingdom the rate is only 6% with a range of between 0 and 20%. Sources of living donors also show substantial variations between countries, notably the extent to which non-genetically related donors are used. A European Commission sponsored study has been established to acquire a broad understanding of the interaction of ethical values, cultural traditions and social customs on willingness to donate. It will also aim to assess the effect of national laws on professional attitudes to living donor transplantation. This is a collaborative project between the University Department of Surgery, Leicester General Hospital, the Department of Law, De Montfort University and the Department of Mathematics, Newcastle University. Transplant units throughout Europe, including France, Germany, Switzerland, Norway, The Netherlands, Eire and Turkey are collaborating to exchange information and views on living donor transplantation.

Key words Living donor transplantation · Ethics · Law Donor health · Consent

Despite numerous changes over the past 30–40 years, there are some constants on the kidney transplant scene, namely waiting list sizes and the very good graft survival results using living donors. In the United Kingdom, 1923 patients were awaiting a kidney transplant in 1980, 3565 in 1987 and 4343 in 1992 [1]. As in the Euro-transplant area, a consistent and substantial increase is evident from these figures despite an improvement in the number of cadaveric kidney transplants performed over this period [2]. With reference to graft survival statistics, although cadaveric results have improved substantially in recent years, studies consistently indicate that living related donor graft survival is at least on a par with cadaveric rates over the short term and is superior over the longer term, i.e. 5, 10 or more years [3–5].

Historically, certain countries within Europe have experienced high rates of living donor transplantation (LDT). For example, the rate was approximately 77% in Greece over the period 1972–1992 [6] and historically around 33% in Scandinavia taken as a whole (higher in Norway) [7]. Nonetheless, in addition to a modest overall historical rate in Western Europe in particular, there has also been an overall decline in the percentages of LDT use over the past decade or so. In the United Kingdom, from a historical average of 10–12%, the percentage of LDTs as a percentage of all transplants performed was 6.7% in 1989, 6.1% in 1990, 5.9% in 1991 and 4.9% in 1992 [8]. This reduction is mirrored elsewhere, for instance in Spain where an historical average of 6% dwindled to 1% by 1992, and in France, the Republic of Ireland, etc. In Eurotransplant the percentage use of LDT was 4.8% in 1988, dropping to 3.6% in 1991 [9]. Although it then rose to 5.5% in 1992, such percentage decline is generally accompanied by a reduction in the actual numbers of LDTs performed during the same period. In the United Kingdom, for example, the number of LDTs performed diminished from 137 in 1988 to 91 in 1992 [10].

There is a highly variable pattern relating to LDT use within Europe; some countries perform very few or no LDTs, a few sustain a substantial rate of use and a few countries are even increasing their rate, e.g. Norway (with a current annual percentage of approximately 48%) [11], the Netherlands and Switzerland. Within the Eurotransplant area the rate has tended to fluctuate over recent years. However, not only is the rate of LDT use variable between countries, there are very marked variations between centres within countries. The regional picture in the United Kingdom relating to LDT is highly variable, for instance. This is no isolated example as for example, Eurotransplant figures demonstrate.

What is the explanation for the marked variations in LDT use between countries and centres within countries? This is the basic remit of the EUROTOLD Project sponsored by the European Commission, with the focus on the legal and ethical factors producing such profiles. Legal and ethical factors are undoubtedly extremely influential in the practice of LDT and are linked to five major issues: (1) commercialism, (2) risks to donor health, (3) voluntariness of consent, (4) assessment of relative quality of life without a transplant, and (5) the relative advantage offered to the recipient contrasted with cadaver donation. Professional perceptions of the permissible boundaries are of particular interest here. Attitudes of surgeons, physicians, nephrologists and co-ordinators will be sought through questionnaire responses supplemented by centre visits.

Clearly, transplantation in whatever form requires explicit public support. The EUROTOLD Project through its LEGISEARCH programme has already compiled a sizeable computer database of laws which display quite a high degree of similarity in scope and content, with the exception of provisions relating to the use of minor and marginal donors. Most European nations provide a permissive legislative framework for LDT, granting broad discretion to clinicians whilst at the same time providing for the most worrisome ethical issues. Laws overwhelmingly prohibit commercialisation in organ procurement, for instance. In the light of this fact, the real issue consequently relates to enforcement. But is there any evidence that in European countries abuses are occurring and are not being detected, prevented or deterred by the official agencies and professional bodies concerned? Is it necessary to abandon LDT entirely to reduce the risks of commercialism to acceptable levels?

There is now quite a large quantity of data addressing the risk to donor health, both short and long term, from LDT. The majority of findings linked to physical health suggest that LDT only presents a small risk of major complication either short or long term, and that the risk of death is only a small fraction of 1% (around 0.06%) [12, 13]. However, much of the existing data is patchy and some of it is rather dated. In addition, outcomes may be influenced by different donor screening and work-up procedures.

The EUROTOLD Project has set up a *Donor Health Registry* on computer database to store and collate data relating to donor health from many European countries provided by the participating centres. Evidence as to postoperative psychological health will additionally be solicited through the medium of a broader questionnaire

sent to hundreds of renal transplant donors around Europe – many existing studies of donor health do not address psychological aspects. The accuracy and quality of such information is essential as a pre-requisite to the obtaining of a satisfactory informed consent to donation, disclosure of the risks to a potential donor being an explicit legal requirement in virtually all jurisdictions. Data procured by these means will enable the creation of a European-wide profile of donor risk.

Another essential aspect of a decision to donate is the voluntariness of the consent given. Leaving aside any possible element of sale, many interested persons have doubted the ability of a living related donor to give a voluntary consent due to the likelihood of intrafamilial pressure. This view demands further and more rigorous legal and ethical appraisal as it is a central issue and one which inflences centre practice. As a further point, we should also ask *who* should be assessing this element of consent. Land has remarked "Again, transplant surgeons/physicians are not in a position to confirm true voluntarism because they lack expertise in the necessary methodology" [14]. But if so, who is properly qualified in this respect? The EUROTOLD Project will attempt to evaluate these issues through questionnaire responses from living donors and organ recipients, and interviews with selected living donors. This will also generate information on patient and family attitudes to LDT.

Quality of life assessments made by clinical staff associated with transplant programmes may favour a high transplant rate as against a high patient dialysis rate or vice versa and, in transplant terms, favour a substantial rate of LDT or otherwise. Such decisions have weighty financial and societal implications. With a pervasive shortage of cadaver kidneys, a failure to use living donors in many cases primarily has the effect of increasing waiting times for transplant. This is no mere inconvencience. As a recent editorial stated "The chance of a successful transplantation decreases as the recipient's illness increases in severity. As an alternative to living donation, a cadaver organ or segment may be found by waiting for an appropriate donor, but waiting too long for a cadaver donor increases the risk that the recipient will die, and decreases the likelihood of a successful transplant" [15]. As mentioned, even in countries where high rates of cadaveric transplantation are sustained, waiting lists are sill lengthy. And what of those countries unable to attain or maintain such high rates of cadaveric transplantation but whose waiting lists continue to rise – even in the context of modest acceptance rates on to the transplant waiting list, e.g. the United Kingdom, etc?

Further research is needed in relation to many issues surrounding LDT to facilitate a proper appraisal of the future role of LDT in Europe. The collaboration of additional centres and interested individuals in the project would be warmly welcomed, as would suggestions as to how the work might be further developed.

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