

International practices of organ donation

C. Rudge^{1*}, R. Matesanz², F. L. Delmonico^{3,4,5} and J. Chapman⁶

¹ Department of Health, Wellington House, Waterloo Road, London SE1 8UG, UK

² National Transplant Organization (ONT), C/Sinesio Delgado 6, 28029 Madrid, Spain

³ The Transplantation Society

⁴ Department of Surgery, Harvard Medical School, Massachusetts General Hospital, Boston, MA, USA

⁵ New England Organ Bank, MA, USA

⁶ Acute Interventional Medicine, Centre for Transplant and Renal Research, University of Sydney, Westmead Hospital, Westmead, NSW 2145, Australia

* Corresponding author. E-mail: cjrudge@btinternet.com

Editor's key points

- Rates of deceased donation vary markedly around the world.
- Living donation is the mainstay of transplantation in many countries.
- Many of the unacceptable transplantation practices come from the exploitation of vulnerable living donors.
- All developments in donation should have equity, quality, and safety at their core.

Summary. Organ donation and transplant rates vary widely across the globe, but there remains an almost universal shortage of deceased donors. The unmet need for transplants has resulted in many systematic approaches to increase donor rates, but there have also been practices that have crossed the boundaries of legal and ethical acceptability. Recent years have seen intense interest from international political organizations, led by the World Health Organization, and professional bodies, led by The Transplantation Society. Their efforts have focused on the development of a series of legal and ethical frameworks, designed to encourage all countries to eradicate unacceptable practices while introducing programmes that strive to achieve national or regional self-sufficiency in meeting the need for organ transplants. These programmes should seek to reduce both the need for transplantation and also develop deceased donation to its maximum potential. Living donation remains the mainstay of transplantation in many parts of the world, and many of the controversial—and unacceptable—areas of practice are found in the exploitation of living donors. However, until lessons are learnt, and applied, from countries with highly developed deceased donor programmes, these abuses of human rights will be difficult to eradicate. A clear international framework is now in place to achieve this.

Keywords: living donors; organ transplantation; tissue and organ procurement; transplantation

Transplantation is the best and sometimes only form of treatment for many patients with end-stage organ failure. Organ donation and transplantation have been the subject of extensive international interest in the past 10 yr at both governmental and professional levels. This interest has been driven by two main factors. First, the universal shortage of organs for transplantation and the wide international variation in donation and transplantation activity. Secondly, the need to ensure that all developments have a firm basis in legal and ethical practice with equity, quality, and safety at their core.

Any comprehensive review of organ transplantation needs to consider both deceased and living donation. Indeed, while deceased donation fails to meet the need for transplantable organs in all countries, it is almost non-existent in many countries, and it is this that has led to ever-increasing use of living donors as a source of kidneys and more recently also livers. Many of the controversial—and unacceptable—aspects of living donation stem from this, and while interest sometimes appears to be focused on steps to stop these practices, there is also an equal emphasis on the need for

all countries to work to achieve 'self-sufficiency' by establishing effective deceased donation programmes.

The international response has been to create two sets of global agreements: an international governmental response created through the World Health Assembly and World Health Organization (WHO), and a professional response created through international societies spearheaded by The Transplantation Society and the International Society of Nephrology.

- (i) Led by the WHO, the World Health Assembly resolved in May 2010 to endorse revised Guiding Principles on Human Cell, Tissue and Organ Transplantation.¹ These refer to both living and deceased donation, are accompanied by a commentary, and contain 11 specific and carefully worded principles (Table 1). It is stated that 'The (following) Guiding Principles are intended to provide an orderly, ethical and acceptable framework for the acquisition and transplantation of human cells, tissues and organs for therapeutic purposes. Each jurisdiction will determine the means of implementing the Guiding Principles'.

Table 1 WHO Guiding Principles on Human Cell, Tissue & Organ Transplantation

- 1 Cells, tissues, and organs may be removed from the bodies of deceased persons for the purpose of transplantation if: any consent required by law is obtained, and there is no reason to believe that the deceased person objected to such removal
- 2 Physicians determining that a potential donor has died should not be directly involved in cell, tissue, or organ removal from the donor or subsequent transplantation procedures; nor should they be responsible for the care of any intended recipient of such cells, tissues, and organs
- 3 Donation from deceased persons should be developed to its maximum therapeutic potential, but adult living persons may donate organs as permitted by domestic regulations. In general, living donors should be genetically, legally, or emotionally related to their recipients. Live donations are acceptable when the donor's informed and voluntary consent is obtained, when professional care of donors is ensured and follow-up is well organized, and when selection criteria for donors are scrupulously applied and monitored. Live donors should be informed of the probable risks, benefits, and consequences of donation in a complete and understandable fashion; they should be legally competent and capable of weighing the information; and they should be acting willingly, free of any undue influence or coercion
- 4 No cells, tissues, or organs should be removed from the body of a living minor for the purpose of transplantation other than narrow exceptions allowed under national law. Specific measures should be in place to protect the minor and, wherever possible, the minor's assent should be obtained before donation. What is applicable to minors also applies to any legally incompetent person
- 5 Cells, tissues, and organs should only be donated freely, without any monetary payment or other reward of monetary value. Purchasing, or offering to purchase, cells, tissues, or organs for transplantation, or their sale by living persons or by the next of kin for deceased persons, should be banned. The prohibition on sale or purchase of cells, tissues, and organs does not preclude reimbursing reasonable and verifiable expenses incurred by the donor, including loss of income, or paying the costs of recovering, processing, preserving, and supplying human cells, tissues, or organs for transplantation
- 6 Promotion of altruistic donation of human cells, tissues, or organs by means of advertisement or public appeal may be undertaken in accordance with domestic regulation. Advertising the need for or availability of cells, tissues, or organs, with a view to offering or seeking payment to individuals for their cells, tissues, or organs, or, to the next of kin, where the individual is deceased, should be prohibited. Brokering that involves payment to such individuals or to third parties should also be prohibited
- 7 Physicians and other health professionals should not engage in transplantation procedures, and health insurers and other payers should not cover such procedures, if the cells, tissues, or organs concerned have been obtained through exploitation or coercion of, or payment to, the donor or the next of kin of a deceased donor
- 8 All health-care facilities and professionals involved in cell, tissue, or organ procurement and transplantation procedures should be prohibited from receiving any payment that exceeds the justifiable fee for the services rendered
- 9 The allocation of organs, cells, and tissues should be guided by clinical criteria and ethical norms, not financial or other considerations. Allocation rules, defined by appropriately constituted committees, should be equitable, externally justified, and transparent
- 10 High-quality, safe, and efficacious procedures are essential for donors and recipients alike. The long-term outcomes of cell, tissue, and organ donation and transplantation should be assessed for the living donor and the recipient in order to document benefit and harm. The level of safety, efficacy, and quality of human cells, tissues, and organs for transplantation, as health products of an exceptional nature, must be maintained and optimized on an ongoing basis. This requires implementation of quality systems including traceability and vigilance, with adverse events and reactions reported, both nationally and for exported human products
- 11 The organization and execution of donation and transplantation activities, and their clinical results, must be transparent and open to scrutiny, while ensuring that the personal anonymity and privacy of donors and recipients are always protected

(ii) The professional response to these challenges have been led by The Transplantation Society, in association with other international professional societies, through publications such as the Amsterdam Forum,² the Vancouver meeting,³ and importantly the Declaration of Istanbul on Organ Trafficking and Transplant Tourism.⁴ Much of the section below on payment for organs and transplant tourism is based on this Declaration.

A further joint initiative between governmental and professional organizations was the Resolution of Madrid, co-sponsored by the European Commission, WHO, Spanish Presidency of the EU, and The Transplantation Society.⁵ This called for all states to strive towards self-sufficiency, both by increasing organ donation activity and by efforts to reduce the burden of end-stage organ failure.

The current position in the UK with respect to several of the Guiding Principles is covered elsewhere in this issue;^{6–8} this article will comment on relevant issues from the remaining Principles and give international examples and data.

International epidemiology of organ donation and transplantation

For many years, information on donation and transplantation activity in European countries has been published in an annual Council of Europe Transplant Newsletter.⁹ Recently, this has been extended to include information from North and South America and Australasia. However, an even more extensive database is the Global Observatory on Donation and Transplantation,¹⁰ established in 2007 under the auspices of the WHO and the Spanish transplant organisation (ONT), which is expected to develop over time to include both activity and outcome data.

Organ donation rates have traditionally been expressed as donors per million of population (pmp). Among the 50 most active countries (in terms of transplantation), some—such as Japan—have relied almost entirely on living donors, while others—such as Spain—on deceased donors. However, in the majority, both forms of donation are practised.

Deceased donation

For many years, Spain has had a donor rate over 30 pmp, and in 2009, it was 34.4 pmp. Portugal is the only other country with a rate >30 pmp, achieved for the first time in 2009. A number of other major countries have donation rates of 20–30 pmp (including France, Italy, and the USA), whereas in the UK, the rate is now 16.4 pmp (Fig. 1). The changing deceased donor rates over 10 yr for selected countries are shown in Figure 2. Countries also differ in the extent to which donation after circulatory death (DCD) is practised, with a tendency towards those with lower donation after brain death (DBD) rates to have more active DCD programmes (such as the Netherlands and the UK). It is a current source of speculation as to whether controlled DCD programmes degrade the potential for DBD, or rather whether they are only possible in countries where treatment withdrawal on the grounds of futility dominate end-of-life decision-making.

While expressing the donor rate in population terms is an accurate measure of activity, it may not be the best measure of the effectiveness of the donation system overall. Many factors influence the number of potential donors, and these could include the incidence of life-threatening trauma and intracerebral haemorrhage, the availability of intensive care facilities, the management—through surgery and interventional radiology—of such patients, and the consent rate. There are also legal constraints in a number of countries. If accurate data on the total donor pool were available, a more meaningful measure would be the proportion of possible donors that become actual donors—the so-called conversion rate. In the UK, the Potential Donor Audit is able to provide an estimate of this figure, although there are considerable anxieties about definitions and data accuracy that are currently being addressed. However, one example demonstrates this point. In Spain, there are over 50 pmp patients whose death is confirmed by neurological criteria, whereas in the UK, the rate is 19 pmp.¹¹

Living donation

Living donation makes a significant contribution to kidney (and to a lesser extent liver) transplantation programmes worldwide and carries a number of advantages. Transplantation becomes elective and can be scheduled to the time the patient needs the transplant. Furthermore, the outcomes are better than if a deceased donor organ is used. However, this is at a cost. The mortality rate for living kidney donors is ~1:3–5000,¹² while for living liver donors, it may be as high as 1:200.¹³ Morbidity occurs in

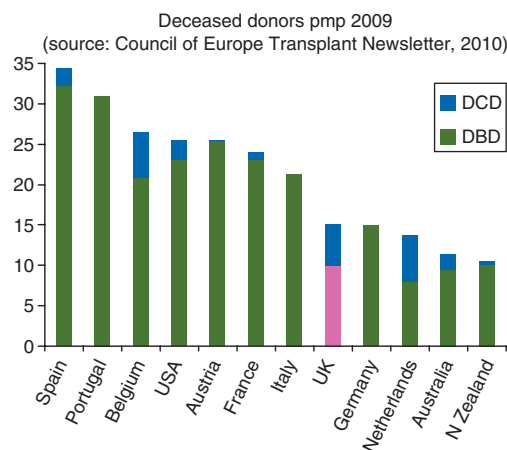


Fig 1 Deceased donor rates (pmp) in selected countries.

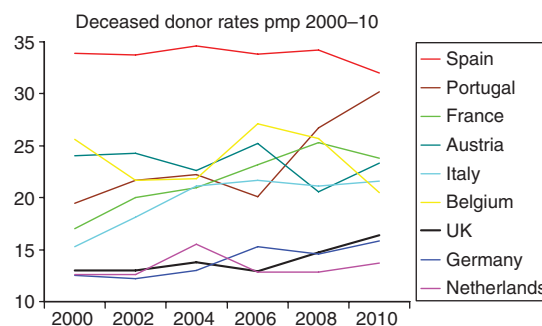


Fig 2 Trends in deceased donor rates in selected European countries over 10 yr.⁸

10–15% of patients and there are the added social and possibly financial costs to the donor. Living donation also opens the opportunity to commercialization and trafficking (see below). Different countries have resolved these issues in different ways, depending at least in part on the availability of deceased donation, and living donor rates vary widely. The Netherlands, Turkey, Norway, and the USA now carry out over 20 pmp living donor kidney transplants per year; in the UK, the figure is 15.9 pmp, whereas in Spain and France, the rate is ~5 pmp.

Transplant activity

Donation is driven by the needs of patients with end-stage organ failure for transplants, and in this regard, the most important metrics are transplant rates, both in terms of the total number of transplants (from both living and deceased donors) and those for specific organs. Figure 3 shows the transplant activity for the four global regions for which good data are available.

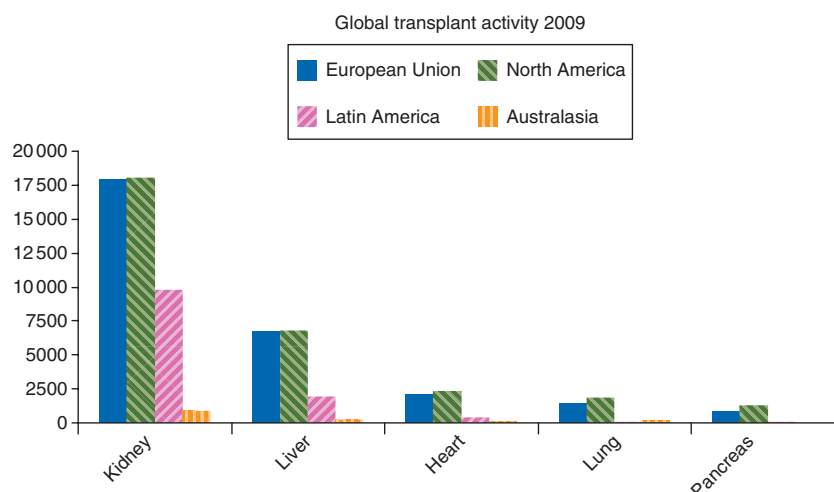


Fig 3 Transplant activity in the four WHO regions.⁸

Models to increase the identification and referral of potential donors

Useful comparative metrics for organ donation require clear and agreed definitions, and The Critical Pathway is an important step towards uniform definitions of both the DBD and DCD pathways.¹⁴ The steps being taken to increase organ donation in the UK have been described elsewhere,¹⁵ but there are valuable lessons to be learnt from other countries.

The USA

The National Organ Transplant Act (NOTA) of 1984 established an Organ Procurement and Transplantation Network (OPTN) in the private sector. Since 1986, the United Network for Organ Sharing (UNOS) has held the federal contract as the OPTN, acting through its 11 regions.

The deceased donor organ donation process can be viewed as a continuum from initial identification of the potential organ donor through to organ transplantation. To maximize the supply and quality of the deceased donor organ pool, every step in this continuum needs to be optimized. Prompt identification of all potential organ donors is critical, and this may be in the emergency department or in the intensive care unit (ICU). Currently, about 90% of actual deceased organ donors in the USA are donors who are declared brain dead (DBD donors) and 10% are donors declared dead after permanent cessation of cardiopulmonary function (DCD donors). Hospitals are required by the Center for Medicare and Medicaid Services (CMS) to identify and refer all potential organ donors to the local organ procurement organization (OPO). The term 'imminent death' has been used to identify those patients who should be referred to the OPO as one of several performance metrics monitored by CMS. To this end, hospitals collaborate with OPOs to organize the identification of imminent deaths,

usually by developing explicit, objective clinical criteria for contacting the OPO. One commonly used approach is to consider any ventilator-dependent patient with a Glasgow Coma Scale score of 5 or less who is expected to die in the hospital as a potential organ donor to be referred to the OPO. This includes patients who are being evaluated for brain death and patients whose families and care team have elected to withdraw support. The impact of decisions to limit or withdraw cardiorespiratory support on the size and nature of the potential donor pool in the USA is unclear and warrants further study.

Australia

Australia has struggled for 20 yr to bring the rate of organ donation up to the level that well-organized developed countries achieve. From 1988 onwards, the Australian approach to organ donation mirrored the national political system—a federal government and state administrations brought together in disconnected, dysfunctional, and unempowered committees. Not surprisingly, the organ donation programme was the result of the voluntary efforts of transplant surgeons and physicians supported by a few dedicated organ donor coordinators with the active participation of a number of intensive care clinicians, but without resources or organizational structure. The outcome was organ donation rates that sank from a high of around 14 pmp in 1989 to eight or nine donors pmp by 2000 as death rates from road trauma and strokes plummeted.

Many people throughout the country came to the understanding that a substantial and significant change would be needed if the benefits of organ transplantation were to be realized for the Australian community. Two processes commenced simultaneously—a grassroots movement involving many prominent community figures on the one hand and a government-sponsored taskforce on the other hand. The report from the taskforce could have languished

Table 2 The nine-measure Australian National Reform Agenda

1	A new national approach and system—a national authority and network of organ and tissue donation agencies
2	Specialist hospital staff and systems dedicated to organ donation
3	New funding for hospitals
4	National professional education and awareness
5	Coordinated, ongoing community awareness and education
6	Support for donor families
7	Safe, equitable, and transparent national transplantation process
8	National eye and tissue donation and transplantation network
9	Additional national initiatives, including living donation programmes

on a government shelf and a community-driven plan to implement a world's best practice organ donation programme could have fallen on deaf ears, but were instead focused by the newly elected Prime Minister, Kevin Rudd. He famously called in his chief health bureaucrats and told them to 'stop stuffing around' and fix the organ donation problem in Australia. The plan was an amalgam of the transformative community plan and the researched and widely consultative taskforce plan, funded with 150 million dollars of Federal government money spread over 4 yr. Nine specific programmes were implemented (Table 2).

The impact has been considerable. The responsibility for the national organ donation rate lies with the Australian Organ and Tissue Authority, while responsibility to tissue type, cross-match, and transplant lies with the individual State Governments. Organization of the organ donation agencies into a cohesive national organization is the remit of Donatelife, who have developed a network of professional hospital intensivists and nurse specialists and provide reimbursement to meet the hospital costs of care of potential donors. They have also delivered a public media campaign, which has won an international business community award—the Gold Quill Award for social responsibility. Donatelife has also developed national organ allocation protocols, supports the care of donor families, and has developed specific strategies such as a national Donation after Cardiac Death protocol and a national paired kidney exchange programme.

The results are already substantial and the donation rate is climbing (30% in the past year) to the highest ever rate, despite the fact that implementation of the original governmental reform package is far from complete. The principle lessons from the Australian experience include: the powerful motivating voice of the community for creating the political momentum for change; the need for a well thought through and consulted plan of action; national determination stemming from the Prime Minister down; disconnection from the voluntarism of the transplant units working to create change, replaced by the critical role of professional intensive care and organ donation staff; and funding to

invest in the National Authority, its network, and its activities.

Spain

The philosophy of the Spanish Model can be summarized as follows:

- 95% of all deceased donations in Spain come from brain dead donors, with the remainder being uncontrolled DCD donors. This implies that most potential deceased organ donors are cared for in an ICU, and this is therefore where the efforts to increase donation are targeted.
- The main cause of loss of donors is the lack of identification and referral of possible or potential deceased organ donors. If organ donation is not considered when people die under specific circumstances, potential donors will be missed.
- The person fundamentally most capable of influencing the process will therefore be a clinician, primarily located in the ICU, who is able to establish an appropriate relationship with those working on the unit, promoting the idea of organ donation as a part of end-of-life care.

In Spain, the National Transplant Organization (ONT) was established in 1989 and introduced Transplant Donor Coordinators (TDCs) as an essential component of the so-called Spanish Model of Donation and Transplantation. The majority of TDCs have always been physicians, supported by nurse coordinators. The excellent results of the Spanish Model very much rely on the key role of TDCs. There are three levels of coordination: national, regional, and hospital. TDCs, representing the hospital level of that organizational network, are responsible for enhancing organ donation within their hospitals and are the cornerstone of the system. Initially, TDCs were largely ICU physicians or to a lesser extent nephrologists working part-time as coordinators and part-time in their parent speciality, but an increasing number are now from a nursing background.

The success of the Spanish model is frequently linked to Spain's legal framework of presumed consent. However, the opting-out system for consent to donation was introduced in 1979 and had no impact whatsoever for the 10 yr that followed enactment of the Transplantation Law. Furthermore, the presumed consent policy has never been strictly applied in practice; relatives are always approached and always have the final say. Only with the establishment of ONT and the introduction of TDCs did donation rates begin to rise, with this being attributable to the skill of the very well-trained transplant coordinators who approach the grieving families. It is notable that the consent rates for foreign nationals living in Spain (coming from other parts of Europe, Latin-America, Asia or Africa) match those of the indigenous population.

A further essential component of the Spanish Model is the Quality Assurance Programme, as a tool to define and

monitor the potential of deceased organ donation and evaluate areas where improvement is possible. An important element of this is an external evaluation, where external observers (who are also TDCs) provide peer-review evaluation of the processes supporting organ donation in individual institutions. Finally, the TDCs in Spain neither depend on, nor report to, the head of the transplant team. The ONT recommendation was quite clear from the very beginning: the TDC should directly report to the medical director of the hospital and should have a major role in promoting organ donation among all health-care and non-health-care professionals. A positive attitude of the entire hospital towards donation is essential to be sure that the process works adequately.

Payment for organs and transplant tourism

In 2004, the World Health Assembly (WHA) adopted a resolution that urged member states ‘to take measures to protect the poorest and vulnerable groups from transplant tourism and the sale of tissues and organs, including attention to the wider problem of international trafficking in human tissues and organs’.¹⁶ As of 2007, the WHO estimated that 10% of organ transplants performed worldwide involved these unacceptable activities.

To address the concerns of the WHA and the growing problem of organ sales, a Summit Meeting of more than 150 international representatives of scientific and medical bodies, government officials, social scientists, and ethicists was held in Istanbul, Turkey, from April 30 to May 2, 2008. The result of these deliberations was the *Istanbul Declaration on Organ Trafficking and Transplant Tourism*.⁴ The Declaration of Istanbul calls for a prohibition of organ trafficking, transplant commercialism, and transplant tourism: ‘because transplant commercialism or the buying and selling of organs targets impoverished and otherwise vulnerable donors it inexorably leads to inequity and injustice and should be prohibited. The vulnerable donors are minors, illiterate and impoverished persons, undocumented immigrants, prisoners, and political or economic refugees’.

The definition of transplant tourism

Travel for transplantation is the movement of organs, donors, recipients, or transplant professionals across jurisdictional borders for transplantation purposes. Travel for transplantation becomes ‘transplant tourism’ if it involves organ trafficking, transplant commercialism, or both or if the resources (organs, professionals, and transplant centres) devoted to providing transplants to patients from outside a country undermine the country’s ability to provide transplant services for its own population. Transplant tourism is different from medical tourism for other kinds of medical care because it involves a live donor, whose interests and well-being must be considered just as important as those of the recipient. The medical resource used in transplant tourism is an exploited live donor. Vulnerable populations (such as those defined above) in resource-poor and underdeveloped

countries have become a major source of organs for so-called ‘transplant tourists’ who can afford to travel and purchase organs.¹⁷

Acceptable travel for transplantation

Not all recipients travel to a foreign country to undergo transplantation is unethical. Travel for transplantation may be acceptable if the following conditions are fulfilled:

For transplantation from a live donor:

- if the recipient has a dual citizenship (in the country of residence and also in the destination country) and wishes to undergo transplantation from a live donor who is a family member in the destination country of citizenship that is not their residence.
- if the donor and recipient are genetically or emotionally related and wish to undergo donation and transplantation in a country not of their residence to gain access to better health services.

For transplantation from a deceased donor:

- if official regulated bilateral or multilateral organ-sharing programmes exist between or among jurisdictions (countries) that are based on reciprocal organ-sharing programmes between or among the jurisdictions.

Consequences of transplant tourism

Transplant tourists prevent deceased donor organs from being available for the people of the destination country because the rich tourists who pay for the organs receive preferential care. In addition, transplant tourists impede the development of deceased or altruistic live donation that otherwise would develop in the client country. If the insurance companies of a country preferentially send patients to the Philippines or Pakistan for organs because the transplant will cost less with a meagre payment to the organ vendor, deceased donation and altruistic living-related donation (in the country that the tourist resides) are affected by that systematic approach to use the poor of the destination country as the source of organs.

Quality and safety

All transplanted human organs carry potential risks to the recipient, either from unsatisfactory organ function or disease transmission from the donor to the recipient, with malignancy and infectious diseases being the most relevant. In the case of living donors, there are also the risks to the donor, both immediate and longer term. A knowledge of these risks is a pre-requisite for consent. However, for some recipients—faced with imminent death without a transplant—even significant risks associated with a specific organ or its donor may be acceptable and better than the alternative of imminent death. From the recipient’s point of view, it is therefore important to approach quality and safety in terms of the risk–benefit balance rather than by attempting to eradicate risk entirely.

The European Commission has recently published a binding Directive on the Quality and Safety of Human Organs for Transplantation,¹⁸ with implementation by all member states required by August 2012. The Directive requires member states to establish and maintain a framework for quality and safety that covers all stages of the chain from donation to transplantation, and to identify a Competent Authority with responsibility to ensure compliance with the specific requirements of the various Articles of the Directive. In the UK, the Human Tissue Authority is now the Competent Authority, although it is able to delegate some areas of its responsibility to other statutory bodies, principally NHS Blood and Transplant. The stages covered by the various Articles are:

- (i) verification of donor identity;
- (ii) verification of the details of the donor's or the donor's family consent;
- (iii) verification of the completion of organ and donor characterization in accordance with specified criteria;
- (iv) the procurement, preservation, packaging, and labelling of organs;
- (v) the transportation of organs;
- (vi) the reporting of serious adverse events and reactions at any stage of the pathway.

Furthermore, it is required that:

'All healthcare personnel involved in the entire process are suitably qualified, procurement must take place in suitable operating theatres, donor selection and evaluation must be performed under the advice and assistance of a doctor of medicine, medical teams shall endeavour to obtain the required information from relatives of the deceased donor or other persons, and tests for organ and donor characterisation must be carried out by laboratories with suitably qualified personnel and adequate facilities and equipment'.

'The Competent Authority must

- (i) licence procurement organisations and transplantation centres,
- (ii) keep a record of the activities of procurement organisations and transplantation centres,
- (iii) issue appropriate guidance to healthcare establishments, professionals and other parties,
- (iv) establish a reporting system for serious adverse events and reactions,
- (v) put in place a traceability system,
- (vi) ensure that appropriate organ and donor characterisation reaches the transplantation centre in due time'.

There will be a certain impact on Specialist Nurses for Organ Donation, retrieval teams, organ transport arrangements, and transplant centres—if only in their need to be licensed by the Competent Authority—but the impact on those who care for potential organ donors (i.e. critical care teams) is likely to be negligible. Moreover, the Directive explicitly acknowledges that it is impossible to eliminate risk

altogether and that a risk–benefit analysis (even when relevant information cannot be obtained) should allow transplantation to proceed whenever it is appropriate.

Transparency and the role of registries in providing data on donation and transplantation activity and outcomes

The commentary on the EU Directive states: 'Transparency can be summarized as maintaining public access to regularly updated comprehensive data on allocation, transplant activities and outcomes for both recipients and living donors'. Many, but not all, countries with active donation and transplantation have a national—or supra-national—registry. The principal registries include the UK Transplant Registry held by NHSBT, the United Network for Organ Sharing and the Scientific Registry of Transplant Recipients in the USA, and the ANZDATA registry in Australia and New Zealand. The Collaborative Transplant Study is one of the largest transplant registries, with patient-level data from over 300 transplant centres worldwide.

Comprehensive data collection, storage, and analysis are a significant undertaking, but offer several important benefits. They allow the generation of a comprehensive overview of donation and transplantation activity and support the development of evidence-based practice (particularly with regard to organ allocation and transplant outcomes). They facilitate dissemination of learning regarding experience with rare diseases and complications and allow recipients of high-risk organs to be tracked should subsequent follow-up be required. Registry data make an important contribution to the monitoring and comparison of individual centres, help ensure equity of access to transplantation, and allow organs to be matched to highly sensitized individuals as effectively as possible.

The quality of registry data is important and involves steps to ensure that complete and accurate data are available, with suitable arrangements for data validation. Nevertheless, it is important to be aware of both the strengths and the weaknesses of registry data. Registries provide *retrospective observational* data with the potential for selection bias, missing data, and incomplete coverage. Furthermore, registry data may not be as detailed as the records at an individual centre. In contrast, although prospectively collected clinical trials data may allow a more robust comparison between different treatments or interventions, the sample size requirements are often prohibitive. In reality, registries play a significant role in providing the evidence base for the development of transplant practice, benefit patients through monitoring of allocation and transplant outcomes, and provide transparency to the entire pathway from donation to transplantation.

Conclusion

Organ transplantation is unique—a patient can only become the recipient of a transplant because another human has

donated the organ, either in life or after death. The dramatic clinical benefits of transplantation (emphasized by the remarkably good outcomes that are now achieved, at least in the short-to-medium term) are, however, not available to all who would benefit. The pressure to increase the number of organs available is felt worldwide, and many countries have introduced systematic programmes to increase donation. Regrettably, in some areas, practices have developed that have gone beyond the limits of ethical and legal acceptability and there has been intense activity—led by both political and professional organizations—to define practice that has a firm legal and ethical basis, which tries to maximize quality and safety. There is a strong movement encouraging all countries and regions of the world to work towards self-sufficiency, with as much emphasis on disease reduction as on increasing donation. Within these frameworks, there remains a great deal to be done to respond to the donor shortage and to offer the chance of a transplant to as many patients as possible.

Declaration of interests

None declared.

References

- 1 Sixty-Third World Health Assembly, May 2010, Resolution WHA63.22. Available from http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R22-en.pdf (accessed October 16 2011)
- 2 Delmonico F. A report of the Amsterdam Forum on the care of the live kidney donor: data and medical guidelines. *Transplantation* 2005; **79**: S53–66
- 3 Barr ML, Belghiti J, Villamil FG, et al. A report of the Vancouver Forum on the care of the live organ donor: lung, liver, pancreas, and intestine data and medical guidelines. *Transplantation* 2006; **81**: 1373–85
- 4 Organ trafficking and transplant tourism and commercialism: the declaration of Istanbul. *Lancet* 2008; **372**: 5–6
- 5 The madrid resolution on organ donation and transplantation. *Transplantation* 2011; **91**: S29–31
- 6 Gardiner D, Shemie S, Manara A, Opdam H. An international perspective on the diagnosis of death. *Br J Anaesth* 2012; **108** (Suppl. 1): i14–i28
- 7 Price DPT. Legal framework governing deceased organ donation in the UK. *Br J Anaesth* 2012; **108** (Suppl. 1): i68–i72
- 8 Farsides B. Respecting wishes and avoiding conflict: understanding the ethical basis for organ donation and retrieval. *Br J Anaesth* 2012; **108** (Suppl. 1): i73–i79
- 9 Council of Europe. Newsletter Transplant 2010. Vol. 15. September 2010. Available from <https://wcd.coe.int/ViewDoc.jsp?id=1227199> (accessed 17 October 2011)
- 10 Global observatory for donation and transplantation. Available from <http://www.transplant-observatory.org/pages/home.aspx> (accessed 17 October 2011)
- 11 Dominguez-Gil B (personal communication). Available from http://www.organdonation.nhs.uk/ukt/statistics/potential_donor_audit/pdf/pda_report_1011.pdf (accessed 17 October 2011)
- 12 Ratner LE, Sandoval PR. When disaster strikes: death of a living organ donor. *Am J Transplant* 2010; **10**: 2577–81
- 13 Brown RS Jr. Live donors in liver transplantation. *Gastroenterology* 2008; **134**: 1802–13
- 14 Dominguez-Gil B, Delmonico FL, Shaheen FAM, et al. The critical pathway for deceased donation: reportable uniformity in the approach to deceased donation. *Transplant Int* 2011; **24**: 373–8
- 15 Murphy PG, Smith M. Towards a framework for organ donation in the UK. *Br J Anaesth* 2012; **108** (Suppl. 1): i56–i67
- 16 World Health Assembly. Human organ and tissue transplantation: WHA57.18. May 22, 2004. Available from http://www.who.int/transplantation/en/A57_R18-en.pdf (accessed 17 October 2011)
- 17 Naqvi SAA, Ali B, Mazhar F, Zafar MN, Rizvi SAH. A socioeconomic survey of kidney vendors in Pakistan. *Transplant Int* 2007; **20**: 934–9
- 18 Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation L 207/14. Official J European Union