

The Reality of Inadequate Patient Care and the Need for a Global Action Framework in Organ Donation and Transplantation

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Background. Transplant therapy is considered the best and often the only available treatment for thousands of patients with organ failure that results from communicable and noncommunicable diseases. The number of annual organ transplants is insufficient for the worldwide need. **Methods.** We elaborate the proceedings of the workshop entitled “The Role of Science in the Development of International Standards of Organ Donation and Transplantation,” organized by the Pontifical Academy of Sciences and cosponsored by the World Health Organization in June 2021. **Results.** We detail the urgency and importance of achieving national self-sufficiency in organ transplantation as a public health priority and an important contributor to reaching relevant targets of the United Nations Agenda for Sustainable Development. It details the elements of a global action framework intended for countries at every level of economic development to facilitate either the establishment or enhancement of transplant activity. It sets forth a proposed plan, by addressing the technical considerations for developing and optimizing organ transplantation from both deceased and living organ donors and the regulatory oversight of practices. **Conclusions.** This document can be used in governmental and policy circles as a call to action and as a checklist for actions needed to enable organ transplantation as treatment for organ failure.

(*Transplantation* 2022;106: 2111–2117).

Received 12 November 2021. Revision received 21 February 2022.

Accepted 21 March 2022.

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INTRODUCTION

Transplant therapy is considered the best and often the only available treatment for thousands of patients with organ failure that results from communicable and noncommunicable diseases (NCDs). According to data from the Global Observatory on Organ Donation and Transplantation, >154 000 organ transplants were performed in 2019, after a steady increase over the last few years (Figure 1).¹ Yet, the World Health Organization (WHO) estimates that this constitutes only 10% of the organs needed for patients with life-threatening organ failure. The disparity between supply and demand of organs has been exacerbated by the COVID-19 pandemic, whose impact has resulted in an 18% decline in global transplant numbers.^{1,2}

This document details the need for a global action framework and sets forth a proposed plan. Our aim is to provide a document that can be used in governmental and policy circles as a call to action and as a checklist for actions needed to enable organ transplantation as treatment for organ failure. The action framework is intended for countries at every level of economic development to facilitate either the establishment or enhancement of transplant activity.

This work is a response to the World Health Assembly Resolution 63.22 (Table 1) and is also linked to the more recent United Nations Sustainable Development Goals.^{3,4} Its rationale is derived from the proceedings of the workshop entitled *The Role of Science in the Development of International Standards of Organ Donation and Transplantation*,⁵ organized by the Pontifical Academy of Sciences and cosponsored by the WHO in June 2021, which addressed the following healthcare issues:

1. Evaluation of the burden of disease that results in organ failure and necessitating organ transplantation for treatment and the need to include transplantation in the treatment continuum of universal healthcare;
2. A compelling case for prioritizing organ transplantation in the treatment of organ failure;
3. Technical considerations for developing and optimizing organ transplantation as a healthcare treatment option for patients with organ failure; and
4. Strengthening the regulatory capacity for oversight of practice.

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The authors declare no funding or conflicts of interest.

B.D.-G., N.L.A., and F.L.D. conceived the workshop. All authors contributed to the writing and approved the final version of the manuscript.

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ISSN: 0041-1337/20/10611-2111

DOI: 10.1097/TP.0000000000004186

EVALUATION OF THE BURDEN OF DISEASE THAT RESULTS IN ORGAN FAILURE AND NECESSITATING ORGAN TRANSPLANTATION FOR TREATMENT AND THE NEED TO INCLUDE TRANSPLANTATION IN THE TREATMENT CONTINUUM OF UNIVERSAL HEALTHCARE

Progressive organ failure resolved by organ transplantation, of course, is not limited to kidney or liver disease but includes cardiorespiratory and intestinal conditions. However, the annual number of affected patients worldwide undergoing organ transplantation is largely done by kidney and liver and thus was a focus of these proceedings.

Chronic kidney disease (CKD) is an important contributor to morbidity and mortality from NCDs and a risk factor for cardiovascular disease.⁶ The burden of CKD has increased in nearly all countries throughout the world.⁷ The drivers of these trends have been an increase in diabetes, obesity, and arterial hypertension, particularly in low- and middle-income countries (LMICs). The same is true for end-stage liver disease or cirrhosis, with an increasing burden despite some areas of progress (eg, hepatitis C therapies), because of conditions such as non-alcoholic steatohepatitis.⁸ CKD and cirrhosis are among the top 10 causes of death in virtually every country and among the top 5 in many. In LMICs, infectious diseases play a greater role in mortality, but emergence as a developed country carries with it increasing chronic disease deaths. All NCDs together accounted for 74% of deaths globally in 2019.⁹

Diseases that affect the need for transplantation impact not only the affected individuals but also communities and societies.^{10,11} The social and economic impact of these diseases (eg, major losses in productivity, people leaving the workforce, spouses leaving the workforce to care for those who are ill, divorces, drop-out from education) provides further justification for immediate action. There is a need to care for the increasing number of patients diagnosed with these diseases and to generate broader social and economic return for the communities at large.

Addressing CKD and liver disease—as well as diseases of the heart, lung, pancreas, and intestine—through transplantation is essential to support attainment of Sustainable Development Goal targets 3.4 (reduce premature mortality from NCDs)¹² and 3.8 (achieve universal health coverage).

A COMPELLING CASE FOR PRIORITIZING TRANSPLANTATION IN THE TREATMENT OF ORGAN FAILURE

Kidney Transplantation

A survey of worldwide countries, of which 155 answered questions pertaining to kidney transplantation (KT), revealed that 74% had KT available, with a median incidence of 14 per million population (range: 0.04 to 70) and median prevalence of 255 per million population (range: 3–693).¹³ Accessibility of KT varied widely; even within high-income countries, it was disproportionately lower for ethnic minorities. Universal health coverage of all KT treatment costs was available in 31%, and 57% had a KT registry. Gender disparity in access to transplantation (and in the burden of living donation) is also well described in the literature.¹⁴

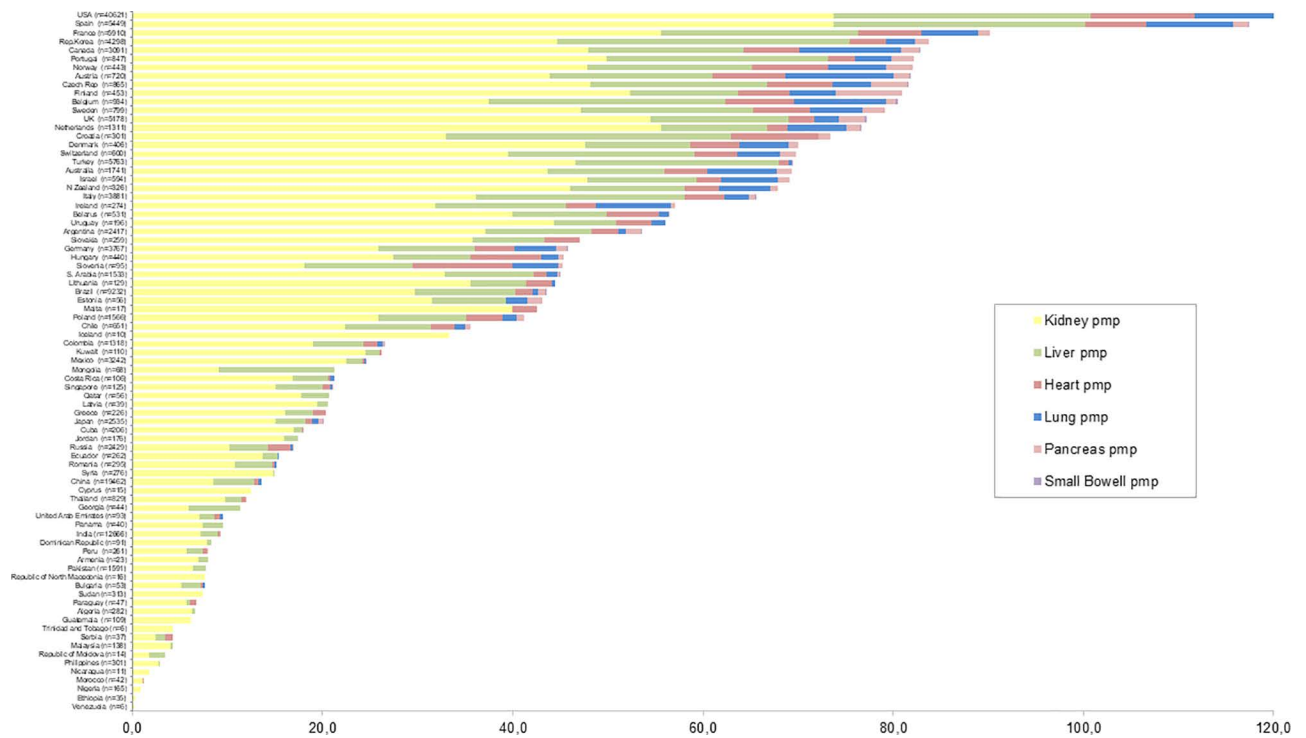


FIGURE 1. Number of transplants per million population (pmp) per transplant type by country in 2019. Source: Global Observatory on Donation and Transplantation. <http://www.transplant-observatory.org/>. Data accessed December 20, 2021.

People with CKD experience a reduced quality of life because of a high rate of disabling symptoms and treatment burden. Once an individual reaches end-stage renal disease, the treatment modalities are limited to KT, hemodialysis, and peritoneal dialysis. There is a disproportionate worldwide use of dialysis as kidney replacement therapy when compared with KT that cannot be explained when governments consider the advantages of KT. Worldwide in 2019, 100 094 kidney transplants were performed,¹ compared with >5 million patients undergoing dialysis annually.

KT versus dialysis is justified by cost-effectiveness, survival, quality of life, acceptability, fairness, and feasibility.^{15,16} What should be a feasible benefit package that governments include as part of universal health coverage for transplantation? We recognize that KT can cost as much as \$1500 per capita, whereas many LMICs have a total health expenditure of \$500 to \$1000 per capita. Investment in dialysis has increased in the last 5 to 10 y both in high-income countries and LMICs because of the dialysis company constituency, whereas there has been limited increase

TABLE 1.
Contents of the World Health Assembly Resolution 63.22

WHA 63.22 urges member states:

- (1) To implement the Guiding Principles on Human Cell, Tissue and Organ Transplantation in the formulation and enforcement of their own policies, laws, and legislation regarding human cell, tissue and organ donation, and transplantation where appropriate;
- (2) To promote the development of systems for the voluntary nonremunerated donation of cells, tissues, and organs as such, and increase public awareness and understanding of the benefits as a result of the voluntary nonremunerated provision of cells, tissues, and organs as such from deceased and living donors, in contrast to the physical, psychological, and social risks to individuals and communities caused by trafficking in material of human origin and transplant tourism;
- (3) To oppose the seeking of financial gain or comparable advantage in transactions involving human body parts, organ trafficking, and transplant tourism, including by encouraging healthcare professionals to notify relevant authorities when they become aware of such practices in accordance with national capacities and legislation;
- (4) To promote a system of transparent, equitable allocation of organs, cells, and tissues, guided by clinical criteria and ethical norms, as well as equitable access to transplantation services in accordance with national capacities, which provides the foundation for public support of voluntary donation;
- (5) To improve the safety and efficacy of donation and transplantation by promoting international best practices;
- (6) To strengthen national and multinational authorities and capacities to provide oversight, organization, and coordination of donation and transplantation activities, with special attention to maximizing donation from deceased donors and to protecting the health and welfare of living donors with appropriate healthcare services and long-term follow-up;
- (7) To collaborate in collecting data including adverse events and reactions on the practices, safety, quality, efficacy, epidemiology, and ethics of donation and transplantation;
- (8) To encourage the implementation of globally consistent coding systems for human cells, tissues, and organs as such to facilitate national and international traceability of materials of human origin for transplantation.

in investment in KT. We acknowledge that some LMICs may perceive a less favorable cost-benefit ratio of KT compared with dialysis; however, the cost-effectiveness analysis of dialysis and KT using quality-adjusted life years favors KT significantly.¹⁷

Liver Transplantation

There is substantial evidence that liver disease is increasing in incidence and is a major source of death and disability in the world. Liver disease affects patients of all ages compromising their life expectancy, quality of life, and productivity. Liver transplantation with both deceased and living donors is an effective treatment for chronic liver disease, fulminant hepatic failure and hepatocellular carcinoma with excellent short- and long-term survival. The alternative to transplantation is death in patients with both acute and chronic liver failure; as such, a cost-benefit analysis that can be done for KT versus dialysis cannot be done for liver transplantation. Many countries do not have active liver transplant programs, and some countries heavily rely on utilizing living donors. These data (Figure 2) show the estimated number of worldwide liver transplants in 2019, by WHO region.¹

TECHNICAL CONSIDERATIONS FOR DEVELOPING AND OPTIMIZING ORGAN TRANSPLANTATION AS A HEALTHCARE TREATMENT OPTION FOR PATIENTS WITH ORGAN FAILURE

The decision to embrace and support transplant activity must be assessed on the background of the community's (country's) burden of disease, loss to the community of productive members, and other health obligations that usually relate to the level of development. LMICs face barriers to building transplant capacity that includes technical expertise and prioritizing financial resources. High-income countries may face different barriers such as the availability of organs to satisfy the transplant needs.

It may be that a given country must start with the program with the greatest potential for benefit (eg, living donor KT in place of dialysis therapy), but ultimately,

these efforts may save enough expenditures to sustain the KT program. Once the infrastructure is in place and the work force has been developed, transplantation services may be expanded to include deceased donor transplants and indications be widened to expand to other life-saving transplants—because much of the transplant infrastructure is shared across all transplant types.¹⁸ In the last decade, the Spanish Organización Nacional de Trasplantes has made an assessment of the savings realized by KT when compared with dialysis, and the estimate revealed that those savings amounted to twice the annual cost of all organ (kidney, liver, heart, lung, and pancreas) recovery and transplantation activities (unpublished data). The savings can be appropriated for a variety of healthcare interventions, including the initiation of liver transplantation.

According to the 2017 Global Kidney Health Atlas, dialysis for treatment of kidney failure is now available in all countries. Given that, amongst the various kidney replacement therapy options, KT is associated with the best clinical outcomes at the lowest cost, it is the optimal form of kidney replacement for the large majority of patients with kidney failure. Therefore, once there is a decision by the government to provide a program of dialysis, the resources appropriated should include the initiation of a pilot KT program. In resource-constrained countries, where basic issues (eg, sanitation, provision of clean water supply, nutrition, control of infections, and maternal health issues) are the fundamental priority in health, the focus should be the protection of the population—through equitable implementation of preventive strategies that decrease the burden of end-stage organ failure and of measures to combat practices that entail the exploitation of the vulnerable.

Requirements for the development of a transplant program are (1) legislation, credentialing, and regulatory oversight; (2) financing of all aspects from donation to the long-term care of living donors and recipients; (3) workforce; (4) interventions and procedures; (5) laboratory; (6) medication; and (7) protocols (Table 2).

Legislation that enables oversight and regulatory capacity is a fundamental component for conducting organ transplantation. Legislation should be adopted to establish

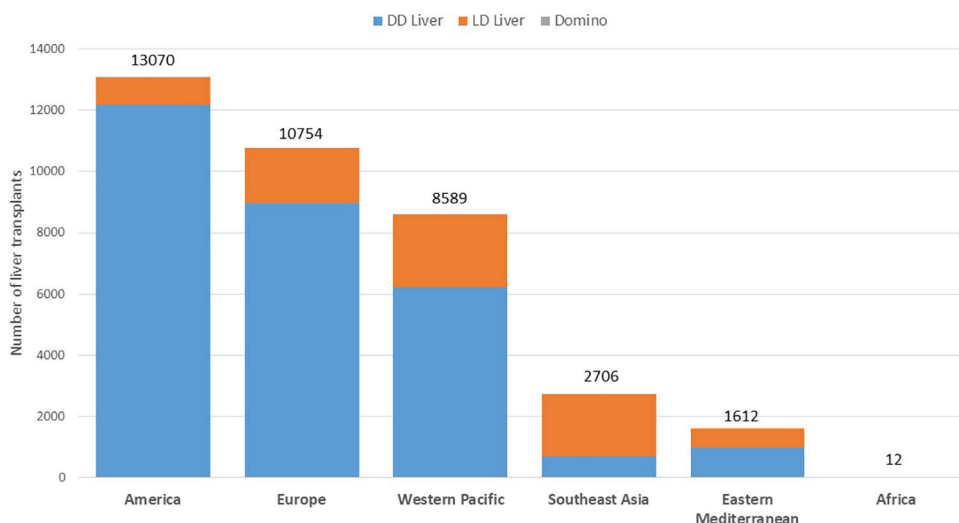


FIGURE 2. Number of liver transplants by region of the World Health Organization in 2019. DD, deceased donor; LD, living donor. Source: Global Observatory on Donation and Transplantation. <http://www.transplant-observatory.org/>. Data accessed December 20, 2021.

TABLE 2.**The essential components for an organ transplant program**

Legislation, credentialing, and regulatory oversight

Financing:

A national funding mechanism covering all aspects of transplantation, from donation to long-term care of donors and recipients, including affordable medication that is consistently accessible.

Long-term reliance on external funding, donors, and charities is not sustainable.

Workforce:

Physician/nephrologist/hepatologist with expertise in all aspects of transplantation (including patient selection).

Surgeon skilled in organ procurement, implantation, and management of surgical complications.

Histopathologist skilled in the interpretation of transplant pathology.

Infectious disease physician.

Access to ancillary services for management of medical problems.

Specialized nursing and support staff.

Interventions and procedures:

Access to dialysis.

Transplant biopsy and histopathological examination.

Interventional radiology.

Laboratory:

Standard laboratory assessment of blood and urine for biochemistry, blood count.

Access to microbiology and virology services, including the ability to screen for diseases that may be transmitted by the donor to the recipient.

Laboratory assessment of drug levels of immunosuppressants.

Access to histopathology for assessment of transplant biopsies.

Access to a laboratory for immunological work up, including HLA typing, crossmatch, and detection of donor-specific antibodies.

Medications:

Standard affordable immunosuppressive agents for induction and maintenance.

Infection prophylaxis.

Other basic medications.

Protocols:

Living donor selection and evaluation, including adequate donor protection and ethical oversight.

Suitability/eligibility of potential recipients including waiting-list management and the criteria for temporarily removing patients from the active waiting list for medical and other reasons

Suitability/eligibility of potential recipients including waiting-list management and criteria for placing active patients on and off hold for medical and other reasons.

Immunosuppression regimens depending on patient risk of rejection.

Retrieval, perfusion, and storage of organs.

Immediate postoperative management, fluid management.

Long-term follow-up of the recipient, including the treatment of rejection and other complications such as technical events.

Long-term follow-up of the donor.

Deceased donor organ consent and procurement.

Management of the deceased donor.

a national transplantation system to include the legal basis for living organ donation and for organ removal from deceased donors (Table 3). Legislation should also ensure altruism and noncommercialization in donation. Organs should be donated freely, without any financial gain or

TABLE 3.**The legal framework for the practice of organ donation and transplantation**

The legal basis for living kidney and liver donation:

The requirement that living donors are selected on the basis of their health and medical history. Persons whose donation could present unacceptable health risks should be excluded.

Rules regarding the nature of the relationship that would allow a person to donate to the intended recipient. Where living donation is allowed in the absence of a close personal relationship, the law should define procedural safeguards against coercion and commercialism.

The requirement that living donors should be legally competent. No organs should be removed from legally incompetent donors, unless narrow exceptions are defined and specific protective measures are in place.

Rules regarding the information to be provided, which should include the nature and purpose of the surgical procedure and the probable risks, benefits, and consequences of donation.

The principle that an organ should only be removed from a living person when that person's free, informed, and specific consent is obtained.

Donor motivation should be evaluated by an appropriately qualified, independent party so as to ensure that they act willingly and free of coercion and any undue influence, such as commercialism.

The requirement that consent should be either in written form or before an official body. The person concerned may freely withdraw consent.

The legal basis to maximize donations from deceased donors:

The principle that organs should not be removed from the body of a deceased person unless that person has been certified dead in accordance with national law.

Requirements for the determination and declaration of death.

The principle that physicians determining the death of potential donors should not be involved in the removal or transplantation of their organs.

The principle that organs should not be removed from the body of a deceased person unless consent or authorization required by national law has been obtained.

Rules regarding the system of consent or authorization, specifying the process of obtaining and recording consent or authorization for organ donation after death. No removal shall be performed if the deceased person had objected to it.

comparable advantage. Healthcare professionals and institutions should not engage in transplantation if organs have been obtained through exploitation, coercion, or payment. Legislation should also ensure equity and privacy in donation and transplantation and the anonymity of donors and recipients. The legal framework should be consistent with WHO Guiding Principles adopted by the World Health Assembly in 2010.¹⁹

Details of finance become relevant to each jurisdiction by the availability of resources. However, such detail is beyond the scope of this manuscript.

STRENGTHENING THE REGULATORY CAPACITY FOR OVERSIGHT OF PRACTICE

There is no standard of data collection by responsible national agencies to assess performance of transplant centers and improve patient care for transplant recipients and living organ donors. Ideally, data should be collected at 3 levels; internationally (exemplified by the Global Observatory on Organ Donation and Transplantation),

nationally, and at a center level. National authorities should facilitate the establishment/strengthening of a national organ donation and transplant registry, including mandatory reporting to the Global Observatory on Organ Donation and Transplantation by linking the authorization of transplant centers to the continuous and reliable delivery of the relevant data to the respective national agencies.

National waiting list, donor, recipient, and follow-up registries are essential to achieve and continuously monitor quality, expertise, safety, and transparency of all steps of the organ donation and transplantation process.²⁰

The establishment of a National Transplant Agency provides oversight, organization and coordination of donation and transplantation activities, and the establishment of registries and a system of traceability and vigilance to ensure safety, efficacy, and quality of organs (Tables 4 and 5).

Registries of living donor transplants should focus on the safety and well-being of the living donor. Complications that require rehospitalization of the living donor should be recorded, and, of course, so should donor deaths associated with the procedure of organ removal. Thus, registries provide important data to base the donor's consent on the assessment of known risks (at the specific center, national, and international level).

Well-established deceased organ donation programs are also essential components of each transplant program and a prerequisite for achieving national self-sufficiency

TABLE 4.
The authority and responsibility of a national donation and transplantation agency

Developing criteria to authorize centers to perform transplants and to certify transplant professionals;
Monitoring the functioning of procurement and transplantation centers;
Accrediting healthcare personnel and developing training programs;
Granting, suspending, or withdrawing authorizations of procurement and transplantation centers;
Issuing guidance to procurement and transplantation centers and healthcare professionals;
The procurement of organs is performed in accredited procurement centers;
Overseeing the maintenance of a waiting list available for patients to undergo organ transplant from deceased donors;
Developing the process of actively monitoring the waiting list and transplant activities of the transplant center;
Addressing the availability of organs and tissues through voluntary, nonremunerated donation and with a focus on donation from deceased individuals,
Overseeing the maintenance of registries that include these data:
organ donors, both living and deceased,
demographics of the donor/recipient relationship and their country of residence,
patients listed for organ transplants,
outcome (patient and graft survival) of the recipients of organ transplants,
transmission of donor infection or malignancy, and
traceability of organs;
Providing information on the need for organs for transplantation and promoting deceased donation; and
Supervising organ exchange with other countries.

TABLE 5.
The core data set to cover all elements of the organ donation and transplantation

The transplant by each organ;
The transplant by donor source: living or deceased;
The identity of the living donor by nationality and relationship to the recipient;
The occurrence of a complication in the living donor; death (including cause) or rehospitalization;
The recipient graft survival at 1 mo, 3 mo, 6 mo, 12 mo, 3 y, and 5 y and causes of graft loss;
The recipient patient survival at the same time intervals and causes of death;
A recording of the immunosuppression; and
Recipient rehospitalization: infection, cancer, and graft function.

(Table 6) with the leadership and guidance of intensive care professional societies. We recognize that cultural attitudes and education are an impediment to deceased organ donation; however, transplant programs should foster deceased donation to minimize the risk for living donors. Therefore,

TABLE 6.
The deceased organ donation process implemented by a national agency

The identification of suitable potential organ donors utilizing the critical pathway of the WHO²¹;
Conducting death audits to ensure appropriate referral of potential organ donors;
The management of deceased organ donors before organ (surgical) recovery;
The recovery of deceased donor organs by authorized transplant centers;
The allocation of recovered organs to a waitlist of candidates medically suitable for transplantation;
The collection of data in a central registry, which provides for an annual report of deceased organ donation, also detailing the distribution of organs;
Professional training and education of physicians and transplant coordinators within intensive care units and donor hospitals;
Public education and involvement of the media in the support of deceased organ donation donor;
Collaboration with regional/international organizations for potential sharing of organs; and
Funding accountability in a review of annual budget.
With hospital accountability:

- to establish a donation committee within each hospital and
- to identify responsible ICU professionals within each hospital for the conduct of organ donation whose responsibility in end-of-life care includes the identity and referral of organ donors and participation in the organ donation committee.

The deceased donor organ program should at least provide tools and national guidelines for a:
rapid alert/response system for close monitoring and reporting of persons with imminent death (possible/potential donors);
end-of life care and optimal donor management;
psychosocial support and step-wise approach to donor families; and
determination of death by neurological and circulatory criteria (medical, legal, and ethical code of practice).

WHO, World Health Organization.

countries should target this goal as a priority when building up transplant programs or optimizing access to transplantation treatment.

DISCUSSION

Organ failure, particularly kidney and liver failure, caused by NCDs and transmitted infectious diseases are exponentially increasing throughout the world. The transplant community has witnessed the life-saving transformation that can be achieved through successful kidney and liver transplantation and has advocated for a more widespread adoption of transplantation activity. KT provides the best survival and quality of life with cost efficiency when compared with dialysis. Thus, in LMICs, when the burden of kidney failure necessitates investment in a national program of dialysis, resources should be appropriated simultaneously to enable the development of a pilot KT center.

An action plan of organization and legislation is needed for all countries, whether low, middle, or high income, given the impact of organ failure upon individuals and the social and economic impact of diseases leading to organ failure. The strategic plan proposed in this document includes the regulatory mechanisms to ensure equitable access to transplantation. Governments have a responsibility to provide adequate numbers of donor organs and protection of living donors and to monitor the data needed to determine accurate outcomes and ensure transparency of the systems. International cooperation (financial, exchange of best practices, and provision of technical expertise) is required to support countries in progressing toward self-sufficiency in transplantation, particularly to low-resource countries.

ACKNOWLEDGMENTS

The enduring support and guidance of President Joachim Von Braun and Chancellor Marcelo Sánchez Sorondo of the Pontifical Academy of Sciences, WHO Assistant Director-General Mariangela Simão, and WHO Director of Department of Health Products Policy and Standards Clive Ondari are gratefully acknowledged. We also express our appreciation to Alexander Capron for insightful comments.

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