

The Madrid Resolution on Organ Donation and Transplantation

National Responsibility in Meeting the Needs of Patients, Guided by the WHO Principles

The Third Global Consultation on Organ Donation and Transplantation was organized by the WHO in collaboration with the ONT and TTS and supported by the European Commission. The Consultation, held in Madrid on March 23 to 25, 2010, brought together 140 government officials, ethicists, and representatives of international scientific and medical bodies from 68 countries.

Participants in the Madrid Consultation urged the WHO, its MS, and professionals in the field to regard organ donation and transplantation as a part of every nation's responsibility to meet the health needs of its population in a comprehensive manner and address the conditions leading to transplantation from prevention to treatment. Donation from deceased persons, as a consequence of death determined by neurologic criteria (brain death) or by circulatory criteria (circulatory death), was affirmed as the priority source of organs and as having a fundamental role in maximizing the therapeutic potential of transplantation.

Every country, in light of its own level of economic and health system development, should progress toward the global goal of meeting patients' needs based on the resources obtained within the country, for that country's population, and through regulated and ethical regional or international cooperation when needed. The strategy of striving for self-sufficiency encompasses the following features: actions should (1) begin locally, (2) include broad public health measures both to decrease the disease burden in a population and to increase the availability of organ transplantation, (3) enhance cooperation among the stakeholders involved, and (4) be carried out based on the WHO Guiding Principles and the

Declaration of Istanbul, in particular emphasizing voluntary donation, non-commercialization, maximization of donation from the deceased, support for living kidney donation, and meeting the needs of the local population in preference to "transplant tourists."

This new paradigm calls for the development of a comprehensive strategic framework for policy and practice, directed at the global challenges created by an increasing incidence of chronic diseases and a shortage of organs for transplantation. Self-sufficiency advocates national accountability for the establishment of an effective planning context for diseases treatable through organ transplantation and characterized by adequate capacity management, regulatory control, and an appropriate normative environment (Fig. 1).

1. National capacity management involves: (a) development of an adequate and appropriate healthcare infrastructure and workforce consistent with the country's level of development and economic capacity; (b) adequate and appropriate financing of organ donation and transplantation programme; and (c) management of need by investment in chronic disease prevention and vaccination.
2. National regulatory control consists of (a) adequate legislation, covering declaration of death, organ procurement, fair and transparent allocation, consent, establishment of transplant organizations, and penalties for organ trafficking and commercialization; (b) regulations covering procedures for organ procurement, reimbursement, and allocation rules; and (c) systems for monitoring and evaluation, including traceability and

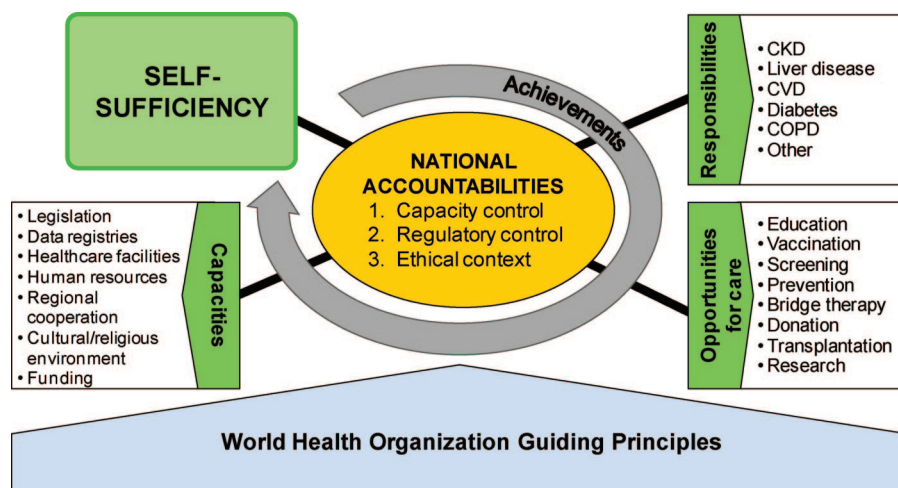


FIGURE 1. Schematic representation of the concept of national accountability in meeting the donation and transplantation needs of the population. CKD-chronic kidney disease; CVD-cardiovascular disease; COPD-chronic obstructive pulmonary disease.

surveillance, and for enabling evaluation of programme performance.

- National authorities need to lead normative change, from a perception of organ donation as a matter of the rights of donor and recipient to one of responsibility across all levels of society, through unambiguous legislation, committed support, and ongoing education and public information campaigns. Meeting needs of patients while avoiding the harms of transplant tourism and commercial donation from living persons is an ethical imperative that relies on the assumption of a collective responsibility for donation after death by all citizens and residents, thereby contributing to the common good of transplantation for all.

The health of all populations will benefit from a comprehensive response to diseases contributing to end-stage organ failure, from prevention to access to effective organ transplantation programmes made possible by a sufficient supply of donor organs. There is also a strong economic imperative to improve rates of transplantation and therefore organ donation: kidney transplantation is less costly to provide than dialysis, and therefore, maximizing rates of kidney transplantation would significantly reduce overall expenditure on renal replacement therapies. Kidney transplantation also results in better survival and quality of life outcomes and enables greater productivity and community participation. The perception of organ transplantation as an expensive and luxury clinical practice is invalid; rather it is cost effective, mainstream, and a cardinal feature of comprehensive health services. Beyond the unmistakable medical benefits to patients affected by end-stage organ failure, organ transplantation is a key to the challenge facing healthcare providers worldwide of unsustainable expenditures on dialysis services and has potential to generate further practical consequences for health systems.

From a public perspective, the pursuit of self-sufficiency relies on a communal appreciation of the value of organ donation after death. The concept of donating human body parts to save the life of another as a civic gesture is one that should be taught at school alongside health education to decrease the need for transplants. The pursuit of self-sufficiency in organs for transplantation exemplifies the public health and community values of equity, transparency, reciprocity, and solidarity, while it is the only safeguard against the temptation of yielding to trade in human organs.

In preparation for and during the meeting in Madrid, eight Working Groups identified specific goals and challenges and proposed solutions and recommendations from a number of perspectives. The Working Groups identified the common challenges faced by both developing and developed countries, the unique issues of particular societies and regions, and provided a rich and extensive set of recommendations directed at governments, international organizations, and healthcare professionals regarding how to best maximize donations from deceased persons (including the development of The Critical Pathway for organ donation; Fig. 2) and how to successfully progress toward meeting the needs of patients.

IMPLEMENTING SELF-SUFFICIENCY: RECOMMENDATIONS FROM THE MADRID CONSULTATION

The human right to health and dignity includes the recognition of all human needs for transplantation. While self-sufficiency is conceived as a common global goal, the capacity to meet patients' needs should be found primarily within each country's own resources, involving regulated regional or international cooperation when appropriate. The requirements of organ donation and transplantation programmes with respect to resourcing, proper organization, regulation and the oversight of procurement, processing and transplantation of human body components from living and deceased persons are matters that rightly come under the responsibility of governments, as outlined in Resolution WHA57.18.

Consistent with the political and ethical obligations of governments toward their citizens, the pursuit of self-sufficiency promotes the health and protects the interests of populations. Although the practical implementation of self-sufficiency will vary for different countries, influenced by economic factors, health sector development, and existing health priorities, the inherent values of the self-sufficiency paradigm and the WHO Guiding Principles on human cells, tissues and organs should guide organ donation and transplantation policy and practice in all contexts. The following overarching aspects of self-sufficiency were identified during The Madrid Consultation as subject to specific recommendations:

Preventing the Need for Transplantation and Increasing Organ Availability Are National Responsibilities

- Organ donation and transplantation have a role in the national health policies of all countries, regardless of current transplant capability.
- Of equal importance to infrastructure and professional development in organ donation and transplantation is sustained investment in prevention to reduce future needs for transplantation, through intervention in the major risk factors for end-stage organ failure and the development of health systems able to meet the challenges of chronic diseases such as diabetes, cardiovascular disease (CVD), and hepatitis.
- National transplantation legislation consistent with the WHO Guiding Principles is fundamental. It provides adequate protection from exploitation and unethical practices and eliminates legislative impediments constraining the science and medicine of donation from deceased persons.
- Public support for organ donation necessitates normative change. To this end, education of the public should begin in school, emphasizing individual and community ethical values such as solidarity and reciprocity. Self-sufficiency is founded in three main ethical premises:
 - The human right to health encompasses transplantation and disease prevention.
 - Organs should be understood as a social resource; equity must therefore govern both procurement and allocation.
 - Organ donation should be perceived as a civic responsibility.

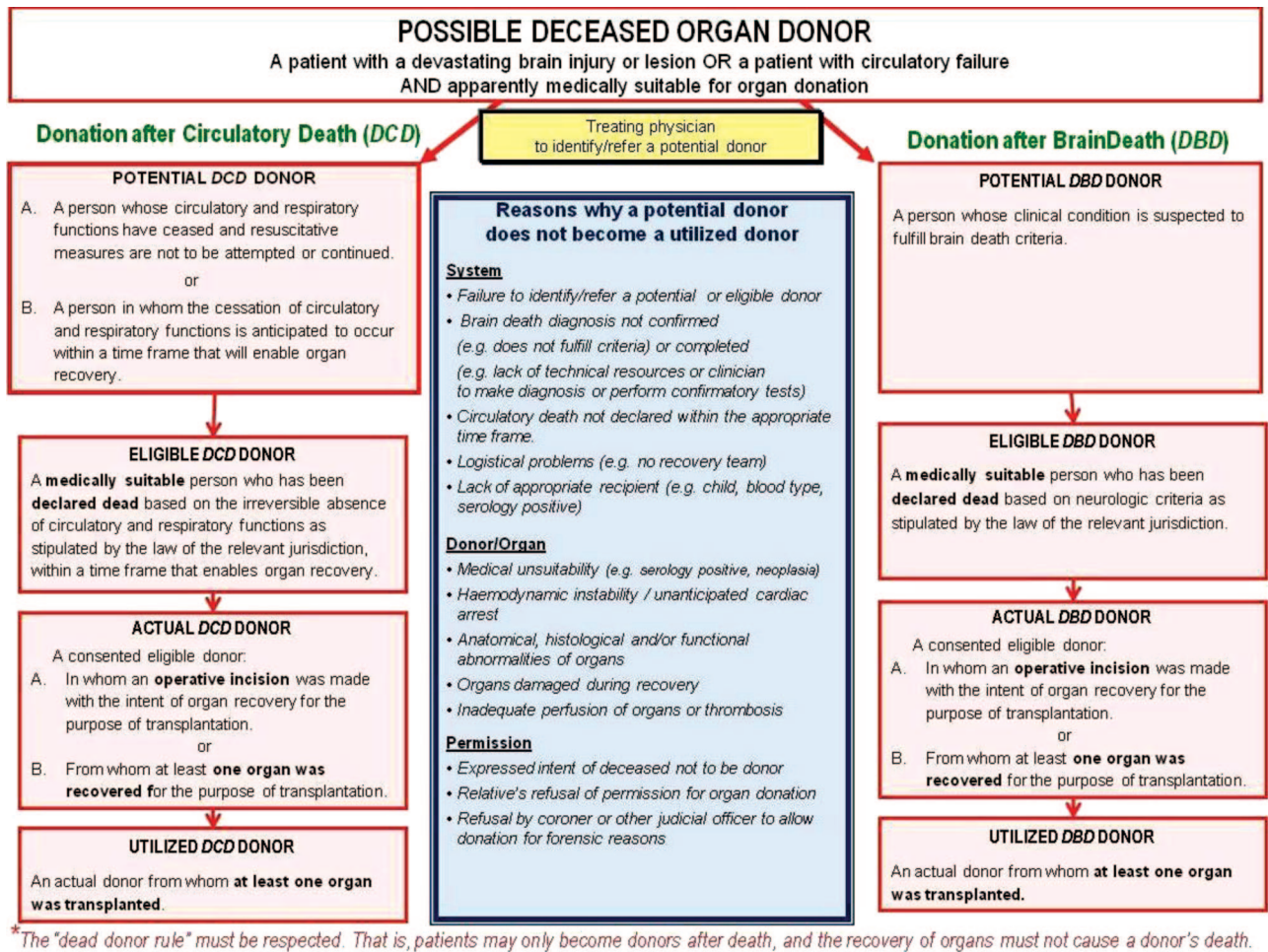


FIGURE 2. The critical pathway for organ donation. This figure was published in *Transplant Int* 2011; 24: 373–378. The figure has been reproduced with permission granted by Wiley-Blackwell.

Donation and Transplantation Reflect Comprehensive Health Care

- The critical functions of oversight, maintenance of professional standards and ethics, regulation, policy setting, and monitoring and evaluation of organ donation and transplantation programmes are most effectively managed by a National Transplant Organization (NTO).
- Data registries are necessary for operational support (waiting list management and organ allocation) and for monitoring and surveillance of practices and outcomes.
- Monitoring and surveillance should encompass the following data: national prevalence and incidence of end-stage organ failure and diseases contributing to end-stage organ failure (need); availability of related infrastructure and access to organ replacement therapies; outcomes of organ replacement therapy; acceptance onto transplant waiting lists and time to receipt of an organ; organ donation practices, standards and activities from living persons; and outcomes of transplantation (patient and graft survival). International harmonization of such metrics would facilitate comparisons between systems and

international benchmarking, identify regions in need of data, guide national policy making, and enable research.

Opportunities to Donate Should Be Provided in as Many Circumstances of Death as Possible

- The critical pathway provides a framework for the process of donation from deceased persons, which will aid global harmonization of practice.
- The key to self-sufficiency is maximizing donation from deceased persons: facilitating donation in as many circumstances of death as possible, maximizing the outcomes from each donor, and optimizing the results of transplantation. Donation after both brain death and circulatory death should be regarded as ethically proper. Organ donation from living persons should be encouraged as complementary to donation after death, by providing appropriate regulatory frameworks and donor care.
- Physicians and nurses involved in acute care have a central role in identifying possible donors and facilitating donation after death, and therefore should be supported by the necessary educational, technical, legal and ethical tools to assume leadership in this regard within their facility.