

## Organ Transplantation 1

# A call for government accountability to achieve national self-sufficiency in organ donation and transplantation

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Roughly 100 000 patients worldwide undergo organ transplantation annually, but many other patients remain on waiting lists. Transplantation rates vary substantially across countries. Affluent patients in nations with long waiting lists do not always wait for donations from within their own countries. Commercially driven transplantation, however, does not always ensure proper medical care of recipients or donors, and might lengthen waiting times for resident patients or increase the illegal and unethical purchase of organs from living donors. Governments should systematically address the needs of their countries according to a legal framework. Medical strategies to prevent end-stage organ failure must also be implemented. In view of the Madrid Resolution, the Declaration of Istanbul, and the 63rd World Health Assembly Resolution, a new paradigm of national self-sufficiency is needed. Each country or region should strive to provide a sufficient number of organs from within its own population, guided by WHO ethics principles.

### Introduction

In 2010, 98 countries were reported by WHO as having organ transplantation services.<sup>1</sup> In virtually all these countries the questions constantly being posed are where and how enough organs for transplantation are going to be obtained. The epidemic of end-stage kidney disease and the need for therapeutic transplantation are far outpacing organ availability, and the organ shortage has become a worldwide crisis. This issue has been unequally addressed by different countries (figure 1, 2). New paradigms are needed to address the inadequate and unequal supply, which has led to unethical solutions, such as transplant tourism and organ trafficking.<sup>2–4</sup> In the context of a global economy, with countries soliciting thousands of medical tourists, commercial models have been proposed to provide a sufficient organ supply, with human organs being treated as commodities to be purchased via business transactions.

The World Health Assembly (WHA) has made clear to member states that they have a responsibility to protect the vulnerable and the poor from being exploited as a source of organs for the rich.<sup>5</sup> WHO has called for the adoption of a new paradigm that involves governments taking national-level responsibility in fulfilling the organ donation and transplantation needs of patients, by accessing resources from within the country's population.<sup>6</sup> This concept is termed national self-sufficiency. The Declaration of Istanbul also states that jurisdictions, countries, and regions should strive to achieve self-sufficiency in organ donation by providing a sufficient number of organs for residents from within the country or through regional cooperation.<sup>2</sup> The pursuit of self-sufficiency in transplantation must entail strategies to decrease the incidence and prevalence of diseases that are treated by transplantation and to increase the availability of organs, as promulgated by the Madrid Resolution.<sup>6</sup>

In our view, if self-sufficiency is to be achieved for donation and transplantation, a comprehensive national

programme must include the following components: a framework of national legislation with regulatory oversight policy; a programme of deceased donation integrated into the national health system, with resources that sustain the programme; ethical practice of live donation that ensures donor safety (but not without deceased donation); donation and transplantation practices in line with worldwide ethics standards, particularly WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation (panel),<sup>7</sup> which have been endorsed in the 63rd WHA Resolution;<sup>8</sup> and a programme of preventive medicine that will avert the growth of the population of patients with end-stage organ failure. These elements need to be addressed by governments and health organisations and professionals in each country to enable the formation of consistent, self-sufficient programmes.

### Legislation and regulatory policies

Organ transplantation is different from other medical services because its practice does not rely solely on professional expertise. Other crucial factors are the medical suitability of donors and recipients and the willingness of live donors or deceased donors' families to donate. According to the 63rd WHA Resolution, governments have a responsibility to ensure appropriate access to safe and ethical transplantation, "with special attention to maximising donation from deceased donors and to protecting the health and welfare of living donors".<sup>8</sup> Mandatory organ-specific registries of transplant recipients and donors should be assembled to enable annual review of data. Analyses should be done of performance of the appropriate stakeholders to continually develop donation and transplantation policies and to improve the care of patients and donors. Legislation should be created to establish national frameworks for overseeing programmes, for instance by ministries of health or designated representative

For more on the [Global Observatory on Donation and Transplantation](#) see <http://www.transplant-observatory.org/Pages/Home.aspx>

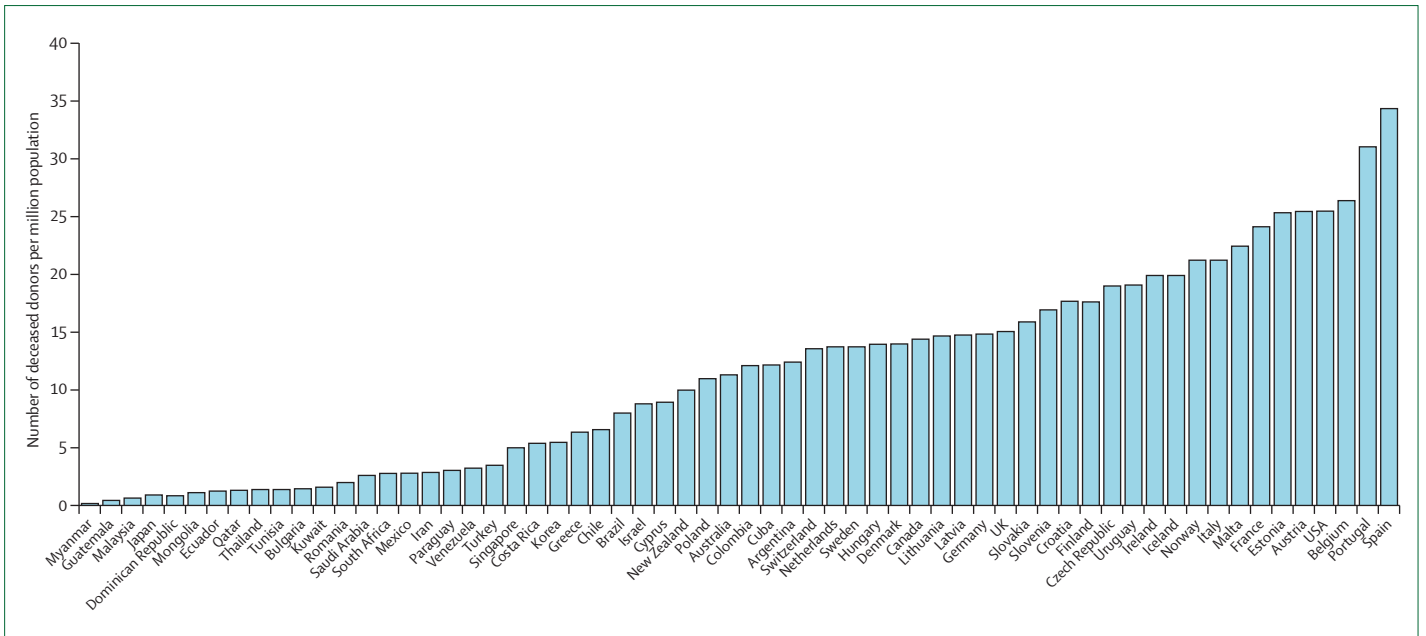


Figure 1: 2009 rates of organ donations from deceased donors for countries with any registered activity at the Global Observatory on Donation and Transplantation<sup>1</sup> Countries are ordered from lowest to highest donation rates. Reproduced from Global Observatory on Donation and Transplantation (GODT) by permission of WHO.

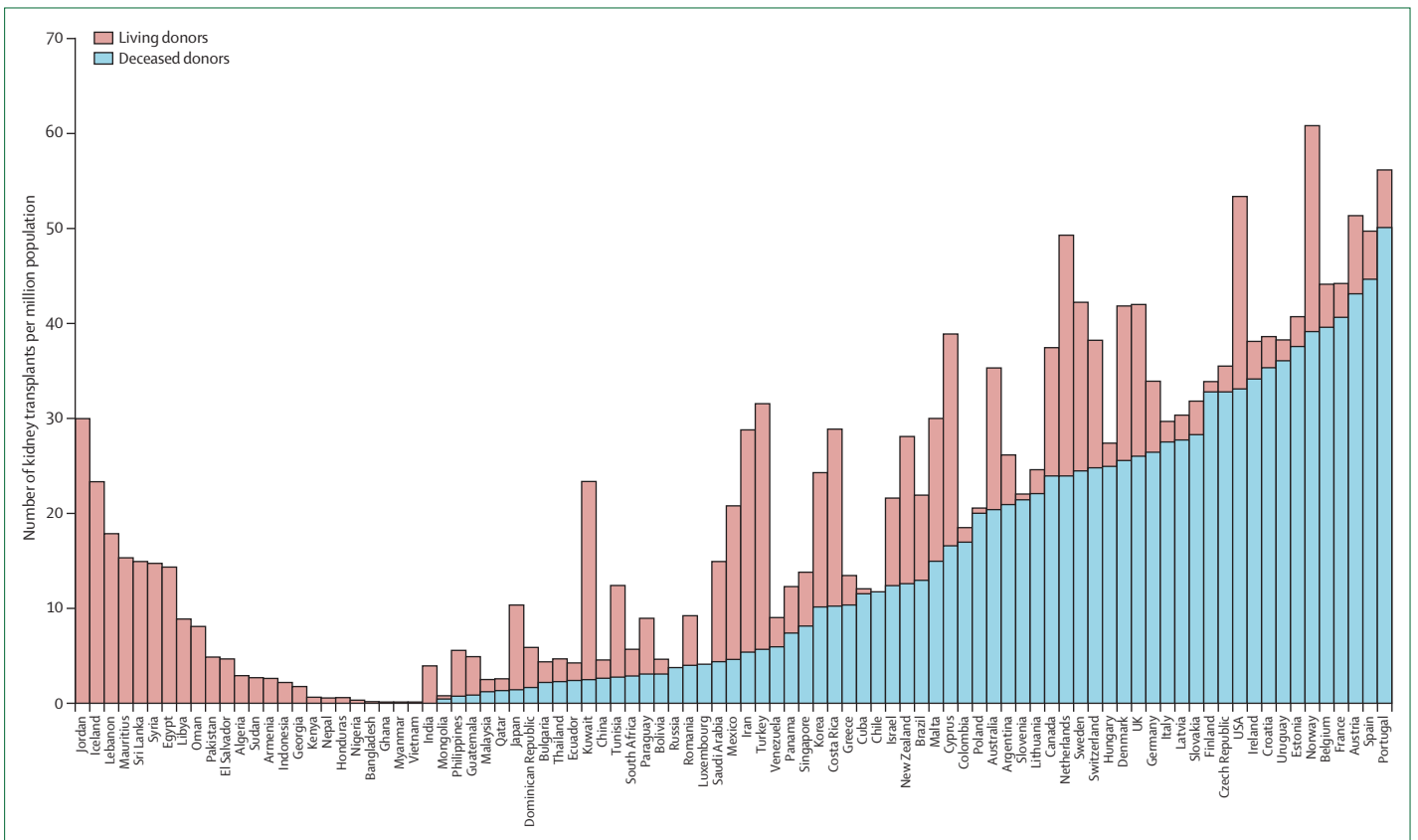


Figure 2: 2009 rates of kidney transplantation from living and deceased donors for countries with any registered activity at the Global Observatory on Donation and Transplantation<sup>1</sup> Countries are ordered from lowest to highest rates of kidney transplantation involving deceased donors. Reproduced from Global Observatory on Donation and Transplantation (GODT) by permission of WHO.

**Panel: WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation**

- Organs may only be removed from the bodies of the deceased patients after appropriate consent is obtained
- Physicians who determine the death of potential donors should not be involved in the removal or transplantation of their organs
- Donation from the deceased should be developed to its maximum therapeutic potential
- Living donors should be genetically, legally, or emotionally related to their recipients
- Minors and incompetent individuals should be protected from exploitation
- Organs should be donated freely without any monetary payment or reward of monetary value
- Advertisement of the need for or the availability of organs that include the offer of monetary payment should be prohibited
- Professional fees should not exceed justifiable limits for the services provided
- Health-care professionals and institutions providing or funding care should not engage in transplantation if organs have been obtained through exploitation, coercion, or payment
- Allocation of organs should be guided by equitable, externally justifiable, and transparent clinical criteria and ethical norms, and not by financial or other considerations
- Quality, safety, and efficacy of transplants and procedures should be ensured
- The long-term outcomes of organ donation and transplantation should be monitored for recipients and living donors
- The organisation and practice of donation and transplantation should be transparent, and the anonymity of donors and recipients should be maintained

organisations. Of the 98 countries with transplantation services, 83 reportedly have a national structure for supervision or coordination of organ donation and transplantation activities.<sup>1</sup> We recognise that the complexity of a national oversight structure might depend on the level of economic development of a country, but it cannot be omitted entirely.

A legal basis should be developed for the recovery of organs from deceased donors. Death, scientifically and medically, means the irreversible cessation of circulatory and respiratory functions or the irreversible cessation of all functions of the brain, including the brainstem.<sup>9-11</sup> Organ donation after death is now internationally referred to as donation after circulatory death or after death determined by neurological criteria or brain death. The percentage of organs recovered from donors after circulatory death remains low in many countries, although the proportions are progressively increasing.<sup>12</sup>

**Integration of deceased organ donation into national health systems**

Governments should establish national organisations that are accountable and that have the authority to organise, authorise, certify, and coordinate programmes for organ donation from deceased donors. The organs must be allocated to valid waiting lists of transplantation candidates who have been included irrespective of sex, ethnic origin, or social status. If patients were restricted from receiving organs, for instance owing to prioritisation according to social status, the motivation of people from all social classes to donate organs could be compromised. The underprivileged and poor should not be the main or sole source of organs, and they should benefit equally from the opportunity of transplantation. People in ethnic minorities who lack access to transplantable organs might distrust health-care systems and, understandably, be reluctant to support deceased donation. Thus, national programmes of deceased donation must promote public understanding of the shared benefit to be derived and shared responsibility to enable transplantation of organs from deceased donors. If a person can be an organ recipient, he or she should also be able to be give an organ, and vice versa. Without this understanding, non-consent to donate organs after death on a cultural basis becomes illogical (and hypocritical) if members of the same community receive organs from deceased donors in foreign countries.

The national organisations should also collect data and provide annual reports on donation activities to develop strategies for improvement. A critical pathway has been developed by WHO that classifies the procedural steps to enable the transition from being a possible deceased donor to an actual organ donor, and then to a utilised donor by the recovery and transplantation of at least one organ.<sup>13</sup> Unawareness of the medical suitability of dying patients is a major reason for physicians not appropriately identifying those who could be organ donors. The national organisations should, therefore, do retrospective audits of deceased patients to provide data and prospectively improve deceased donation.<sup>14-17</sup> The formal appointment of physician coordinators of organ donation in intensive care units is widely recognised as an effective approach to increasing organ donation.<sup>18</sup>

Some functions of the national organisations should be prescribed: medical assessment and management of deceased organ donors; overseeing of the consent process; implementation of the WHO donor pathway;<sup>13</sup> provision of care for the family of the deceased; and the creation or maintenance of a national registry to trace donated organs and tissues and to monitor outcomes in transplant recipients and live donors.

Adequate funding will be required to maintain infrastructure and activity. We recognise that the Human Development Index<sup>19</sup> strongly correlates with deceased donation activities, which indicates that a minimum level

of development is required to establish and maintain a national deceased donor programme.<sup>3</sup> The epidemic of end-stage renal disease is, however, causing difficulties for all countries. In response, emerging and developing countries, such as those in west Africa, are establishing programmes of dialysis. Kidney transplantation, however, is less costly and provides better quality of life and survival for patients, and such countries should be encouraged to allocate resources to donation and transplantation programmes that reduce the need for and expenditure related to dialysis.

### Ethical practice of live donation

The international transplant community has published medical guidelines for the use of living donors, created in forums convened in Amsterdam and Vancouver.<sup>20,21</sup> Live kidney donation has proven to be safe when done within an appropriate framework of donor care, although a small risk of death is well documented.<sup>22</sup> Transplantation of kidneys from live donors is considered a necessary adjunct to achieving national self-sufficiency, but the WHA has urged member states not to have national programmes that use only living donors.<sup>3</sup> In some countries transplanted kidneys are recovered mainly or solely from live donors (figure 2).

The Declaration of Istanbul calls on governments to ensure the protection and safety of living donors while combating transplant tourism, organ trafficking, and transplant commercialism.<sup>2</sup> Governments should deter travel to foreign destinations for the purpose of undergoing kidney transplantation from living donors that are unknown to the recipients. Israel has set an important example by prohibiting the authorisation of insurance benefits to cover the costs of transplantation in a foreign country that does not conform to the provisions of the Israeli 2008 Organ Transplant Act, which condemns organ trade.

Registries of live donors should include data on complications that required readmission to hospital and deaths associated with organ donation. These data will be important to improve information on the assessment of known risks provided when consent for donation is requested.

### Medical strategies to prevent end-stage organ failure

The prevention or delay of end-stage organ failure must be accomplished to reduce the need for organ transplantation and to achieve national self-sufficiency. This approach is especially relevant to low-income countries, where resources can be better used for other pressing medical needs. Thus, education programmes about organ donation for the public and the media should also address the maintenance of a healthy lifestyle. Early detection and prevention of diseases leading to end-stage organ failure, such as diabetes, cardiovascular disease, and kidney disease, is necessary.

### Conclusions

Governments can no longer abdicate responsibility for the organ donation and transplantation needs of their people. Legal restrictions in some countries make transplant tourism difficult to arrange and costly to accomplish, but a new paradigm of national self-sufficiency is urgently needed. We recognise that not all countries are able to provide comprehensive transplantation services. Thus, regional cooperation between countries with reciprocal availability to deceased organ donors will be necessary. Reductions in the demand for organs through medical strategies to prevent end-stage organ failure will also be necessary to achieve self-sufficiency. Without such a change, patients will continue to seek illegal and unethical organ transplants in remote parts of the world but return home for complicated medical care.

#### Contributors

All authors contributed equally to the concepts and recommendations expressed in the paper. FLD and BD-G wrote and corrected the drafts of the article. RM and LN reviewed the drafts.

#### Conflicts of interest

The authors declare that they have no conflicts of interest.

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