

Part 2: Reports From the Working Groups

WORKING GROUP 1: ASSESSING NEEDS FOR TRANSPLANTATION

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A Common Framework for the Accurate Assessment of Transplantation Needs

In an attempt to move toward sustainability and self-sufficiency with respect to organ donation and transplantation, nations must use a common framework and set of metrics. The goal of defining these metrics is that by doing so, a broader understanding of the gaps and issues facing different countries will be more apparent. Solution generation and dissemination may be facilitated if we start with a greater global understanding of the issues that currently exist.

Organ transplantation is the part of a continuum of care and health, which commences with recognition of risk factors, documentation of chronic conditions, and management of end-stage organ failure, which includes identification of the optimal treatment of that organ failure. Thus, a better understanding of organ transplantation requires an appreciation of the interaction between population needs, healthcare systems, and the availability of living and deceased donors as a source of grafts. It is well recognized that organ availability varies widely between and within countries, because of different combinations of cultural, ethical, religious, social, organizational, and practical issues. Furthermore, the care and outcomes of patients with failing organs varies depending on the organ affected.

Strategies for greater self-sufficiency in organ donation and transplantation must be informed by the accurate assessment of the needs of populations. Therefore, recognizing the diversity of outcomes, situations, and challenges facing trans-

plantation in different countries, internationally applicable metrics are required, which will support a consistent global approach to transplantation needs assessment. Through the comparison of a common set of key indicators, it is possible to establish the notion that end-stage organ failure and transplantation are indeed global issues; thus, the assessment of needs across regions and political and geographical boundaries, based on a framework of internationally applicable metrics, should stimulate comparisons, discussions, and ultimately common solutions to similar problems.

The Requirement for Common Metrics and Definitions

The requirement for common metrics and definitions has several aspects:

- a. A need for the clear identification of need according to standard definitions:
 - We strongly advocate for inclusivity of case reporting. That is, all cases of (incident) end-stage organ failure must be documented irrespective of treatment availability, cause, or eligibility/availability of organ replacement (true need). The availability of treatments introduces bias and must be acknowledged as a limitation of current metrics available and in current use around the world. Reporting of true need will help to focus public and political attention on the problem of insufficient donor organs available to meet transplantation needs.
 - Organ failure in all age groups and of all organs so as to ensure a true reflection of societal burden of illness.
- b. A need for the clear identification of drivers of need: this includes the identification of the number of individuals with multiple conditions to highlight the complexity of conditions, and the linkage between multiple organ dysfunction and end-stage organ failure within individuals.

Key Points

- *The application of an internationally consistent framework to the assessment of transplantation needs will enable a broader understanding of the issues facing different countries, and facilitate the identification of global solutions. Yet there is currently a paucity of the necessary metrics, tools, and definitions required to make standardized needs assessment possible.*
- *An international organ transplantation registry, using common definitions and metrics, should be established. For the purposes of this registry, the following national-level data should be made available: (i) true incidence and prevalence of end-stage organ failure, reported annually, (ii) availability of treatment for end-stage organ failure, (iii) waiting-list statistics, (iv) data relating to the identification of organ dysfunction and progression to organ failure, (v) referral to organ replacement therapy (transplant and non transplant), and (vi) time for workup, time to acceptance onto waiting list, and time to receipt of an organ.*
- *Governments should: (i) support identification of transplantation needs as a priority for public health improvement; (ii) create a registry for conditions leading to the need for organ transplantation; (iii) invest in prevention programmes; (iv) ensure the equity principle is applied in need assessment; and (v) create or support infrastructure and allotment of resources for all aspects of need assessment.*
- *The WHO should: (i) identify as a resolution that all countries shall have the ability to assess their needs for transplantation by 2020; (ii) identify and outline the need for a core minimum data set by which international comparisons will become meaningful.*
- *Professional societies and their members should: (i) ensure consistency in definitions and use of terms; (ii) support identification of organ failure /dysfunction as a strategic priority for the organization; (iii) foster international cooperation and intra-societal cooperation; (iv) support education concerning technical issues in needs assessment; (v) promote scientific enquiry in the area of needs assessment; and (vi) ensure linkages with governmental agencies and policy makers for translation of research into policy.*

- c. A need for the clear identification of factors that may impede ability to define true need: there is a need to systematically identify and document the nonmedical factors (e.g., economic, social, competing needs, bias, and attitudes) that influence the ability to conduct an accurate needs assessment with respect to organ transplantation or the prevalence/incidence and treatment of end-stage organ failure itself.

An International Registry for Organ Transplantation

To appreciate the international scope of challenges facing organ transplantation, an international registry of transplantation need using common definitions and metrics should be established. The development of common metrics relating to organ transplantation, and the reporting of these data to a central international registry, is intended to enrich currently available international data, and to harmonize reporting practices so as to permit a more cohesive global understanding of needs for organ transplantation. General points:

- Uniform data based on the true incidence of condition(s) should be forthcoming on an annual basis from each country.
- The documentation of the availability of organ replacement therapies should serve as a measure of “other resources” available but should not be used to define need. Comparison between countries who do and do not have supportive therapies available [e.g., dialysis and left ventricle assist device (LVAD)] should be of value.
- Mortality and morbidity statistics should be used to estimate theoretical needs for organ transplantation.
- Supplementary data from population-based, prospective, or cross-sectional studies, or from other cohort studies, would support the findings from mortality data.
- A set of useful indicators to inform needs assessment should be established in the absence of formal registries of transplantation need (and to ensure an understanding of the continuum of care and health in organ failure).

Key indicators include:

- High-risk conditions (incidence and prevalence) leading to organ failure;
- Organ failure (all age groups/all organs);
- Outcomes of patients with respect to
 - movement through stages of diseases (complex)—risk factors, early identification, end-stage organ failure, and replacement;
 - dynamic nature of chronic conditions adds complexity to data capture;
- individuals who have received organ replacement therapy, for example, the location of therapy delivered (inside vs. outside country);
- variability between and within regions with regards to
 - Acceptance criteria to organ replacement therapy,
 - Attitudes/nonmedical factors determining uptake of various therapies.
- Economic factors driving resource availability (equipment/facilities).

International Data Requirements

It is imperative that we are able to identify needs-related data that are relevant (to the pursuit of self-sufficiency at a national level) and thus would ask that the following information be available to all:

- By country, and as appropriate by region:
 - Prevalence and incidence of end-stage organ failure,
 - Prevalence and incidence of particular diseases contributing to end-stage organ failure,
 - Availability of treatment for organ failure (transplant and non-transplant);
- Waiting lists have different purposes and start times; thus, it would be of value to determine “true” wait times for organ replacement therapy (especially organ transplantation therapy);
- Wait lists keep growing because patients are not taken off despite being obviously unsuitable for transplantation, which needs to be recognized and factored in;
- A uniform method of tracking chronic organ failure would be of value, specifically a uniform tracking of key time points in the trajectory of disease;
- Data relating to the identification of organ dysfunction and the progression of organ dysfunction;
- Referral to organ replacement therapy (includes assist devices, and transplantation);
- Time for workup, time to acceptance onto waiting list (living donor or deceased as applicable), and time to receipt of organ.

In the context of international data comparisons, it is also relevant to consider: (1) what methods of successful needs prevention currently exist in the different regions? (2) Does the presence or absence of formal structures impact on the availability of data or resources? Any programme that aims to prevent end-stage organ failure will directly impact on the population need for transplantation, as needs will be favorably affected by the success of such programmes. Implementation of early detection and prevention programmes also strengthen data collection efforts and hence would make possible a more accurate assessment of the affected population. The need for prevention is more acute in countries with limited resources (though organ replacement therapy is expensive everywhere). This would need support from the health policy makers.

With respect to current international prevention strategies:

- Need to recognize the existence of such programmes, their scope, implementation methodology, and success. Examples include those among the Aboriginal population in Australia, Dharan (Nepal), and Chennai (India). Others may also exist in South America and Africa, but formal documentation of these need to be undertaken.
- There is a need to document variability across regions.
- To impress the planners, metric needs to be developed that would enable the estimation of the projected cost savings from prevention programmes.

The current state of data availability around the world should form phase 1 of the international assessment of transplantation needs, collated as an “information avail-

ability world map,” which documents the availability or non-availability of data on the indicators described earlier. This map would inform an understanding the “gaps” in “needs assessment” itself. (Note that the ideal source of these data would be national/regional registries, but other sources, such as smaller cross-sectional studies and representative population cohorts also have utility for this purpose.)

Metrics or Milestones: How Do We Know We Are Getting There?

- a. Create world map describing the current state with regards to ability to capture any data concerning the need for transplantation. This will allow benchmarking of the current state and methods of data monitoring and surveillance abilities for reporting change/improvements. This map may be used to:
 - Determine change by updating the map on an annual basis;
 - Identify areas of particular need.
- b. Road map/process, by which increasing data collection will inform transplantation needs worldwide, should be constructed:
 - Describing key elements of need assessment in hierarchical manner (information that will be pivotal in informing change);
 - Acknowledging regional variation in timelines to achieve this;
 - Acknowledging strategies that foster international collaboration (in data collection, dissemination, and possibly transplantation process itself).
- c. Showcase examples of successful meeting of needs for transplantation do exist, for example, Iceland. Such examples may be considered as case studies and reviewed for elements that exist within that community that have enabled it to achieve its current state; use as a benchmark against which to map the progress of other countries based on key indicators.
- d. Compare and contrast elements in each of the different situations of organ transplant success (excellent, moderate, and poor), so as to confirm the importance of each of the elements required for “needs assessment.”

Responding to the Challenges of Transplantation Needs Assessment

Challenges

There are a set of recognized challenges to the implementation of these goals which include, but are not limited to:

- a. A lack of clear definition as to who or what or when or where the responsibility for needs assessment (data collection and dissemination) lies within regions and countries.
- b. Competing needs in different regions or countries pertaining to the “human condition.” In those countries where infection, infant mortality, poverty, war, and starvation are key concerns on a day-to-day basis, organ transplantation needs must be regarded within the context of existing health and social priorities. At the same time, the framework by which achievements in organ

transplantation are assessed should be adaptable to all contexts, reflecting differing realities with respect to health system development and competing public health priorities and thus empowering the stepwise development of organ donation and transplantation systems in all nations, commensurate with the pace of development.

- c. Large variability across and within regions in their willingness to invest or allocate resources to information collection and a systematic approach to needs assessment.
- d. The fact that, despite the proposed need for uniformity of definitions and essential data elements across regions, this has not yet been achieved even in the developed world where data are more easily obtained and greater resources exist with respect to registries and data collection tools.
- e. A paucity of human resources (trained medical and other professionals) to assist in all aspects of needs assessment and treatment of organ failure—be it care, documentation, evaluation, and implementation.
- f. Difficulties in facilitating collaboration between various stakeholders in the pursuit of common goals within countries or regions because of political, economic, or other barriers.
- g. There is a need to identify opportunities for interregional or national collaborations where local resources would not support an independent programme. This would lead to improved outcomes and standardization of processes. It is recognized that given the diversity of international issues, these collaborations may vary over time, organ types, and situations.

Responses

Given the challenges above, the following responses are suggested:

- a. Each country or region should have the ability to:
 - Assess the incidence and prevalence of conditions that may lead to end-stage organ failure or the need for organ replacement therapy (transplantation), noting that prevalence is confounded by availability of therapies/survival outcomes/competing risks and is also relevant as a proxy indicator of need;
 - Assess the ability to accurately project progression of diseases and predict future incidence and prevalence of end-stage organ failure (future needs);
 - Assess the ability to deliver treatments to delay or prevent conditions that lead to need for transplantation (management of current and future needs);
 - Describe the nature and performance of current structures and organizations (or lack thereof) responsible for addressing the need for organs for transplantation (transplantation rates and waiting lists);
 - Describe accurately outcomes of patients with organ dysfunction/failure/transplanted and non-transplanted.
- b. Current state assessment:
 - It is important to acknowledge the variability of the capacity of individual countries or regions to identify those in need;

- It is important to recognize the diversity of resources available across the world and that strategies for increasing organ donation rates will vary depending on those resources;
 - The need for transplantation (vis a vis “other replacement therapies”) may differ in different parts of the world depending on:
 - patient demographics (e.g., need may be greater in countries where patients are younger or there is large population growth, or higher life expectancy),
 - availability of complimentary adjunct therapies for organ dysfunction,
 - availability of human and physical resources (trained professionals medical and nonmedical).
- c. Unanswered questions:
- Does the legal framework of a country impact need assessment? For example, a country may not have a legal framework that permits donation from deceased persons. This will change the assessment with respect to the achievability of organ donation from all appropriate sources.

Recommendations and Solutions

The following set of solutions and recommendations is defined according to organization/stakeholder. Note that each stakeholder is important to the process and the success of the strategy.

Governments should:

1. Support identification of organ failure/replacement needs as a priority for public health improvement.
2. Create a registry for conditions leading to the need for organ transplantation (all organs and all ages).
3. Invest in prevention programmes as the strategy to reduce needs (requires identification of at risk and early disease patients).

4. Ensure the equity principle is applied in need assessment (irrespective of access and resources).
5. Create or support infrastructure and allotment of resources for all aspects of need assessment (human and tools).

The WHO should:

1. Identify as a resolution in the WHA that all countries shall have the ability to assess their needs for transplantation by 2020 (which would include the capacity for data collection and information sharing).
2. Identify and outline the need for use a core minimum dataset by which international comparisons will become meaningful (Table 1).

Professional societies and their members (healthcare providers) should:

1. Ensure consistent definitions and use of terms in data collection.
2. Support identification of organ failure/dysfunction as a strategic priority for the organization (for instance in research, core mission, and advocacy).
3. Foster international cooperation and intrasocietal cooperation to ensure that data are available for the purpose of the evaluation of transplantation needs.
4. Promote and support education about needs assessment issues (methods, importance, and application).
5. Promote scientific enquiry in the area of needs assessment (validation).
6. Ensure linkages with governmental agencies and policy makers (translational research: bench to bedside to policy).

Patient groups should:

1. Be involved in public health initiatives and policy.
2. Be involved in educational programmes for peers/fam-

TABLE 1. Draft template for the assessment of needs for transplantation

| Stages: potential to actual needs | Assessment of potential needs (data requirements) | Tools for assessment (mechanisms) | Action/purpose (results) |
|--|---|--|--|
| Stage 1: diseases contributing to organ failure | Estimation of disease prevalence and incidence Chronic disease assessment Coexistence of multiple diseases (potential needs) | Population studies Registries Cohort studies | Identification of opportunities for prevention Future planning to ensure needs are met |
| Stage 2: organ failure/health conditions requiring organ replacement therapy | Identification of patients with organ failure/dysfunction | Education of primary healthcare professionals Reporting | Early intervention to manage organ failure and delay needs for transplantation Planning for future management |
| Stage 3: end-stage organ failure | Identification of transplantation candidates (actual needs ^a) Identification of those unsuitable for transplantation | Wait-listing/registering candidates Referral to appropriate specialists | Transplantation Provision of alternate therapies |
| Stage 4: transplantation | Registration of transplant recipients | Routine follow-up and monitoring of outcomes | Analysis of success in meeting needs, preventing needs, measuring benefits to recipients, etc. |

^a The accuracy of the measurement of “actual needs” will be influenced by numerous factors. We suggest mechanisms for monitoring accuracy, for example, through auditing of provinces and comparisons with national data, be developed in conjunction with other data requirements for this enterprise.

ilies and society to ensure value of registration and data collection well understood by all.

WORKING GROUP 2: SYSTEM REQUIREMENTS FOR THE PURSUIT OF SELF-SUFFICIENCY

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Essential Requirements and Key Functions of Organ Donation and Transplant Systems

To achieve self-sufficiency, it is necessary to both minimize the need for transplantation and maximize the utility of available resources through efficient organ procurement, successful transplantation, and optimal graft survival. This requires a number of specific systems, structural, organizational, and regulatory developments (Fig. 6).

Essential requirements for system development:

- Government support,
- Appropriate legislative, regulatory, and ethical frameworks,
- Adequate healthcare infrastructure,
- Adequate resources for programmes, including the long-term care of patients,
- Independent oversight,
- Share knowledge and experience with other system models.

Key responsibilities of organ donation and transplantation systems:

- Organ procurement,
- Establishment and maintenance of a transplant recipient waiting list,
- Allocation of organs,
- Exchange and transportation of organs both nationally and internationally,
- Approval of transplant teams and institutions,
- Safety and quality standards for organs,

- Traceability of all organs,
- Monitoring and auditing of transplantation procedures, using a transplant registry,
- Education of health professionals and the general public about transplantation and the importance of organ donation, including media engagement.

Essential organizational structures:

- NTO,
- Hospital transplantation programmes,
- OPOs,
- An allocation system,
- Traceability and surveillance systems,
- Data registries.

System Requirements

Legislative and Regulatory Frameworks

Clear legislative and regulatory frameworks are an essential system requirement to ensure ethical and transparent practices in organ procurement, retrieval, allocation, and transplantation. Specific requirements are as follows:

- a. Legislation: clear definition of brain death and circulatory death is necessary to enable donation from deceased persons, together with legislation governing the procurement and transparent allocation of organs and the establishment of OPOs. Legislation should also cover prevention of organ trafficking and commercialism and formal procedures for consenting donors. Critical areas for legislation are:
 - Declaration of death;
 - Organ procurement (deceased and living);
 - Fair and transparent allocation principles;
 - Consent;
 - Establishment of transparent organizations;
 - Prohibition of organ trafficking and commercialism.
- b. Regulation and oversight: regulatory bodies are needed to monitor practices, standards, and outcomes of organ donation and transplantation programmes and, therefore, must be informed by comprehensive surveillance and data collection. Regulatory oversight should guide ethical

Key Points

- Legislation must cover death declaration, consent, procurement, and allocation and must govern organ donation and transplantation practice in accordance with the WHO Guiding Principles.
- Regulatory bodies must establish ethically proper organ procurement and allocation processes, review existing practices, and standardize procedures and oversee performance.
- Proper legislation and regulation enhance progress toward self-sufficiency and enable policy making for improved organ donation; for example, countries may adopt “presumed consent” or “required request” by legislative/regulatory processes.
- National Transplant Organizations should be the highest authority in organ transplantation, responsible for maintaining transparency of programmes, monitoring and surveillance, policy setting and innovation to increase the donor pool; for example, utilization of expanded criteria donors and donation after circulatory death.
- Organ Procurement Organizations may enhance progress toward self-sufficiency by optimizing processes in the identification and management of potential donors: for example, critical pathways, education, death audits, mandatory reporting of potential donors, quality management, and coordination.
- Effective coordination of local, regional, and national systems involved in organ donation and transplantation is fundamental. Each country that performs transplantation requires a unified national coordination network that supports the entire system, through the oversight and regulation of organ distribution, transport, waiting lists, information dissemination, and policy implementation.

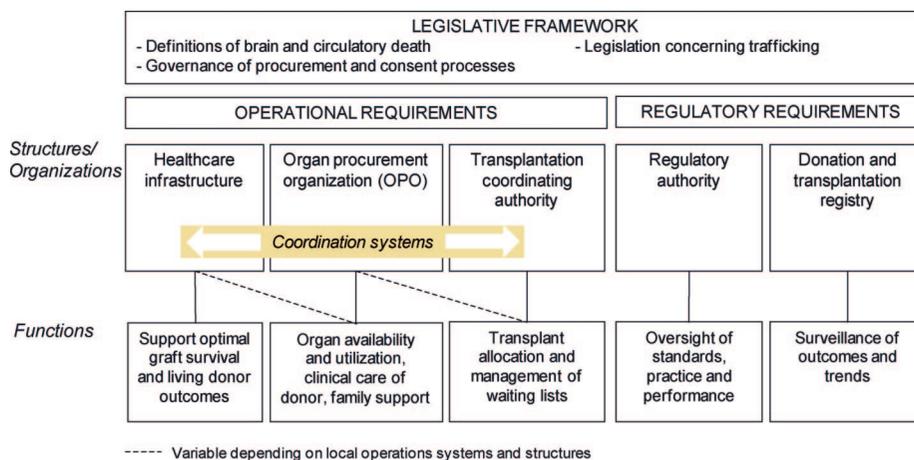


FIGURE 6. Flow diagram of system requirements supporting successful organ donation and transplantation programmes.

standards, development of policy, and quality management. Essential areas for regulation and oversight include:

- Organ procurement procedures;
- Development of new policies and introduction of new procedures;
- Reimbursement policies;
- Eligibility of living donors and consent processes;
- Quality assurance systems (control/audit and professional education and training);
- Allocation rules.

Key National, Provincial, or Regional Organizations

- a. The NTO: the NTO must have regulatory functions and provide oversight to all activities in organ donation and transplantation. They may also be responsible for the management of waiting lists, matching, and allocation and the maintenance of comprehensive registries that enable collation and analysis of data concerning the current status of organ donation, transplantation, and graft survival, to monitor trends, evaluate performance, and inform policy (see also Working Group 4).
- b. OPOs: the functions of the OPO include surveillance to detect potential donors, donor management (medical management before and after brain death), and procurement of organs (including donor assessment, ascertainment of consent, support to donor families, clinical care of the donor, and liaison with surgical teams). May be centralized and government led, or be under non-governmental authority; may be hospital-based OPOs (HOPOs) or independent OPOs (IOPOs). IOPOs operate outside the hospital setting and provide services to multiple transplant centers.
- c. National donation promotion programmes: governmental and NGOs have an important role in promoting community support for donation after death. This is achieved largely through public education to increase awareness, by engaging in public relations through the media and by acting as a consumer advocate group (see Working Group 6). Donation promotion may also extend to the promotion of ethically acceptable living donor programmes.

Hospital Transplant Programmes

Well-organized and professional hospital transplant programmes are essential to self-sufficiency.

- a. Hospital transplant programmes require specialist personnel (transplant surgeons, transplantation physicians, anesthesiologists, and transplantation coordinators) and infrastructure (intensive and high dependency care unit, hemodialysis unit, and transplantation laboratory).
- b. Organ procurement by authorized OPO: the OPO is a separate organization, which may operate within the hospital's transplant center or outside the hospital setting.
- c. A centralized hospital transplantation management team: responsible for regulation and oversight, encompassing a brain death determination team, the hospital ethical committee, and centralized oversight of education and quality control.
- d. Hospital efforts to expand the donor pool: evidence-based strategies for enhanced organ availability and utilization should be pursued as appropriate, including expanded criteria donors (ECDs), DCD, and desensitization protocols (see Working groups 3 and 5).

Coordination Systems

Multiple systems functioning at local, regional, and national (and sometimes international) levels are involved in organ donation and transplantation, necessitating an overarching system for coordination. National coordination systems provide a support agency for the entire organ donation and transplantation system, responsible for organ distribution, transport organization, waiting-list maintenance, information distribution, and any actions that can contribute to improved outcomes. International coordination facilitates cross-border exchange of organs, information, and research and is critical for combating organ trafficking and transplant tourism.

System Challenges

- a. Challenges for legislation:
 - Legislation absent or inadequate.
- b. Challenges relating to government support for key organizations:

- Lack of NTO,
 - Lack of control over the system or corruption,
 - No assessment of national needs or existence of donation and transplant registries,
 - Lack of system integration or professional consensus,
 - Lack of adequate financial support (understanding true costs associated with diagnosis and treatment is essential to building the business case for funding)
 - Competing governmental or health priorities.
- c. Challenges for healthcare systems:
- Lack of professional expertise in transplantation medicine and systems management,
 - Difficulties in identifying potential donors, managing their care, and procuring organs,
 - Lack of hospital infrastructures for management of potential donors,
 - Lack of coordinated in-hospital procurement team,
 - Inadequate healthcare system/resources/funding,
 - Inequitable access to health care,
 - Lack of follow-up of living donors.
- d. Challenges relating to public awareness and education:
- Poor public knowledge or understanding about donation and transplantation,
 - Absence of school education programmes regarding the importance of organ donation and transplantation,
 - Discomfort and inexperience of medical students and professionals regarding death diagnosis or transplantation and donation procedures.
- e. Challenges for societies:
- Lack of public solidarity and trust,
 - Misconceptions concerning organ donation and transplantation,
 - Cultural and religious perceptions or lack of awareness of brain death and donation,
 - Negative media attitudes.

Recommendations and Solutions for Governments

1. Incorporation of donation and transplantation into national health policies as a priority.
2. Investment in basic infrastructure and legislative frameworks required for transplantation.
3. Adoption of WHO Guiding Principles for Human Cell, Tissue, and Organ Transplantation.
4. Creation of necessary systems for regulation and oversight, to ensure transparency and facilitate review of progress and implementation of new strategies for success.
5. Incorporate education regarding donation and transplantation into school curricula and medical education.
6. Support for deceased donation programmes.
7. Creation of national registries, responsible for the maintenance of the transplant waiting list, and the ongoing registration of data on deceased and living donor activity, transplantation activity, transplant outcomes, and follow-up of recipients and donors.

Examples and References

An expanded report on the system requirements for self-sufficiency in organ donation and transplantation, with detailed examples and references is provided in Appendix 1.

WORKING GROUP 3: MEETING NEEDS THROUGH DONATION

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Organ Donation as a Critical Element in the Pursuit of Self-Sufficiency

Countries or jurisdictions should aim to maximize donation from deceased persons, maximize the outcome from each deceased donor (organs transplanted per donor), and optimize results of transplantation. Countries or jurisdictions should also aim to enable transplants from living donors by providing an ethical and legal framework and appropriate donor care.

- a. Donation from deceased persons is a requirement, because transplantation activity cannot rely only on the living donors. Both DBD and DCD are to be considered.
- b. Donation from living persons is a necessary component in the pursuit of self-sufficiency.

Challenges and Obstacles to Maximizing Organ Donation Activities

Legislation and Government

- Legislative frameworks concerning transplantation are absent in certain countries. Nine (9%) of 99 countries reporting to the GODT do not have yet a legislative framework for donation and transplantation. Two of the nine countries with no specific legislation on donation and transplantation reported kidney and liver transplantation activity in 2008; (1)
- Regulatory oversight of donation and transplantation activities is also absent in several countries. Of those countries reporting to the GODT, 15.3% had no official body nor other designated organization overseeing and coordinating donation and transplantation activities at a national level;
- Legislative impediments, such as the prohibition of DCD or other specific limitations to donation from deceased persons (e.g., viral diseases) are contained within the legislative frameworks on organ donation and transplantation in some countries.
- Inadequate support (including financial support) for donation and transplantation activities in the healthcare agenda.

Key Points

- Countries should aim to maximize deceased donation, maximize the outcome from each deceased donor (organs transplanted per donor), and optimize the results of transplantation.
- Deceased donation is a requirement, to be complemented by transplants from living donors. Both donation after brain death and donation after circulatory death are to be considered.
- The Critical Pathway for organ donation is to be considered a general framework of reference for systematizing the deceased donation process.
- Governments should: (i) establish legal frameworks that support and regulate the development of the medicine and science of donation and transplantation, and ensure quality, transparency, and equity of processes; (ii) support donation and transplantation in the health care agenda, allocating adequate financial resources for the development of the required infrastructure, organizational systems, technical expertise, and data registries for ongoing evaluation of programmes, and (iii) promote a culture of donation by engaging with the general public and health professionals to increase awareness and understanding, and to overcome misconceptions and cultural/religious barriers.
- The support of health professionals is critical to efforts to maximize organ recovery and transplantation.
- The WHO has a role in promoting implementation of the critical pathway, monitoring international data for benchmarking, and fostering regional cooperation for efficient organ sharing practices.

Public Attitudes and Media

- Cultural and religious barriers;
- Misunderstanding of brain death, circulatory death, and donation procedures.
- Public mistrust of the organ donation process;
- Social inequities that undermine consent for donation; populations or certain groups within a given population with no access to transplantable organs are reluctant to support donation after death;
- Misconceptions by the media and inadequate reportage of the benefits of organ transplantation.

Support From Healthcare Professionals

- A lack or inadequacy of knowledge, understanding, and support concerning organ donation and transplantation on the part of healthcare professionals, particularly for identification and referral of possible donors;
- Intensive care professionals not recognizing or supporting donation as a part of end of life care;
- Insufficient family care.

Organization and Systems

- Lack of a designated authority to oversee the process of donation and transplantation;
- Lack of OPO(s) with appropriately trained personnel;
- Lack of the basic infrastructure necessary for development of a deceased donation programme in resource-poor environments;
- Limited availability of mechanical ventilation and intensive care resources;
- Lack of protocols for the determination of death;
- Lack of technical expertise to recover organs from deceased donors;
- The availability of DBD may be limited;
- Lack of systematic approach to the process of donation from deceased persons, limiting the ability to realize the potential of organ donation from deceased persons particularly in terms of the number of organs transplanted per donor.
 - Failure to identify or refer potential deceased donors is to be considered the main limitation.
 - Other reasons why a potential donor does not become a utilized donor are specified in Appendix 2.

Recommendations and Solutions

Governments Should:

1. Create a legislative framework to enable and regulate donation and transplantation;
2. Eliminate legislative impediments that might constrain the medicine and science of organ donation and transplantation;
3. Provide adequate support (including financial support) for donation and transplantation in the healthcare agenda;
4. Ensure social equality in the access of patients to transplantation therapies and in the distribution of organs, while ensuring the transparency of the system;
5. Establish an authority to oversee the process of donation and transplantation. This authority should ensure the development of a systematic approach to the process of donation from deceased persons and be responsible for:
 - a. The systematic implementation of processes for donation from deceased persons, according to local realities with respect to legislation, cultural/religious beliefs, and technical capability. The Critical Pathway (Fig. 2) is to be considered a general framework of reference for systematizing the process of organ donation from deceased persons;
 - b. Appointment of qualified and trained professionals, including donor coordinators, to take specific responsibilities in every step of the process and be accountable for performance;
 - c. Definition of protocols for each step in the process of donation from deceased persons as described in the Critical Pathway, consistent with the local legal framework. This would include the timely identification and referral of possible deceased organ donors to the appropriate authority or organization. Recommendations in this regard are provided in Appendix 2.
 - d. Development of a quality assurance programme, including a data registry, for a continuous evaluation of organ donation and transplantation processes. This programme should estimate the potential of donation from deceased persons, evaluate overall performance in the deceased donation process, identify areas for improvement, and ascertain factors critical to success in each step of the deceased donation process, that is:
 - Identification and referral

- Consent
 - Evaluation of medical suitability
 - Donor maintenance
 - Organ recovery
 - Organ preservation
 - Organ transportation to transplant center
 - Organ transplantation
- e. Development of a training programme for those professionals direct or indirectly involved in the process of donation from deceased persons.
 - f. Promotion of a culture of donation by engaging the general public, specific groups (religious leaders, coroners, media, and academics), and healthcare professionals.

The WHO Should:

1. Promote the implementation of the Critical Pathway and related recommendations.
2. Monitor the collection of relevant data, assess international performance in donation from deceased persons for the purposes of benchmarking, and facilitate the exchange of knowledge and experiences among countries, as described in more detail in Appendix 2.
3. Foster regional cooperation in sharing of organs that preserves equity between donor and recipient populations and the efficient transplantation of otherwise discarded organs.

Healthcare Professionals Should:

1. Support the process of organ donation;
2. Identify and refer possible deceased organ donors in a timely manner; this particularly applies to intensive and emergency care physicians (see Working Group 5);
3. Make every effort to maximize the number of organs recovered and transplanted;
4. Promote the recovery of organs from DCD.

Donation From Living Persons:

1. Healthcare professionals should present the option of donation from living persons to families of individuals with organ failure.
2. The practice of donation from living persons should be consistent with the principles of Istanbul Declaration on organ trafficking and transplant tourism.

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WORKING GROUP 4: MONITORING OUTCOMES IN THE PURSUIT OF SELF-SUFFICIENCY

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Data Monitoring in the Pursuit of Self-Sufficiency

Self-sufficiency means satisfaction of the transplantation needs of a given population, using resources obtained from within that population. Importantly, populations may be defined by national or regional boundaries. The availability of reliable data on population needs with respect to transplantation, on the availability of organs from deceased and living donors, on patient access to transplantation, and on transplantation outcomes is of crucial importance in this framework. Only with this information it is possible to develop and determine the impact of policies and initiatives in the pursuit of self-sufficiency.

Areas of Relevance for Data Collection in the Self-Sufficiency Framework

Available Infrastructure

- a. Intensive care capacity
 - ICUs, beds, and ventilators
- b. Treatment of end-stage disease
 - Dialysis units and availability of other bridge therapies

Key Points

- *The pursuit of self-sufficiency is supported by data collection for the purposes of monitoring population needs, organ availability, access to transplantation, transplantation outcomes, and the broader policy/ regulatory environment and systems supporting organ donation and transplantation programmes.*
- *In all countries/regions, data should be collected on the following: (i) available infrastructure (hospital and organizational); (ii) regulatory oversight and health policy; (iii) current and likely future needs for transplantation; (iv) access to the waiting list and to transplantation; (v) waiting list outcomes; (vi) travel for transplantation and transplant tourism; (vii) organ donation from deceased persons; (viii) organ donation from living persons; and (ix) outcomes of transplantation (patient and graft survival). In each of these areas, a minimum dataset should be defined, based on common definitions and standard metrics, to facilitate international comparisons, benchmarking, and the identification of key performance indicators.*
- *Governments should: (i) support national/regional data registries with infrastructure and human resources; (ii) establish responsibility for operation and governance of this registry; (iii) facilitate cooperation between government and NGOs in monitoring outcomes and disseminating information to the scientific community, the public and policy makers; and (iv) use registry data to assess the impact of policy change and inform the need and direction of new legislation and policy.*
- *Professionals and Professional Societies should: (i) provide content expertise; (ii) cooperate on the consistency of data elements across the continuum of organ failure (i.e., CKD, dialysis, and transplantation); and (ii) facilitate development of an International Data Group for the ongoing collection of data that will empower individual countries and regions in the pursuit of self-sufficiency.*
- *This International Data Group should: (i) establish standardized definitions/metrics; (ii) provide/help to establish data registries in all countries/regions involved in organ donation and transplantation; (iii) perform international benchmarking and disseminate effective strategies and details of best practice; and (iv) conduct international studies to address specific data deficiencies.*

c. Transplantation services

- Transplant units and transplant programmes
- Transplant surgeons
- Living donor paired exchange, capacity to treat ABO incompatible and highly sensitized patients

d. Donation services

- Coordinators
- OPOs

An inventory of infrastructure (material and human resources) required to support organ donation and transplantation will permit comparisons between countries or regions with similar gross domestic product (GDP) and should assist countries or regions in advocating for necessary resources. Sharing of this information could facilitate international or regional initiatives for shared infrastructure developments (i.e., a human leukocyte antigen [HLA] laboratory or a training programme). Similarly, a longitudinal assessment of infrastructure over time in a region would help demonstrate the extent to which a country or region is improving. This effort would be advanced by the establishment of standardized “tiers” of infrastructure, that is, “minimal/essential, desirable, and optimal.”

Health Policies

- Regulatory oversight
 - Registration of transplant centers
- Financing (public/private)
- Recognition and prevention of end-stage organ failure
- Transplantation
 - Donation and organ recovery
- Selection of candidates for transplantation
 - Indications and contraindications for transplantation, guidelines for transplant referral and acceptance
 - Legislation governing practice of organ donation after death
 - Deceased donor organ allocation policies
- Living donor transplantation
 - Legislation governing practice of living donor transplantation

Information regarding the existence of legislation and regulatory oversight to ensure safety and the ethical practice of or-

gan donation and transplantation in accordance with international standards is fundamental to self-sufficiency. An inventory of health policies governing organ donation and transplant practices would provide useful information regarding the status of organ donation and transplantation in a given country or region. Furthermore, availability of international standards and policies governing donation and transplantation would facilitate identification of best practice in the pursuit of self-sufficiency.

Need for Transplantation

Underlying diseases, current (and future) demand for a transplantation (see also Working Group 1)

- Incidence or prevalence of underlying diseases such as HCV and diabetes mellitus (DM; this information could be obtained by International Classification of Diseases (ICD) codes, data from pharmaceutical companies regarding sales and use of specialized therapeutics),
- Use of bridge therapies (e.g., dialysis register, mechanical heart support),
- Deaths from end-stage organ failure (renal and non-renal organs) from national death registry,
- Population burden of renal and non-renal end organ failure.

Organ transplantation needs are correlated with the number of individuals suffering end-stage organ failure. If information on the incidence of underlying diseases is not available, death rates from end-stage organ failure might be a more easily accessible parameter. With this information, the demand for organ transplantation can be estimated, but perhaps more importantly, areas where preventative strategies might lead to a reduced need for transplantation can be identified. Cooperation between NGOs could support information sharing in this area; for example, there is significant overlap between cardiorenal diseases and diabetes and therefore cooperation between NGOs focused on these specific diseases should be encouraged. Kidney transplantation is cost effective in comparison with dialysis but is still an extremely expensive and resource-intensive intervention. The cost of caring for patients with end-stage failure of other organs would be useful in advocating for the investment of resources in prevention. The societal costs including lost wages, taxes, etc. and would also be useful to capture.

Access to the Waiting List and Transplantation

- a. Number of registrations on the waiting list (absolute number and per million population)
 - Basic demographic data on patients registered on the waiting list and comparison to population with end-stage organ failure.
- b. Derived indicators
 - Proportion of patients with end-stage organ failure that are wait listed;
 - Time to transplantation from any donor source from outset of end organ failure.
- c. Characteristics of transplanted individuals (compared with those of general population or, if available, population with end organ failure).

Patients should have equal access to the waiting list and to transplantation. The criteria for registration on the waiting list should be transparent and medically based. Documenting compliance with agreed guidelines should be prioritized. Comparing patient groups with an underlying disease in the population with those registered on the waiting list would allow monitoring of access to the waiting list. In countries or regions where the availability of bridge therapies (i.e., dialysis) and deceased donor transplantation is limited, waiting lists will be a poor indicator of access to transplantation. In these regions, the characteristics of transplanted individuals in relation to the characteristics of the general population, or the population with end-stage organ failure if these data are available, will provide some indication of the nature of access to transplantation.

Waiting List Outcomes

- a. Number of drop outs, deaths, and transplants (deceased/living donors, absolute number/ per million population).
- b. Differences in waiting times, preemptive listing, and time to wait listing.
- c. Proportion of preemptive kidney transplants.
- d. Outcomes for special patient groups (high urgency patients, highly immunized patients, and children).
- e. Compliance/deviation from rules governing organ allocation.

Monitoring longitudinal changes in time to transplantation, waiting time until transplantation, and death on the waiting list reflect both allocation policies and the availability of donor organs. The efficacy and fairness of an allocation and transplant system become especially evident when looking at special patient groups experiencing biologic barriers to transplantation. Transparent reporting of organ allocation rules and compliance with such rules is an essential component of any organ donation and transplant system.

Travel for Transplant, Transplant Tourism—Transplantation Outside the Population

- a. Occurrences in the population of delisting from the waiting list without transplantation.
- b. Need for post-transplant therapy without registration of a transplant.

Assessment of transplant tourism activity is an indirect indicator of sufficiency.

Organ Donation

- a. Identifying potential DBD and DCD donors in the hospital, converting potential donors to actual donors (see also Working Group 3).
- b. Identification of steps in donation process (identification of potential donors, approach, consent, organ recovery, utilization, and organ discard).
- c. Selection of donors, including risk management.
- d. Characterization of the donor—part of a meaningful assessment of system performance and transplant outcomes.

Outcome of Transplantation—Patient and Graft Survival

- a. Graft survival and patient survival
- b. Complications
 - Organ function—measured by glomerular filtration rate for kidney transplant recipients, measures of organ function in non-renal organs are not defined
 - Tumor, infection, etc.
- c. Derived: influence of donor characterization, derived from selection of donors (see *Organ Donation*, part c).
- d. Derived: influence of recipient characterization, derived from selection of recipients (see *Access to the Waiting List and Transplantation*)
- e. Benefit generated by transplantation
 - Life years from transplant concept
 - Reducing the need for retransplantation

The available donor organs should be used in an effective way, and optimal allocation policies and recipient management can increase the long-term benefit.

Living Donor Transplantation

- a. Access to living donor transplantation
 - Preemptive living donor transplantation
- b. Outcome of living donor transplantation
 - Living donor follow-up: documentation of policies for donor follow-up; mechanisms to identify negative outcomes in living donors (e.g., end-stage organ failure).
 - Recipient follow-up (graft and patient survival): similar to deceased donor transplant follow-up.

In living donor transplantation, not only do the recipient outcomes need to be monitored, at least as important is for donor outcomes to be monitored.

Establishment of Data Systems/Registries: Standardization, Technical And Legal Requirements, and Quality Assurance

Governance and Oversight for the Registry

- a. National policies/oversight to ensure adequate data collection, data integrity, and security
 - Objectives of registries have to be defined at a
 - National level (national health authorities and national medical societies)

- International level (WHO and international medical societies)
- b. Registry steering group/oversight body
 - Mandate and terms of reference
- c. Policies
 - Access to the data has to be defined on national and on an international level
 - Rules for data exchange have to be established
- d. Accountability/registry performance
 - Internal and external audits/performance reporting
 - Transparency

Clear ownership of the data, including the rights on reporting combined with established data privacy measures, is not only a legal obligation in most countries but are also mandatory to establish and maintain trust in the system. Ongoing assessment of registry performance is necessary to ensure transparency, compliance with governing principles, and the attainment of objectives.

Structure of Registries, Organization of Data Delivery to or Collection by Registry, and Quality Assurance

- a. Responsibility for data delivery/acquisition has to be clearly assigned.
- b. Multiple methods of data delivery (based on local infrastructure and needs).
- c. Secure data transfer consistent with national data protection regulations.
- d. Quality and timeliness of the data has to be assured, reinforced by auditing processes.
- e. Standardized registry maintenance policies have to be in place.

Data Elements

- a. Identification of essential data elements
 - Harmonization with existing national and international registries
- b. Modular system with different tiers of data with increasing complexity (required vs. optional data elements, adaptation to national needs and capabilities)
 - Age appropriate data elements have to be included (recognizing pediatric patients)
- c. Identification of derived key performance indicators with corresponding metrics for benchmarking.

Individual data elements need to be defined taking into account the availability of the data and the purpose to be achieved by collecting this information. The set of relevant and measurable factors may be different in the developing and the developed world. A comparison between countries (benchmarking) will only be possible if common definitions are used.

Financing of the Registry

- a. Financing of the registry has to be established by national health authorities
 - Maintenance of the registry

- Data collection and delivery to the registry (directly or indirectly)
- Data analyses, reporting

- b. National and regional registries contribution to an international registry should be free of charge.

Recommendations and Solutions

Overarching recommendations:

1. In all countries or regions data should be collected on the need for transplantation/burden of end-stage organ disease.
2. In all countries, whether or not there is an existing transplant programme, information on (the potential for) organ donation from deceased persons should be collected.
3. In countries with existing transplant activities, data on waiting lists, transplantation activities, and transplant outcomes should be registered.
4. In each of these areas, a minimum dataset with common definitions, allowing international comparisons and information exchange, should be defined.
5. The minimum dataset shall include standard methods/metrics by which to measure the sufficiency of organ transplant programmes and identify the key performance indicators relevant to monitor progress towards self-sufficiency. These include:
 - a. Need for transplantation,
 - b. Organ donation (deceased/living),
 - c. Access to transplantation,
 - d. Outcome of transplantation,
 - e. Transplant tourism.

Governments should:

1. Support the development and operation of national or regional registries. This includes investment development of infrastructure and human resources.
2. Establish responsibility for the operation and governance of the national or regional registry.
3. Ensure cooperation between bodies responsible for clinical care and those in charge of the registry.
4. Support national or regional registry participation in international data initiatives.
5. Facilitate cooperation between government agencies and NGOs to avoid duplication of efforts and promote the sharing of resources and data.
6. Ensure information is accessible by all stakeholders (scientific community, public, and policy makers). Reporting has to be adapted for each of these groups, with the common aim of uniting the lay public, engaging policy makers, and improving scientific knowledge.
7. Ensure data acquisition to assess impact of policy change and inform the need and direction of new legislation or policy.
8. Facilitate the development of an International Data Group for the ongoing collection of data that will empower individual countries and regions in the pursuit of self-sufficiency.

Professional societies should:

1. Provide content expertise necessary to support collection of national and international data relevant to the pursuit of self-sufficiency.

2. Cooperate to ensure consistency of data elements across the continuum of organ failure [i.e., chronic kidney disease (CKD), dialysis, and transplantation].
3. Advocate for appropriate national or regional infrastructure.
4. Support development of national or regional policies.
5. Facilitate development of an International Data Group for the ongoing collection of data that will empower individual countries and regions in the pursuit of self-sufficiency.

Recommendations for an International Data Group:

1. Establish standardized definitions or metrics.
2. Define “tiers” of data.
3. Provide/help to establish data registries in all countries/regions involved in organ donation and transplantation.
4. Showcase international success stories and disseminate effective strategies and details of best practice relating to organ donation and transplantation.
5. Organize and conduct international studies to address specific data deficiencies.
6. Publish global information and international comparisons relevant to the aim of sufficiency.
7. Facilitate cooperation between international NGOs.
8. Support national/regional efforts to achieve self-sufficiency.

Patient groups should:

1. Lobby policy makers for necessary resources.
2. Ensure common messages are being delivered to the lay public and policy makers.
3. Ensure patient need is the primary consideration of policies and legislation.

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WORKING GROUP 5: FOSTERING PROFESSIONAL OWNERSHIP OF SELF-SUFFICIENCY IN THE EMERGENCY DEPARTMENT AND INTENSIVE CARE UNIT

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The Critical Role of Emergency Department and Intensive Care Unit Professionals

Organ donation is a distinct, time-critical medical process that provides individuals with end-stage organ failure access to transplantation and its life saving, and life changing, benefits. Transplant programmes can rely on living-related donors to meet some of the need for donated kidneys, but self-sufficient donation programmes require a robust system of donation from deceased persons (not only hearts, livers, and lungs but also kidneys). The majority of deceased donor organs originate in EDs and ICUs, but in most countries currently, organs are obtained from only a small minority of ED and ICU patients who would be potential donors.

For a country (or region) to achieve self-sufficiency in organ donation, health professionals (principally physicians and nurses) involved in acute health care need to be aware of their indispensable role in identifying potential donors, in using their expertise in the medical management of these critically ill, dying patients in a manner that allows and facilitates donation, and in encouraging the families of these patients to consider donation and supporting them as they do so.

To be successful, organ procurement programmes must, therefore, seek to engage healthcare professionals in planning and executing organ donation in their facilities, especially in EDs

and ICUs. Doctors and nurses need to become aware of their responsibilities to the broader community and the relevance of their skills to organ donation; further, they must have confidence to support the delivery of this service. Healthcare professionals who participate in this work deserve to have their skills and endeavors recognized by their peers, policy makers, funders, and the community.

Conditions for Self-Sufficiency

- ICU and ED doctors and nurses are aware of the need for organ donation and therefore want to facilitate it;
- ICU and ED doctors and nurses know how to facilitate organ donation and have the educational, technical, legal, and ethical tools to do so;
- ICU and ED doctors and nurses are supported by their colleagues, hospitals, and health authorities in facilitating organ donation;
- Identified doctors and nurses in EDs and ICUs are recognized as experts in this area and in educating their colleagues about it;
- These doctors and nurses are expected to take the lead in enabling their ED or ICU to provide this service, including appropriate counseling for families.

Goals for Each Country/Region

Barriers to achieving Goals 1 and 2:

- ICU/ED physicians and nurses are not aware of the extent of the need for organs and the crucial role the ICU can play in meeting that need;
- ICU/ED physicians and nurses do not see organ donation as a part of their responsibility in caring for patients (potential donors) and families;
- ICU/ED physicians and nurses believe that responding to need for organs would represent a conflict of interest with their obligations to dying patients;
- ICU/ED physicians are not familiar or comfortable with determining death in donors or are not, or do not feel, competent to perform relevant tests;
- Specific resources or expertise are not always available in a timely manner to support the diagnosis of brain death (e.g., cerebral angiography);
- ICU/ED physicians and nurses are not compensated or rewarded for the time spent in facilitating organ donation;
- Limited ICU/ED resources restrict the ability of physicians and nurses to be involved in organ donation;
- ICU/ED physicians and nurses face, or believe they will face, difficult ethical and legal issues in caring for potential organ donors;
- Organ procurement staff are not available in a timely fashion to interact with ICU/ED patients and their families;
- The country lacks adequate infrastructure/resources to procure and use organs for transplantation.

Barriers to achieving Goal 3:

- Cultural factors in a country preclude using techniques that work in EDs and ICUs elsewhere;
- Organizational factors (from national to institutional level) interfere with importing techniques that work in other EDs and ICUs;

Key Points

- *The majority of deceased-donor organs originate in EDs and ICUs. Hence the pursuit of self-sufficiency requires ICU and ED doctors and nurses to: (i) be aware of the need for organ donation and are motivated to facilitate it; (ii) know how to facilitate organ donation and have the educational, technical, legal, and ethical tools to do so; (iii) be supported by their colleagues, hospitals, and health authorities in facilitating organ donation; (iv) have identified doctors and nurses in EDs and ICUs recognized as experts in this area, who take the lead in enabling their ED or ICU to provide this service, including appropriate counselling for families; and (v) be involved in the development of protocols for organ donation within their ICU/ED.*
- *Goals for each country/region with respect to the pursuit of self-sufficiency in the ED and ICU are that: (i) every death in ICU of a potential donor will lead to a timely decision regarding donation; (ii) every death in an ED of a potential donor will lead to a timely decision regarding donation; (iii) each country will be offered solutions that can be customized to apply to the specific circumstances of its EDs and ICUs.*
- *Governments should develop clear legal and ethical frameworks to guide ICU and ED professionals in the care of potential donors, including: (i) standards for determining death that are enacted by the legislature and accepted by the public; (ii) tests and methods that physicians can readily use to apply these standards; and (iii) clear statements regarding the responsibility of various care providers to donors and recipients, ensuring individual intensivists and ED physicians are not vulnerable when facilitating organ donation processes.*
- *National Professional Bodies should: (i) provide clear protocols on how treatment decisions relate to donor status and to alternative (circulatory/respiratory and neurologic) bases for determining death; (ii) provide clear protocols on how to manage dying process for patients whose deaths will be determined on circulatory/respiratory or neurologic grounds, as and on post-death maintenance of body; and (iii) educate nurses and physicians on how to make donation an understandable and acceptable choice for families.*
- *Hospitals should: (i) facilitate local ED/ICU staff “ownership” of potential donor management; (ii) identify champions of organ donation within the ICU/ED team; (iii) appoint donor coordinators within hospitals to facilitate communications amongst ICU/ED staff, families and transplant authorities; (iv) include the possibility for organ donation in every end-of-life care pathway within the ICU and ED; (v) improve the interface with the local transplant team and responsible national authority; (vi) identify strategies to optimize available resources for the conversion of potential donors to actual donors; and (vii) audit outcomes of the donation process.*

- The public does not understand or accept the goals of organ donation and believes that ethical conflicts exist when physicians and nurses in EDs and ICUs are involved in organ procurement.

Recommendations and Solutions

Governments should:

1. Develop clear legal and ethical frameworks to guide ICU and ED professionals in the care of potential donors, including:
 - a. Standards for determining death that are enacted by the legislature and accepted by the public;
 - b. Tests and methods that physicians can readily use to apply these standards in EDs and ICUs;
 - c. Clear statements, at institutional and governmental levels, regarding the responsibility of various care providers to donors and recipients.
2. Provide clear and unambiguous guidance from the ministry of health (and other responsible authorities) and hospitals to ensure individual intensivists and ED physicians and nurses are not vulnerable when aiding organ donation processes.

Professional Bodies should:

1. Offer training and guidance for ED and ICU nurses and physicians on how to identify potential donors, communicate with family, determine death, optimize donor

physiology, and interact with OPO and transplant team. Specifically, this should cover:

- a. Clear guidance on how treatment decisions are reached (e.g., for patients with severe neurologic injuries) in the context of potential organ donors and on the circulatory and neurologic criteria for determining death;
 - b. Clear protocols on how to manage dying process for patients whose deaths will be determined on circulatory or neurologic grounds;
 - c. Clear protocols on the optimization of donor physiology in brain dead donors to maximize the number of organs donated and the quality of those organs;
 - d. Education for nurses and physicians on how to make donation an understandable and acceptable choice for families of dying patients.
2. Support the development of academic and scientific research activity in the emergency and intensive care communities to create a professional investment in the best practice approaches that emerge.

Hospitals Should:

1. Give local ED and ICU staff “ownership” of solving the problems and developing protocols for managing the care of potential donors.
2. Identify individuals within the ICU or ED team who can act as role models or “champions” to increase the profile of

Goal 1

Every death in ICU of a potential donor will be preceded by a timely decision regarding donation

Goal 2

Every death in an ED of a potential donor will be preceded by a timely decision regarding donation

Goal 3
Each country will be offered solutions that can be customized to apply to the specific circumstances of its EDs and ICUs

organ donation within individual ICUs and EDs and provide education for the team on all relevant issues.

3. Appoint donor coordinators within hospitals to facilitate communications among ICU/ED staff, bereaved families, and transplantation services.
4. Include the possibility or potential for organ donation in every end-of-life care pathway within the ICU and ED (Fig. 7).
5. Improve the interface between ICUs/EDs and the local transplant team and responsible national authority.
6. Identify strategies to minimize the effects of lack of resources on the conversion of potential donors to actual donors.
7. Audit outcomes of the donation process within each ICU/ED and hospital to allow potential areas for improvement to be identified and achievable targets to be set.

Examples and References

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WORKING GROUP 6: THE ROLE OF PUBLIC HEALTH AND SOCIETY IN THE PURSUIT OF SELF-SUFFICIENCY

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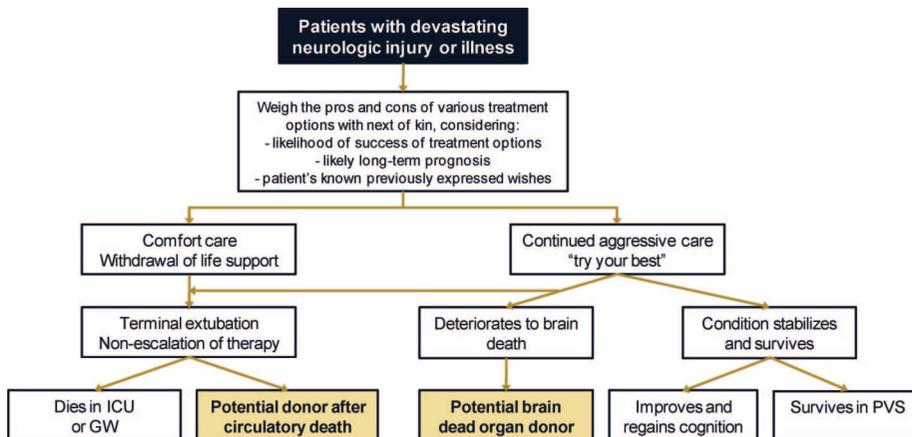


FIGURE 7. Flow chart for decisions regarding patients with severe neurologic injuries (example). ICU, intensive care unit; GW, General Ward; PVS, Permanent Vegetative State.

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The Relationship Between Public Health and Society and the Pursuit of Self-Sufficiency

Public Health and society are closely interrelated because: (1) the mission of public health is the fulfillment of society's interest in assuring the conditions in which people can be healthy; (2) the substance of public health is organized community efforts aimed at the prevention of disease and the promotion of health; and (3) the organizational framework of public health encompasses both activities undertaken within the formal structure of government and the associated efforts of private and voluntary organizations and individuals (1).

Public health is to play a key role in the pursuit of self-sufficiency by reducing demand through prevention of end-stage organ failure potentially leading to transplantation and by promoting donation among health professionals and the general public. Another contribution of public health is through the establishment of a well-developed healthcare system and transplant programme.

Society must possess the willingness to promote and support donation, otherwise there would be no organs to transplant. A second societal contribution to the pursuit of self-sufficiency is in the form of community funding for donation and transplantation through public finance and charitable sources. Table 2 summarizes the roles of public health and society in the pursuit of self-sufficiency.

Role of Public Health

Prevention of End-Stage Organ Failure

Certain causes of end-stage organ failure potentially leading to transplantation are amenable to primary, secondary, and tertiary prevention (Table 3).

NCDs are the global leading cause of death, accounting for approximately 60% of all deaths in 2005, with 80% of NCD-related deaths occurring in low- and middle-income countries (2). This mortality burden attributable to NCDs is predicted to continue to increase rapidly in coming years. Approximately half

of NCD-related deaths are attributable to preventable CVD, DM, cancer, or chronic respiratory disease, with the magnitude of this disease burden a result of two main factors: (1) changing patterns of lifestyle-related risk factors—increased levels of exposure to tobacco use, unhealthy diets, physical inactivity, and the harmful use of alcohol—and (2) issues of access to effective and equitable healthcare services, most acutely affecting populations of low- and middle-income countries.

These data have important implications. First, NCDs impose a heavy burden on socioeconomic development and are closely associated with poverty. Second, CVD, DM, cancer, and chronic respiratory diseases can lead to end-stage organ failure, potentially requiring transplantation. Primary prevention is of utmost importance, particularly in the setting of financially constrained, underdeveloped healthcare systems that are unable to bear the costs and resource requirements of chronic disease management. WHO has launched the 2008–2013 Action Plan for the global strategy for the prevention and control of non-communicable diseases (3) with the aim of reducing the main modifiable risk factors in common for these diseases, specifically unhealthy diets, lack of exercise, tobacco, and harmful use of alcohol. Secondary and tertiary prevention are also extremely important to reduce the risk of chronic complications and organ failure potentially leading to transplantation.

There are numerous examples of successful chronic disease prevention strategies around the world. The Kidney Early Evaluation programme is a free community screening programme aimed at early detection of CKD among high-risk individuals, including those with DM, hypertension, and family history of DM, hypertension, or CKD. It began in the United States and now routinely operates in Australia, Japan, and Mexico (4–7). Metformin use and lifestyle intervention have been associated with reduction in the incidence of type 2 diabetes of 31% and 58%, respectively, in a US randomized trial (8). CVD prevention with a multidrug regimen has been shown to be cost effective in the developing world (9). It is recognized that CKD prevention would be most cost-effective as a part of an integrated strategy targeting chronic vascular diseases (10). An example of this type of integrated in-

Key Points

- Public health is to play a key role in self-sufficiency by reducing demand for transplantation through disease prevention, promotion of donation among health professionals and the general public, and contributing to effective and well-developed health systems
- The frequency causes of end-stage organ failure (diabetes, hypertension, alcohol abuse, HBV, HCV, CAD, and COPD) must be met by primary, secondary and tertiary prevention. Prevention must address the two principle drivers of this disease burden, (i) lifestyle risk factors – tobacco use, unhealthy diets, physical inactivity, and harmful use of alcohol, and (ii) ineffective and inequitable healthcare services.
- Donation education and promotion, drawing on public health methodologies, is necessary to strengthen public commitment to organ and tissue donation, and increase the willingness of medical professionals to be involved in the donation and transplantation process. Society must have a willingness to promote and support donation, else there would be not organs to transplant.
- The act of donation is itself an individual decision that interacts with the social setting and the institutional and regulatory framework into which an individual is embedded. Family refusal, together with failure to identify potential donors, is the most significant impediment to increase rates of donation. Public education efforts need to counter poor awareness, distrust of medicine and misconceptions about donation and transplantation, while instilling notions of reciprocity, solidarity, and an appreciation of the uniquely life-saving nature of donation.
- In low-income settings, where health sector development constrains the development of organ donation and transplantation, prevention of end-stage organ failure within the context of wider public health goals is crucial to self-sufficiency. Adverse public attitudes and legal restrictions may pose additional obstacles to transplantation, therefore culturally appropriate education and the endorsement of donation and transplantation by community and religious are essential. Service delivery may use both private and non-governmental means of financing, and grow from synergies between governments, NGOs, and charities.

TABLE 2. Roles of public health and society in the pursuit of self-sufficiency

| | |
|---------------|---|
| Public health | <p>Screening and prevention of end-stage organ failure potentially leading to transplantation</p> <p>Promotion of donation among health professionals and the general public</p> <ul style="list-style-type: none"> - Skills and knowledge development among health professionals - Promotion of trust in organ donation throughout the community <p>Development of efficient healthcare systems and transplant programmes</p> <ul style="list-style-type: none"> - Development of efficient donor procurement organizations - Develop society and medically acceptable recipient selection and organ allocation systems for deceased donor transplantation - Optimize accredited transplant programmes - Ensure transparency in support of equity - Ensure maintenance of safety and quality of donation and transplantation - Create national programmes but implement them locally |
| Society | <p>Willingness to promote and support organ donation</p> <p>Community funding through public finance and charitable sources</p> |

TABLE 3. Frequent causes of end-stage organ failure and common risk factors

| End-stage organ failure | Frequent causes | Common risk factors |
|-------------------------|---------------------------------------|------------------------|
| Kidney failure | Diabetes hypertension | Unhealthy diet |
| Liver failure | Alcohol abuse | Lack of exercise |
| | Hepatitis B virus | Tobacco use |
| | Hepatitis C virus | Harmful use of alcohol |
| Heart failure | Coronary artery disease | Intravenous drug abuse |
| | Hypertension | |
| Lung failure | Chronic obstructive pulmonary disease | |

intervention has shown success in rural India, achieving blood pressure and DM targets, and lowering prevalence of CKD at an annual cost of US \$0.43 per capita of population (11). This programme minimized costs by using nonphysician health workers and cheapest available diagnostic tests and drugs. Combination pharmacotherapy, a fixed dose of aspirin, a statin, an angiotensin-converting enzyme inhibitor, and a diuretic/ β -blocker, may also have potential as an integrated approach to chronic vascular disease in low- and middle-income countries (12).

Promotion of Donation

Public health can help to increase organ donation through education, information, encouragement, and pro-

motion of donation and transplantation among health professionals and the general public.

Health Professionals

Many publications have demonstrated that the willingness of healthcare professionals to participate in the donation process can improve the donation rate (13, 14). Donation education of health professionals, particularly of transplant coordinators, emergency and ICU doctors, and family practitioners, is critical (15). In Spain, transplant coordinators are trained as managers of educational programmes and resources, are responsible for administrative tasks, and are also in charge of media relations (16). There are also reports of donation education for medical students as a way to enhance the link between physicians and procurement professionals (17–20).

Because nurses are usually the first people among the healthcare staff to recognize a patient as a potential donor, they have an important role in the procurement of organ and tissue from deceased donors. Educational programmes can enhance nurses' knowledge and commitment to the organ donation process and, ultimately, increase the donation rate. In a recent report from Pakistan, knowledge and attitudes toward organ and tissue donation improved significantly after nurses attended a 1-day workshop on organ donation (21). Consequently, it is of great importance for OPOs to offer regular training programmes for all their healthcare staff (22).

General Public

Public attitudes to and awareness of organ donation and transplantation are key elements affecting donation rates. Public health methodology applied to donation education programmes consists of assessing the status of donation-related public education, identifying existing needs in donation education by applying principles learned from other public health education programmes, and identifying roles that can be assumed to help strengthen the public's commitment to organ and tissue donation (23). A systematic review of the literature yielded eight elements of effectiveness that could be used to assess donation education efforts (23). They are the use of:

- Formative research,
- Strategic planning,
- Appropriate messages,
- Audience-based strategies,
- Multiple channels,
- Collaboration with other groups in a community,
- Evaluation, and
- Coordination of information exchange in the transplant field.

Oberley (24) examined barriers to donation and assessed educational materials and programmes, concluding that grassroots, community-based programmes were essential to supplement mass media efforts and that well-researched campaigns, targeted to specific audiences, were also key to success.

Challenges and Recommendations for Public Health in the Pursuit of Self-Sufficiency

It is important to note that sustainability of public health programmes is driven by the critical processes of sys-

temization and standardization. In particular, improving sustainability may require stabilization of organizational resources, attention to incentives, and standardization of policies at the national level (25). The Working Group identified several barriers to public health efforts in the pursuit self-sufficiency and provided some solutions and recommendations (Table 4).

Role of Society

The act of donation is in itself an individual decision that requires a depth of understanding that interacts with the social setting and the institutional and regulatory framework into which an individual is embedded. Decisions are influenced by regulation (presumed consent), awareness of regulation, and social interactions, such as the ability to count on others in case of a serious problem, also known as reciprocity (26). Other factors, such as age, race, education, socioeconomic status, and religion, among others, determine willingness to donate one's own organs and consent to the donation of those of a relative (27).

Donors, Recipients, and Their Families

In any society, individuals' and families' attitudes toward donation are critical factors in self-sufficiency. Families' refusal of organ donation, together with failure to identify donors, remain the most important impediments to improve rates of organ donation from deceased persons in most high-income countries. In a study that compared donor and nondonor families, donation was more likely when the deceased had made his or her donation intentions known and the next-of-kin had more favorable organ donation beliefs, but was less likely when family members were not in complete agreement about donation (28). These findings highlight the need for continued public education efforts to maximize positive beliefs about organ donation and promote the necessity of sharing donation intentions with others (29, 30).

Little is known about how best to educate patients and their families about donation from living persons. In a study of living donor kidney transplantation (LDKT), patients were randomized to receive clinic-based (CB) education alone or CB and home-based (CB+HB) education (31). The latter involved home visits with the patient, family, and other potential donors by one or two trained health educators. When compared with CB, more patients in the CB+HB group had living donor inquiries, evaluations and LDKTs (30.4% vs. 52.4%, $P=0.013$). Both groups demonstrated an increased LDKT knowledge after the CB education, but CB+HB led to an additional increase in LDKT knowledge and in willingness to discuss LDKT with others and a decrease in LDKT concerns.

The Wider Community

The messages delivered by public education efforts must be clear, well defined, positive, and essentially shared by all those involved in the process of organ donation and transplantation. A Spanish multiethnic national survey documented a significant relationship between the degree to which the public is prepared to accept organ donation, and the conviction that transplantation is a good and positive element of health care (32). The mass media can be both useful in pro-

TABLE 4. Challenges and recommendations for public health in the pursuit of self-sufficiency

| Barriers | Solutions and recommendations |
|---|--|
| Prevention of end-stage organ failure | |
| Lack of or insufficient programmes to prevent end-stage organ disease | Reduce transplant demand by preventing end-stage organ failure from diabetes, hypertension, cirrhosis of the liver, and chronic pulmonary disease |
| Ineffective and inequitable care for chronic diseases | Reduce transplant demand by effective and equitable care of chronic diseases, particularly diabetes and hypertension |
| Promotion of donation | |
| Insufficient donation education of health professionals | Encourage ICU and Emergency Room ER doctors and residents to assume responsibility for organ donation Education of primary care physicians, nurses, medical students, and other allied health professionals |
| Insufficient donation education of the general public | Develop culturally sensitive awareness programmes Use public health methodology Involve communication specialists |
| Efficient healthcare systems and transplant programmes | |
| Competing factors and resource limitations | Use private and non-governmental sources of funding |
| Lack of/inadequate transplant programmes because of issues of infrastructure, organization, health system financing, legal and ethical regulation of the transplant process, and high cost of immunosuppressive drugs | Establish synergies between the government and NGOs/charities (e.g., Sindh Institute of Urology and Transplantation in Karachi, Pakistan) International collaboration |

ICU, intensive care unit; NGO, non-government organization.

moting, but also risks adversely affecting organ donation (29, 33). Managing adverse publicity is a complex and time-consuming task that must be combined with adequate and systematic spread of the positive and life-enhancing aspects of organ donation and transplantation. Success depends not only on provision of adequate information to the public but also on the transparency of donation and transplantation systems. Direct publicity campaigns are not guaranteed to positively influence the attitude of the public toward organ donation and are costly. One cost-effective strategy is that used by the Spanish Model, in which ONT provides information to the public and the media by means of a 24-hr transplantation hotline and periodic meetings with journalists, communication experts, and leaders in transplantation. Health professionals, who are responsible for identifying potential donors and in some cases approaching the grieving families, should also be a key target of education efforts (15).

Donation education should also target specific groups, such as religious leaders (27) and school students (34). Al-

though most clergy are supportive of organ donation, religious objections are often cited as a reason for refusal to give consent for donation. School-based education programmes concerning organ donation and registration of intent to donate have been systematically developed in The Netherlands to enable adolescents to make well-informed decisions about organ donation (37). Also, donation education for Departments of Motor Vehicles clerks, who in several countries serve as gatekeepers to organ donation registration, is an effective way to increase knowledge, attitudes, and beliefs among these key individuals and may increase donor registration rates among the public (38, 39).

Public education concerning organ donation and transplantation needs to take into account cultural diversity. Promoting organ donation and transplantation in a multicultural environment represents one of the major challenges facing the transplant community (40). Different attitudes, cultures, and values systems mean that a blanket standard approach to organ shortages will not be effective. Promotion of donation and transplantation should involve a team of healthcare workers who are sensitive to the values and the traditions of individual groups in society, in addition to a coordinated effort to clear any misconceptions about organ donation, improve public education and awareness, and promote communication with the general public. Respect for cultural diversity and a better understanding of the cultural influences involved will build stronger support for transplantation and more successful organ donation campaigns.

Overcoming barriers toward organ donation from deceased persons in public opinion is a real challenge. Resistance to organ donation after death derives from lack of awareness, religious uncertainties, distrust of medicine, hostility toward new ideas, and misconceptions about organ donation and transplantation. Education should be used to reshape public opinion about the use of organs for transplantation (41). To optimize organ donation in any given society, it is important that the community accept that use of body parts is moral and offers a source of health for everybody. The concept that using deceased donor organs implies sharing a source of health ideally forms a social agreement between all members of society. Suggestions for improving organ shortage include (1) developing an understanding that during one's life one is more likely to need to be an organ recipient than an organ donor and (2) cadaver organs are an irreplaceable source of health.

Challenges and Recommendations for Society in the Pursuit of Self-Sufficiency

The Working Group identified several challenges for societies in the pursuit of self-sufficiency and provided some solutions and recommendations (Table 5).

Challenges of Underdeveloped Healthcare Systems

Limited per capita health expenditure and underdeveloped health care systems affecting capacity for transplantation are important challenges facing organ donation and transplantation in low- and middle-income countries. Additional challenges in these settings may include low levels of education, cultural antipathy, and adverse public

attitudes toward organ donation and transplantation. Adverse legislation may also be an obstacle in some countries. In Nepal, for example, donation from living persons is only permitted from individuals in direct relation to the recipient from the paternal side, which has brought about a disparity in number of recipients and donors. Regulation or organ donation from deceased persons is also lacking in this country.

As in high-income countries, education about organ donation and transplantation is essential to the pursuit of self-sufficiency. The message that transplantation, as the result of donation from a living or deceased donor, is the means by which people suffering from end-stage organ failure may have hope, should be communicated in a culturally sensitive way to the general public. The role of teachers, priests, political and social leaders, and celebrities is crucial in achieving this goal. For organ donation after death, trained counselors are required for education of potential donors and relatives.

Despite these challenges, there are examples of successful transplantation programmes in the developing world, such as the Sindh Institute of Nephrology and Transplantation in Pakistan (42). This model of government-community partnership receives 40% of its budget from the government and the rest from the community as donations. The scheme has been extremely successful in providing free medical care and support for thousands of patients. It has been sustained over the past two decades by complete transparency, public audit, and accountability.

TABLE 5. Challenges and recommendations for society in the pursuit of self-sufficiency

| Barriers | Solutions and recommendations |
|---|--|
| Lack of awareness about donation | Provide regular and consistent behavioral change communication programmes Develop culturally sensitive awareness programmes directed to general public, religious leaders, schools, Department of Motor Vehicles' clerks, among others Cultivate community role models and champions for organ donation and transplantation Provide public recognition to donors and their families Develop a positive attitude about donation through mass media, films, TV shows, radio programmes, books, and social networking sites |
| Adverse publicity | Actively manage adverse publicity |
| Distrust of medicine | Provide adequate information and transparency about all aspects of donation and transplantation |
| Misconceptions about donation and transplantation | Develop educational programmes to dispel myths about donation and transplantation Take into account people's beliefs and values and the broader sociocultural context in which they live |

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WORKING GROUP 7: ETHICS OF THE PURSUIT OF SELF-SUFFICIENCY

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Ethical Foundations

Self-sufficiency is to be understood as a strategic approach rather than as an ethical imperative. It aims to foster the adequate provision of organs and transplantation services to meet the needs of a given population, using resources from within that population. Responsibly administering the scarce and precious resource of human organs for transplantation also encompasses actions directed toward the prevention of organ failure.

The pursuit of self-sufficiency requires a paradigm shift, from a perception of organ transplantation as a matter of the rights of a donor and a recipient, to one of responsibilities at the family, community, national, and international level. It is also important to recognize the profound emotional, psychosocial, and experiential components connected with the act of donating and receiving an organ, in addition to traditional clinical and biologic concerns.

Ethical Premises

- a. The human right to health requires that countries undertake measures to prevent end-stage organ failure, and treat those suffering from end-stage organ failure through the use of transplantation where this is appropriate.
- b. Organs should be understood as a social resource; equity should govern both procurement and allocation.
- c. Organ donation should be perceived as a civic responsibility toward fellow citizens. Organ markets and transplant tourism lead to morally unacceptable coercion and exploitation of the disadvantaged.

Ethical Principles

In accordance with the Declaration of Istanbul (1), self-sufficiency promotes the following ethical principles:

- a. Minimizing harm/reducing suffering: through an emphasis on the reduction of need for transplants while aiming to maximize the number of organs available for transplantation.
- b. Justice: by promoting a more equitable distribution of benefit and burden (potential recipients as potential donors and vice versa), and censuring practices that involve the exploitation of any party.
- c. Respect for persons: by avoiding undue incentives, while appealing to the community-oriented values of solidarity and civic responsibility.

Self-sufficiency is an aspirational concept, which can be implemented in different, locally relevant ways, and therefore

progress in the pursuit of self-sufficiency needs to be measured by context-dependent benchmarks. Clearly not embracing the pursuit of self-sufficiency would be healthcare systems that:

- Do not strive to develop capacity to prevent end-stage organ failure or provide for the transplantation needs of their population (where health system development is sufficient to support transplantation programmes);
- “Outsource” transplantation and provision of organs by sending their citizens to other countries;
- Encourage organ sales, domestically or to nationals of other countries.

Questions and Challenges

- a. Will self-sufficiency encourage an insular attitude rather than global solidarity?
- b. Is self-sufficiency an achievable goal for developing countries?
- c. Potential abuses.
 - Organ markets disguised as regional cooperation;
 - Domestic financial incentives;
 - Inequitable allocation or lack of transparent waiting list;
 - Unethical practices in the donation of organs from living persons.
- d. Diversity in cultural approaches to death/deceased persons/dead bodies and related implications for attitudes toward donation.
- e. Lack of awareness and education among public and health professionals.

Recommendations

Recommendations to Health Authorities

1. Acknowledge that the pursuit of self-sufficiency does not preclude a collaborative approach, capacity building, or humanitarian assistance;

Key Points

- *The self-sufficiency paradigm reframes organ transplantation from a matter of the rights of a donor and recipient, to one of responsibilities at the family, community, national, and international level. This paradigm is based on three main ethical premises: (i) the human right to health means that countries should invest in the prevention of end-stage organ failure and in its treatment through maximizing access to transplantation; (ii) organs are a social resource, the management of which must be transparent and equitable; and (iii) organ donation should be perceived as a civic responsibility, in contrast to organ markets and transplant tourism, which lead to morally unacceptable coercion and exploitation of the disadvantaged.*
- *The pursuit of self-sufficiency promotes the ethical principles of minimizing harm/reducing suffering, justice, and respect for persons.*
- *Health authorities should: (i) take responsibility for meeting transplant needs and actions to prevent organ failure; (ii) be accountable for the ethical integrity of the system; and (iii) acknowledge the role for collaborative approaches, capacity building, and humanitarian assistance within the self-sufficiency paradigm.*
- *Health professionals should: (i) receive training in ethical aspects of organ transplantation; (ii) contribute to the education of the public; (iii) maximize the utilization of donated organs; and (iii) be vigilant concerning unethical/illegal behavior and willing to report it to judicial, professional, and human rights bodies.*
- *Professional societies should also foster research on questions of culture, values, and ethics as they relate to self-sufficiency. There is also a need for research in particular reference to the nature of the implementation of self-sufficiency to inform unresolved ethical questions.*
- *Civil society should: (i) establish an ethos of social responsibility and solidarity in meeting transplantation needs through participation in deceased donation; (ii) be sensitive to the needs of both donors recipients; and (iii) engage NGOs, community and faith-based organizations.*

2. Take responsibility for meeting transplant needs and actions to prevent organ failure;
3. Be accountable for the ethical integrity of the system.

Recommendations to Professionals

1. Receive training in ethical aspects of organ transplantation;
2. Contribute to the education of the public;
3. Maximize the utilization of donated organs;
4. Be vigilant concerning unethical/illegal behavior and willing to report it to judicial, professional, and human rights bodies.

Recommendations to Civil Society

1. Establish an ethos of social responsibility and solidarity in meeting the community's transplant needs through participation in donation after death;
2. Be sensitive to the needs of both the donor and the recipient;
3. Engage NGOs and community- and faith-based organizations.

Recommendations to Scientific and Professional Bodies and Funding Agencies

1. Foster research on questions such as:
 - a. How is the pursuit of self-sufficiency consistent with the values in different cultural and religious contexts?
 - b. What are cultural, social, and religious obstacles to donation after death, and how might they be overcome?
 - c. How does the emphasis on organs as a community resource impact on motivation to participate in prevention programmes/donation after death?
 - d. How to maintain equity within regional cooperation to preserve mutual benefits and avoid an unbalanced flow of organs or other related resources from one country to another.
 - e. What constitutes an equitable donation pattern?

Examples of Ethical Approaches to Challenges in the Pursuit of Self-Sufficiency

- a. Tanzania: because of a lack of transplantation services in Tanzania currently, a programme has been arranged to ethically and safely match altruistic living-related kidney donors to those requiring transplantation. Donors and their recipient relatives are flown abroad to India where procurement and transplantation is performed at the cost of the Tanzanian government, and patients then return home for follow-up care. This temporary solution to the problem of unavailable transplantation services in Tanzania is highly valued but is neither cost effective nor sustainable in the long term. Therefore, Tanzania is working toward the development of transplantation services, so that, in the future, patients and donors may receive all their care locally, avoiding the need to rely on the services of foreign countries (L. Ezekiel, personal communication).
- b. Spain—Portugal exchange for lung transplantation: Portuguese patients have been officially admitted to the

lung transplant waiting list in Spain while transplant teams in Portugal develop technical expertise. This led to an official agreement between the two countries, whereby the lungs suitable for transplantation in Portugal are offered to the Spanish teams, who take care of organ recovery and subsequent transplantation.

REFERENCE

1. Steering committee of the Istanbul Summit. Organ trafficking and transplant tourism and commercialism. The Declaration of Istanbul. *Lancet*, 2008; 372: 5. Available at: <http://www.declarationofistanbul.org>.

WORKING GROUP 8: EFFECTIVENESS IN THE PURSUIT OF SELF-SUFFICIENCY - ACHIEVEMENTS AND OPPORTUNITIES

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A Framework for Progress in the Pursuit of Self-Sufficiency

Achieving self-sufficiency is a journey, with the pace of progress dictated by resource availability, systems development, and the extent of national commitment to this goal. Progress may be defined as levels of transplantation capability, which reflect the evolution and achievements of organ donation and transplantation systems. The objectives of specifying levels of transplantation capabilities are as follows:

- a. To ensure that every nation or region has, or acquires, the necessary attitudes, policies and plans, resources, skills, and infrastructure to provide solid organ transplantation for its population for the purpose of treating end-stage organ failure;
- b. To provide tools for every nation or region to self-assess its own progress in the pursuit of self-sufficiency in solid organ transplantation for the purpose of treating end-stage organ failure;
- c. To provide tools for nations or regions to identify gaps or barriers to progress in the pursuit of self-sufficiency;
- d. To identify the resources required by nations or regions to resolve gaps or remove barriers that present obstacles to the attainment of self-sufficiency and to identify priority interventions in the pursuit of this goal;
- e. To provide a framework that has relevance in all contexts, whatever the local reality in terms of economic and health system development, for the stepwise development of organ donation and transplantation systems toward self-sufficient models.

Therefore, by defining stepwise levels of transplantation capability, it is possible to construct a roadmap of how individual nations or regions can progress toward self-sufficiency. Progress from one level of transplantation capability to the next requires government commitment toward developing and implementing policies and programmes,

Key Points

- *In the journey toward self-sufficiency, the capability of individual countries/regions to meet transplantation needs is determined by economic resources, systems development, and existing health priorities. By defining successive levels of capability, the inclusive nature of the self-sufficiency paradigm is reinforced, and it is possible to describe a framework for evolution and achievement in organ donation and transplantation that is adaptable to all contexts.*
- *The minimum level of transplantation capability (level 1) is defined as the presence of a few medical professionals who have the capability to provide appropriate presurgical and postsurgical management of transplant recipients and living donors in a context of no local transplantation activity; maximum capability (level 6) is defined as a comprehensive multiorgan transplant programme that provides an adequate supply of transplantable organs to meet the needs of the population.*
- *At every level, the pursuit of self-sufficiency involves the development and implementation of strategies aimed at increasing regional/national capabilities in each of the following domains: (i) donation and coordination, (ii) legislation and regulation, (iii) transplant services, (iv) government resourcing, (v) community involvement, and (vi) assessment and minimization of needs. With progressive achievements in each of these domains, at a level consistent with local realities, countries/regions evolve toward greater self-sufficiency in organ donation and transplantation.*
- *To enable the evolution of organ donation and transplantation systems toward models of self-sufficiency, governments should: (i) acknowledge their responsibility and address the problem of end-stage organ failure, from prevention to organ replacement therapy, in an integrated manner for the optimal management of resources; (iii) include the elements of organ donation, and transplantation in the national health plan; (iv) allocate adequate resources, develop infrastructure, and strengthen health systems for the achievement of these goals; and (v) foster regional and international cooperation in the pursuit of these goals.*
- *To support these efforts, the WHO should: (i) urge all nations to self-assess their level of transplant achievement; (ii) expand data collection and monitor international progress in the pursuit of self-sufficiency; and (iii) develop international standards, guidelines, and tools for the advancement of transplantation policy and practice.*
- *To support these efforts, healthcare professionals and professional societies should: (i) acknowledge responsibilities with respect to professional development, ethical practices, and maintenance of standards and training in donation, organ procurement and transplantation; (ii) encourage research directed at optimizing the benefits and minimizing costs of transplantation; (iii) support the establishment and work of national societies; and (iv) provide professional advice, and assistance in the development of standards for accreditation and quality assurance.*

commensurate with local resources and competing health priorities, within each of six key domains:

- Resources and professional development for donation and coordination;
- Legal and regulatory frameworks;
- Resources and professional development for transplant services;
- Government and other resources;
- Community involvement;
- Assessing and minimizing need for organs.

Levels of Transplantation Capability

Six levels of achievement within each domain are defined:

Level 1

This level defines nations or regions that have a few medical professionals who have the capability to provide appropriate pre and postsurgical management of transplant recipients and living donors, taking into consideration guidelines concerning the care of transplantation patients as developed by international consensus, such as the Amsterdam Forum on the Care of the Live Kidney Donor and the Vancouver Forum on Live Donation of Extrarenal Organs. This level also defines nations or regions that have begun to assess their needs for renal replacement therapy, including transplantation therapy, by developing a registry of end-stage kidney disease.

Level 2

This level defines nations or regions that have a clinical kidney transplant service within their own borders

with the capacity to provide kidney procurement surgery from living donors, kidney transplantation surgery, and postsurgical management of kidney transplant patients. The transplant center follows established standards, guidelines, and care protocols for living kidney donors and kidney transplant recipients, taking into consideration the relevant international consensus documents, in particular the Declaration of Istanbul. The transplant center has developed mechanisms for monitoring outcomes for its kidney transplants in key areas including graft and patient survival. This level also defines nations or regions that have begun to assess their needs for organ replacement therapy, including transplantation therapy, by establishing registries of end-stage kidney disease/liver failure/heart failure (as per country needs).

Level 3

This level defines nations or regions that have one or more centers providing clinical kidney transplant services within their own borders. The transplant centers have established standards, guidelines, and care protocols for living kidney donors and kidney transplant recipients, taking into consideration the consensus documents developed by the Amsterdam and Vancouver Forums on care of the live donor, the Declaration of Istanbul, and the Kidney Disease: Improving Global Outcomes (KDIGO) Clinical Practice Guidelines for the Care of Kidney Transplant Recipients. The transplant center has developed mechanisms for monitoring outcomes for its kidney transplants in key areas including graft and patient survival.

This level also defines nations or regions that are establishing the framework for a deceased donor kidney

transplant programme within their own borders, including legislative developments and training of organ procurement professionals.

This level furthermore defines nations and regions that, in addition to the development of end-stage organ failure registries, have begun to address the risk factors for end stage organ failure by identifying their prevalence in the nation and introducing interventions to delay its progression.

Level 4

This level defines nations or regions that have initiated deceased donor kidney transplant services within their own borders and have capacity to perform kidney procurement surgery from deceased and living donors, kidney transplantation surgery, and postsurgical management of kidney transplant patients. The nation or region has effected legislation that covers organ procurement from deceased donors and provides high level governance over organ procurement and transplantation activities. The transplant centers have established standards, guidelines, and care protocols for living kidney donors and kidney transplant recipients, taking into consideration the consensus documents developed by the Amsterdam and Vancouver Forums on care of the live donor, the Declaration of Istanbul, and KDIGO Clinical Practice Guidelines for the Care of Kidney Transplant Recipients.

This level also defines nations or regions that have a clinical liver and heart transplant service within their own borders, with the capabilities to provide liver and heart procurement surgery from deceased donors, liver and heart transplantation surgery, and postsurgical management of liver and heart transplant patients. The transplant center follows established standards, guidelines, and care protocols for living organ donors and transplant recipients. This level furthermore defines nations or regions that are developing other organ transplant programmes, including lung, pancreas, and combined transplant programmes.

Level 5

This level defines nations or regions that have an established multiorgan deceased donor organ transplant programme that is capable of providing kidney, liver, and heart transplantation for its patients with end-stage kidney disease, end-stage liver failure, and end-stage heart failure. Critical elements of legislation and regulation of the various aspects of organ donation and transplantation, government commitment to resourcing infrastructure and developing professional capacity, governance and oversight by national authorities, and surveillance and monitoring of organ donation and transplantation activities are all well established. A national or regional network that optimizes deceased donor organ procurement and a framework for organ allocation to patients on a national waiting list is an essential development.

Complementary to the deceased donor transplant programme, living donor transplantation is performed to provide kidney and liver transplants for a proportion of its end-stage kidney disease and emergent end-stage liver failure patients, following the standards, guidelines, and care protocols set forth in the Amsterdam and Vancouver Forums.

Complementing deceased donor kidney transplantation with LDKT maximizes the rate of kidney transplantation

per million population and the percentage of incident end-stage kidney disease patients receiving a transplant.

Nations and regions with this level of capability have established detailed end-stage organ failure registries for the ongoing evaluation of the need for organ transplantation and have developed and implemented preventive interventions to reduce the demand for organs for transplantation.

Level 6

This level defines nations or regions that have a comprehensive multiorgan transplant programme that provides an adequate supply of transplantable organs to meet the needs of its population with end-stage kidney disease, end-stage liver failure, and end-stage heart failure. Other features of such a programme include:

- Death of patients on the transplant wait list(s) is nonexistent;
- Travel for transplantation is nonexistent;
- The system has capacity to provide expertise to assist the development of transplant programmes in level 1 to 5 nations or regions;
- Exchange of organs between programmes, based on established guidelines for international cooperation.

Recommendations

Governments should:

1. Acknowledge their responsibilities in managing the end-stage organ failure of their population, and designate a competent authority, responsible for policy making, regulation, and oversight and coordination at a national level;
2. Address the problem of end-stage organ failure, from prevention to organ replacement therapy, in an integrated manner for the optimal management of resources;
3. Include the elements of organ donation and transplantation in the national health plan;
4. Allocate adequate resources, develop infrastructure, and strengthen health systems for the achievement of these goals;
5. Establish appropriate legislation and regulatory frameworks;
6. Report national data on organ donation and transplantation activities to a global observatory;
7. Foster regional and international cooperation in the pursuit of these goals;
8. Participate in public education, engaging communities, and NGOs.

The WHO should:

1. Urge all nations to self-assess their level of transplant capability, to assist in the identification of areas for improvement;
2. Expand the framework of relevant quantifiable indicators in alignment with the GODT (<http://www.transplant-observatory.org/>);
3. Monitor international progress in levels of achievement in the pursuit of self-sufficiency;

4. Develop international standards, guidelines, and tools for the advancement of transplantation policy and practice.

Healthcare professionals and professional societies should:

1. Acknowledge responsibilities with respect to their own professional development, ethical practices, maintenance of standards and training in donation, organ procurement, and transplantation;
2. Encourage research, especially clinical research directed at optimizing the benefits and minimizing costs of organ transplantation;
3. International societies should support the establishment and work of the relevant national societies to further their missions with respect to organ donation and transplantation;
4. Provide professional advice to MS;
5. Provide assistance to MS for the development of standards for accreditation and quality assurance;
6. Participate in public education.

Examples

The pursuit of self-sufficiency involves the development and implementation of strategic policies and programmes aimed at increasing regional or national levels of capability within each of the domains of (1) donation and coordination, (2) legislation/regulation, (3) transplant services, (4) government resourcing, (5) community involvement, and (6) assessment and minimization of needs. Examples of strategies that have successfully developed capacity for self-sufficiency at a regional or national level are given below:

European Training Programme on Organ Donation (<http://etpod.il3.uib.edu/etpod.html>)

The European Training Programme on Organ Donation (ETPOD) project was conceived with the objectives of: (1) developing and validating a professional ETPOD that would increase organ donation knowledge and maximize growth of organ donation rates; (2) providing training to healthcare professionals from EU countries, to develop Transplant Coordinators with the expertise, competencies, and motivation in the organ donation process to lead efficient and successful organ donation-procurement programmes; and (3) to build a solid European collaborative partnership in the organ donation-transplantation process that will enable countries to respond to the growing demand for transplantation by increasing donation rates. Cofunded by the European Commission Grant Agreement 2005205, the project was developed during the period from January 2007 to December 2009. The execution of the project was carried out through four working groups:

- Data Base Source Group—responsible for establishing the training needs in each target area and for evaluation of the ETPOD project;
- Basic Training Group—responsible for training for trainers and essentials in organ donation (EOD) training programmes;

- Professional Training Group—responsible for professional training on organ donation and e-learning virtual modules;
- Managers Training Group—responsible for managers training on organ donation.

One hundred twenty-five health professionals were trained by the ETPOD project in each of 25 target areas across Europe, with this number including 2 senior transplant coordinators (training for trainers), 2 junior transplant coordinators (professional training), 1 transplant area manager (organ donation quality managers training), and 120 health professionals involved in donor detection (EOD).

ETPOD in Turkey (communication from Levent Yüçetin): eight EOD seminars were held in Ankara between September and October 2009, with 500 participants. In December 2009, eight EOD seminars were held for 1600 participants in İstanbul. Another four EOD seminars were held in April/May 2010 for 700 participants in İzmir.

Evaluation of the impact of ETPOD on organ donation rates at national, regional, and local level (communication from Gloria Pérez): to evaluate the effect of ETPOD courses, data on key indicators were collected in 2006 (before project commencement) and again in 2009. The impact of the training programmes on rates of brain death diagnosis, identification of potential donors, refusals, effective donors, and procured organs was assessed for each of the target areas. The number of procured organs increased in 19 of the 25 target areas, from 1242 in 2006 to 1483 in 2009 (1). Assessed per million population, procured organs increased from 43.2 to 51.8 per million population, whereas brain death diagnoses increased from 28.2 to 39.8 per million population. The importance of donor coordinators was emphasized in this evaluation—those target areas which had increased their number of coordinators between the years 2006 and 2009 demonstrated significantly greater improvements in organ procurement than those target areas with a steady or reduced number of personnel devoted to coordination in 2009 compared with 2006.

Gift of Life Donor Programme (United States—Communication From Howard Nathan)

Gift of Life (Philadelphia, PA) is an urban-based, non-profit OPO/Tissue Recovery/Eye Bank established in 1974 that is the largest in the United States with approximately 34 staff in the field, divided between procurement and education/marketing professionals, and generating the highest volume of organ donors in 2009 in US history (439 organ donors from a population of 10.2 million).

The Pennsylvania Act 102 was initiated by families whose loved ones died waiting for a transplant. Originally drafted as a presumed consent law, the provisions of the Act are as follows:

- Routine referral of all deaths to the OPO at or near the time of death;
- Medical suitability of potential donors determined by OPO personnel;
- Family approached by trained requestor/OPO personnel with hospital staff;

- Medical record reviews to determine donor potential and missed referrals of all deaths, with provision for fines for missed referrals.

Therefore under PA Act 102, routine referral started in 1994. The law states that hospitals are required to refer all patient deaths and imminent brain deaths to the OPO in a timely manner, so that medical suitability can be evaluated and that the option of organ donation is preserved for families. The standard educational message to the hospital staff was to refer all nonretrievable, neurologically injured, vent-dependent patients at the first sign of imminent brain death. Clinical parameters for referral were not specified, removing barriers to early reporting and encouraging hospital staff to call the OPO as soon as this type of patient presented in the emergency room (ER) or ICU. A top down approach to hospital development was adopted, reinforcing the early referral message to administrators, physicians, and nurse managers on a one-on-one basis. Maintaining the commitment to send a coordinator out on site for every referral that fit criteria is critical to the routine referral policy.

Because of the success of PA Act 102 in the Gift of Life service area, from August 1998, a National Routine Referral policy was introduced whereby all US hospitals were required by Medicare to adopt routine referral as a “condition of participation.” Over the 15 years since the introduction of the PA Act 102 for Routine Referral, Gift of Life has experienced a doubling in rates of organ donation. These positive outcomes extend beyond organ donation; bone donation has increased in the Gift of Life jurisdiction from 174 donations in 1992, before the introduction of Routine Referral, to 1026 donations in 2009.

SEUSA (Spain, Europe, United States—Communication From M. Paula Gómez)

In response to low organ donation rates in Apulia, a South-Eastern Italian region, a new international collaborative strategy to increase donation activity was introduced in 2007. This collaboration involves international experts from Spain, Europe and the United States working with the Apulia Transplantation Regional Center (ATRC), Azienda Ospedaliero—Universitaria Policlinico di Bari, with the goal of reorganizing the entire regional organ do-

nation system. This SEUSA programme includes: (1) institution of area coordinators, (2) periodic meetings with ICU coordinators and hospitals leaders, (3) implementation of technical strategies to better detect all brain and heart deaths in ICUs, (4) constitution of an organ and tissues procurement team in each ICU, (5) allocation of dedicated financial resources direct to the procurement system, and (6) training courses for members of the procurement teams. Analysis of data on procurement parameters in 21 ICUs from the ATRC computer network, registered before and after the commencement of the programme, indicated a significant increase during the first 2 years of the Spain Europe USA (SEUSA) programme in of the number of brain death assessments and organ donors and a decrease in the refusal rate.

However, despite the successes of the first 2 years of the programme, organ donation rates in the Apulia region remained lower than the Italian national average rate, with indications that potential donors were still not being effectively identified. Therefore, in January 2009, Apulia introduced a Deceased Alert System (DAS), a new monitoring and reporting system for brain and circulatory death, which functions synergistically with the Registry of Head Injury and the Donor Manager. Under the DAS, when an ICU patient has a severe acute brain injury or goes into circulatory death, an automated message is sent through the internet to the ATRC and simultaneously to the mobile phone of the local coordinator, who is therefore kept up-to-date in real time on the presence of a potential donor in the ICU and can therefore initiate appropriate procedures. During the first 5 months of the DAS being operational, actual donors increased by more than 57%. Referral of potential donors increased gradually with increasing confidence in the new system, and these initial data indicate that increasing use of the DAS could significantly reduce losses of potential donors through failure to report.

REFERENCE

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APPENDIX 1: Expanded Report on System Requirements for the Pursuit of Self-Sufficiency (Working Group 2)

To achieve self-sufficiency, it is necessary to both minimize the need for transplantation and maximize the utility of available resources through efficient organ procurement, successful transplantation, and optimal graft survival. This requires a number of specific system-related, structural, organizational, and regulatory developments.

ESSENTIAL LEGISLATION AND REGULATION

Legislation

Legislation is necessary to ensure that clear definitions of brain death and circulatory death exist to allow procurement of organs from deceased donors. It is also required to define protocols concerning consent, including presumed consent, and the fair and transparent allocation of organs. Finally, legislation must govern transplantation practice in accordance with the WHO Guiding Principles. In particular, this means promoting the altruistic character of organ donation and prohibiting organ trafficking and commercialism.

- a. Legislation concerning organ trafficking: consistent with the WHO Guiding Principles, each country requires legislation prohibiting organ trafficking and sales to prevent human rights abuses. The export and import of organs or tissues or cells and transplantation for foreign patients should also be governed by legislation.
- b. Legislation concerning declaration of death: each country performing deceased donor transplantation must legally define brain death, consistent with international standards. There should be legal provision to remove organs from a deceased person, in accordance with local statutes on determination of brain death and circulatory death.
- c. Legislation concerning organ procurement procedures: organ recovery can only be justified through a strict consent process that is guaranteed by autonomy of the donor who is sufficiently informed or in the setting of legislated presumed consent to donation after death (1). Organ donation from living persons who are minors or individuals unable to provide informed consent should be prohibited (2). Although it is hoped that the consent of relatives to donation after death will be actively sought in all circumstances, in some jurisdictions where the preferences of relatives may conflict with those expressed by the potential deceased donor, the latter may be upheld (This is not the case in all countries. In practice, relatives' wishes are often upheld over donor wishes. See Uniform Anatomical Gift Act, United States).
- d. Legislation to establish transparent organizational structures and authorities for the coordination of organ donation and transplantation (refer *Monitoring and Regulation of Organ Donation and Transplantation, Organ Procurement Organizations, National Donation Promotion Programmes, Hospital Transplant Programmes*).

- e. Legislation guaranteeing transparency of organ allocation: the criteria for organ allocation should be set in accordance with medical utility, mindful of the characteristics, and preferences of each region or country and the principle of equity (3).
- f. Presumed consent for donation after death (optional): legislation may be enacted to establish presumed consent for organ donation. This may be effective in increasing potential deceased donors, provided there is social consensus regarding presumed consent (4, 5). For example, in Spain and France if a brain-dead person has never expressed his or her intention for donation, his or her consent is legally presumed (6). In Germany and selected other European countries, from 13 years of age, individuals may draw up a document rejecting donation of their organs, and therefore, persons with such a document are considered to be objectors to organ donation, and persons without such a document, assenters. The presumed approach has contributed to an increased provision of organs for these countries, but the local sociocultural contexts of different countries need to be considered before enacting a mandatory system.
- g. Routine Inquiry laws: for example, Required Request Legislation introduced in the United States in 1986 requires that hospitals or their designees ask families of patients and potential donors about their wishes concerning organ donation (7).

Regulation

Regulatory bodies should monitor the activities of organ procurement, allocation, and transplantation organizations to ensure they take place in accordance with local, regional, and international law and in an ethical and effective manner. Regulation is necessary for oversight and guidance related to ethical standards, the development of transplantation policies, and quality management in all organ procurement and transplantation practices.

- a. Transplantation ethics
 - Regulatory bodies have an important role in establishing ethically appropriate organ procurement and allocation processes.
 - Ethics committees, under the local, regional, or national regulatory authority, guide (1) organ procurement processes such as informed consent, (2) the implementation of new procedures or practices that have ethical implications, such as DCD, and (3) eligibility criteria for living donors and approving the relationship between a potential donor and a recipient.
- b. Development of transplantation policy
 - Through surveillance and data collection, regulatory bodies are able to review existing processes and develop more effective transplantation policies. Data relevant to transplantation policies include the reported rate of brain deaths in each hospital, factors contributing to nonprocurement from potential donors, and donor and recipient outcomes. For example, in the United States a death audit is carried out every year and identifies, according to the medical records, whether

potential donors have been missed. All hospitals should have a continuous quality audit programme concerning brain deaths to ensure that every brain death patient has been detected and evaluated by the transplant coordinator.

- Regulatory bodies must evaluate and make recommendations concerning the appropriate standards for age, disease, use of ECDs, and DCD.
- Regulatory bodies must additionally consider, and implement where appropriate, innovative strategies for increasing the availability of donor organs such as paired kidney exchange programmes between living donors (8).
- Regulatory bodies are also responsible for the development of whole-of-system strategic policies to better meet the transplantation needs of the population. Examples of comprehensive strategic policy include:
 - The Organ Donation Breakthrough Collaborative (United States): started in 2003 to vitalize organ DBD and also promote best practice in organ donation, the Breakthrough Collaborative targets hospitals or OPOs with a large potential in terms of DBD. Each hospital is encouraged to identify opportunities for improving practice and collaborate with OPOs in the introduction of new strategies to enhance organ procurement. After implementing this system, DBD increased by 4% (9–11);
 - The “40 donors per million population plan” (Spain): Spain is trying to increase its rate of organ donation from deceased persons to 40 donors per million population, by targeting the key areas of (1) detection and management of brain-dead donors, with specific focus on access to ICUs, new forms of hospital management, foreigners and minorities, and evaluation/maintenance of thoracic organ donors; (2) ECDs, looking at aging, donors with positive tests to certain viral serologies, and donors with rare diseases; (3) special surgical techniques, and (4) DCD. In addition, Spain seeks to open new DCD programmes in cities with more than 300,000 inhabitants and trying to reduce the rate of potential donor families’ refusal to 10% (12).

c. Transplantation quality management and professional education

- Regulatory oversight helps to standardize, and maintain quality in, transplantation performance by promoting uniform procedures and monitoring the performance of each individual transplantation center.
- Regulatory bodies are responsible for ensuring adequate education and training of transplant staff, for example:
 - United States: transplant professionals must demonstrate the ability to execute their tasks independently and pass a test hosted by North America Transplant

Coordinator Organization, which also provides continuing education, conducts research, and gives advice concerning organ procurement processes (13);

- Spain: the Transplant Procurement Management (TPM) curriculum includes family meetings and consent of organ donation.

THE NATIONAL TRANSPLANT ORGANIZATION

National Transplantation Organizations (NTO) embody all processes involved in organ procurement and transplantation at the governmental level. Although they may be responsible for various functions such as the management of waiting lists, matching and allocation, and the maintenance of comprehensive registries, above all they should ensure the implementation of national policy concerning donation and transplantation. Hence, the NTO must have regulatory functions and provide effective oversight of all activities in organ donation and transplantation, monitor trends and performance, and guide informed policy.

Allocation of Organs

There are two models of organ allocation: a centralized system led by government (e.g., ONT, Korean Network of Organ Sharing [KONOS]) or private corporation aggregate run by a non-profit corporation (e.g., UNOS). Regardless of the structure of organ allocation bodies, their operation and organization should be intimately connected with the NTO. Examples of organ allocation models:

- a. The EIF, found in 1967, is responsible for the mediation and allocation of organ donation procedures in Austria, Belgium, Croatia, Germany, Luxemburg, the Netherlands, and Slovenia (<http://www.eurotransplant.org>).
- b. Agence de la Biomedicine (France) is the public body in Europe to combine the four allocation region services de régulation et d’appui (SRA) of organ procurement (<http://www.agence-biomedecine.fr/>).
- c. KONOS: a government controlled system responsible for registry, allocation, and database management for three geographic regions (<http://www.konos.go.kr/>).
- d. ONT, Spain: a system of interdependence between distinct/regional based procurement arrangements, which works as part of a NTO (<http://www.ont.es>).
- e. UNOS (United States): the national UNOS membership is divided into 11 geographic regions for procurement, allocation, and transplantation (<http://www.unos.org>).

To maximize utility, organs are generally allocated based on medical urgency and blood/tissue type matches. Distribution is usually made first on a local, then regional, and finally national level. Kidney and pancreas allocation is usually made based on a point system, using an algorithm that takes into account blood group, waiting time, type of HLA match, degree of sensitization, and age. Local patients with the highest points are allocated the

Suggestions for enhancing progress toward self-sufficiency through legislation and regulation:

- ▶ Proper legislation and regulation
- ▶ Policy making for improved organ donation
- ▶ May adopt “presumed consent” or “explicit consent” by legislation or regulation

organs in descending order, then they are distributed regionally in descending point order, and finally nationally, in the same order (14, 15). Liver allocation takes into account degree of medical urgency, blood group, and time waiting and also used a point-based system for these factors. Degree of urgency is classified using a scoring system such as Mayo End-stage Liver Disease score (16–18).

Monitoring and Regulation of Organ Donation and Transplantation

Registries play a vital role in transplantation systems, including maintenance of the organ transplant waiting list and facilitating the allocation of organs from deceased donors in accordance with transparent distribution criteria (see Working Group 4). They also enable review of the current status of donation and transplantation, thereby facilitating quality control, evidence-based research, and the development of policies that are guided by the best available information concerning the management of patients and their needs. Each country performing transplantation should develop a registry of organ donation and transplantation activities.

Transplantation authorities need access to transplantation data for several policy and regulatory purposes. Key applications of registry data include:

- a. Performance standards: transplant data can be used to assess and set performance standards for transplant centers. The data can be used to evaluate the number of transplants performed by individual transplant centers and the outcomes at those centers. The data can show the impact of patient mix on patient and graft survival and the effects of race, blood type, and other variables on pretransplant waiting time.
- b. Legislative and regulatory policy: transplant data are important for setting government policies and passing laws related to transplantation. For example, data can be used to determine the impact of federal OPO regulations that require demonstrated ability of each OPO to meet a minimum procurement rate. Data can also be used to determine the effects of cold ischemia time (time without blood supply to the organ) on graft survival. Such information can be used to develop optimal geographic organ sharing policies.
- c. Quality control: data can also be used to examine such issues as accuracy in histocompatibility testing and graft survival for specific transplant procedures.
- d. Internal benchmarking: registry data are also useful for healthcare professionals and research organizations for improving practices and setting standards. It also helps to facilitate communication with relevant international organizations concerned with transplantation.

Best practice with respect to registries consists of, where possible, computer-based, real-time sharing of donor information. For example, when donor information is

provided to the EIF and UNOS (DonorNet®) computer systems, staff at the hospital where the transplant candidate is located can share real-time information and show intention of acceptance in the system, by which allocation and distribution are made. Other examples of registries and large-scale databases in organ donation and transplantation include:

- a. SRTR (United States): supports the ongoing evaluation of the scientific and clinical status of solid organ transplantation. The SRTR contains current and past information about the full continuum of transplant activity, from organ donation and waiting-list candidates to transplant recipients and survival statistics. This information is used to help develop evidence-based policy, to support analysis of transplant programmes and OPOs, and to encourage researches on issues of importance to the transplant community (www.ustransplant.org).
- b. Collaborative Transplant Study (Europe): with the active support of more than 400 transplant centers in 45 countries, the Collaborative Transplant Study is the largest international voluntary study in the field of medicine. More than 400,000 datasets for kidney, heart, lung, liver, and pancreas transplants have been collected. This wealth of data has provided invaluable insights into transplantation-related problems such as effects of immunosuppressive drugs, long-term toxicity of immunosuppressant, causes of long-term graft loss, factors influencing patient survival, etc (www.ctstransplant.org).
- c. Sistema Nacional de Información de Procuración y Trasplante (Argentina): run by the National Institute for Organ Donation and Transplantation Instituto Nacional Central Unico Coordinador de Ablación e Implante (INCUCAI), Sistema Nacional de Información de Procuración y Trasplante is an online data system that administrates, manages, and supervises organ, tissue, and cell procurement and transplantation activities in the national field. It allows online monitoring of dialysis registries, waiting lists, procurement procedures, and the distribution and allocation of organs and tissues. It also facilitates traceability from donor to recipient and vice versa. The data are used to generate reports about transplant activity from organ donation and waiting-lists patients, to transplant recipients (<http://www.incucai.gov.ar>).

ORGAN PROCUREMENT ORGANIZATIONS

An OPO is an independent organization responsible for the process of systematic surveillance for the identification of potential donors and the procurement of deceased donor organs (19). The identification of potential donors is

To enhance progress towards self sufficiency, NTOs should:

- Be the main authority for organ transplantation programmes
- Maintain transparency in organ allocation
- Maintain a useful national data system
- Promote innovation to increase the donor pool, including consideration of paired kidney exchange programmes between living donors
- Develop allocation policies for expanded criteria donors and donation after circulatory death

the starting point of transplantation, and its optimization is possibly the most important process in maximizing the procurement of organs for transplantation.

Structure of an OPO

In setting up an OPO, its region of jurisdiction/responsibility will be influenced by population size, geographical features, and the number and size of hospitals and transplantation centers available. Limits must be set to ensure the region is appropriate for management by a central OPO responsible for the distribution of organs for transplantation. OPOs require the involvement of experts concerned with medical administration, clinical management, logistics, education and so forth, and the support of a variety of institutions.

OPOs are divided into two organizational models: HOPOs and IOPOs. HOPOs originally served as exclusive procurement entities for the transplantation facilities in which they were located. IOPOs operate outside the hospital setting and provide services to a number of transplant centers. IOPOs are usually structured as non-government, nonprofit organizations. Regardless of the model, there should be an approval process involved and oversight provided by appropriate government authorities to ensure transparent management. In both models, procurement activity occurs independently from transplant units, although transplant surgeons are in charge of organ recovery. Decisions about the adoption of a particular system of organ procurement should be made with consideration of each national and regional situation. The following sections review the advantages and disadvantages of both models.

a. HOPO

- Advantages: because a HOPO creates no additional costs, it would be suitable for a country with only one transplantation center or just starting deceased transplantation.
- Disadvantages: HOPOs are often hampered by funding conflicts and inefficiencies. In addition, the identification of potential donors is likely to be unsystematic because of the small scale of operations of an HOPO compared with an IOPO. Furthermore, HOPOs are vulnerable to ethical conflicts because of the in-house nature of their operations.

b. IOPO

- Advantages: IOPOs are more effective in organ procurement than HOPOs, because they have a larger integrated system and a centralized authority, that can help to provide more consistency of service, minimize inefficiencies, and optimize the potential donor pool through large scale programmes of education and surveillance. In the United States, an organ procurement system has evolved gradually from an HOPO- to an IOPO-based system.
- Disadvantages: this system may be financially unviable or practically inappropriate in countries lacking multiple transplantation centers.
- Examples:
 - Instituto Nacional Central Unico Coordinador de Ablación e Implante (INCUCAI, Argentina) is

responsible for donor detection, screening and management, organ distribution, and allocation coordinating 24 OPOs around the country (www.incucai.gov.ar);

- Agence de la Biomédecine (France) is a public body combining the four allocated regions (SRA) for organ procurement (www.agence-biomedecine.fr);
- Deutsche Stiftung Organtransplantation (Germany): since 1984, Deutsche Stiftung Organtransplantation has conducted identification of potential brain death donors and organ extractions; however, allocation is executed by Eurotransplant (www.dso.de);
- Korea Organ Donation Agency (KODA): set up in 2009, KODA is responsible for donor detection, screening, and management in each three geographic regions, working separately from KONOS (www.koda1458.kr);
- ONT, Spain: ONT is in charge of the national network of OPOs (www.ont.es);
- UNOS (United States): under UNOS are 59 OPOs in 11 regions, working with transplant medical institutions, laboratories, and civic groups (www.unos.org).

Personnel Involved in OPOs

- a. OPC: OPOs may employ highly trained professionals called procurement coordinators who carry out the organization's mission (20). The OPC is a key person responsible for integrating the actions noted above; for possible donor detection, donor management, working with donor families, hospital staff, and also development of donor detection programmes and protocol etc. Therefore, OPC need to maintain professional qualification by regular education and certification eligibility (American Board for Transplant Certification, www.abtc.net, USA; Transplant Procurement Management, www.tpm.org, Spain).
- b. Physicians and nurses: nephrologists, critical care specialists, and also other physicians and nurses can engage in the activities of the OPC. An OPC needs to be able to manage both ECDs and DCD.
- c. Subordinate coordinators: in the case of LifeLink (Atlanta, United States), the roles of the OPC are divided across a local call center, referral coordinator, designated coordinator, surgical coordinator, and organ placement coordinator; each department is responsible for specific tasks. Some OPOs may also employ "after-care coordinators."
- d. Organ donation representative or organ facilitator: this person may help to identify potential donors within a facility. In countries with a limited number of OPCs, designated experts within a hospital may take on the role of organ donation representative.
- e. Team or committee responsible for brain death diagnosis: may include two or three medical specialists including a neurologist.
- f. Organ procurement team: transplant surgeons, physicians, and medical staff of the OPO work in collaboration with each other. A standardized donor management protocol, or a Critical Pathway, for organ donation after death is an important tool to en-

able the work of the organ procurement team and the effective identification of all possible deceased donors (see also Working Group 3).

The Functions of the OPO

- a. Surveillance: the detection of potential donors needs to occur at every acute hospital. For example, the Donor Action Programme (www.donoraction.org), originating in Europe, is a quality management programme designed to maximize the donation potential of hospitals by conducting a diagnostic review of practices, including a medical record review and hospital attitude survey, enabling hospitals to identify problems and find solutions (21).
- b. Donor management: the recovery of viable organs for transplantation is dependent on appropriate medical management both before and after brain death. The medical team managing the potential donor must anticipate and prevent or detect and treat abnormalities that can cause circulatory collapse or permanent damage to otherwise transplantable organs, which ultimately make it possible to recover better functioning and multiple organs without loss (22, 23).
- c. Procurement: potential donors should be carefully assessed to exclude contraindications to donation pending the necessary clinical and legal procedures required to establish and certify brain death (24). The relatives will have to be approached and interviewed to obtain formal consent or to obtain a social history about the potential donor. Adequate support for the family from trained staff (preferably a procurement coordinator) at this time is essential; once consent for donation is finalized, the procurement coordinator manages the clinical care of the donor together with the hospital donor management team. Donor information is provided to the donor allocation center to find a match for the donated organs. The procurement coordinator also coordinates the organ recovery process with the surgical teams and provides follow-up information to the donor family.

Suggestions for Enhancing Progress Toward Self-Sufficiency Through OPOs (Fig. 8)

- a. Optimize identification of potential deceased donors, through:
 - Instituting quality management programmes, as in the example of Donor Action (www.donoraction.org);
 - Facilitation of the interaction between the OPC and transplantation team in local hospitals;
 - Assisting hospitals to develop systems for flagging potential deceased donors;
 - Provision of education for medical staff throughout the hospital, in particular in emergency and ICUs;
 - Conducting death audits, healthcare financing administration, condition of participations, compliance monitoring, etc;
 - Providing official recognition and support to hospitals to achieve high rate of organ donation;
 - Use of mandatory reporting for candidate deceased donors.

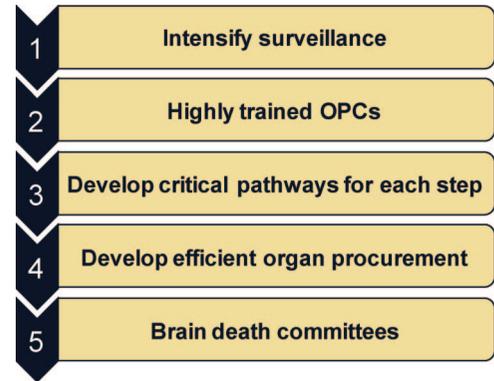


FIGURE 8. Key strategies for adoption by Organ Procurement Organizations (OPOs) to enhance progress towards self-sufficiency.

- b. Best practice management of potential deceased donors, through:
 - Standardization, development, and implementation of critical pathways for donor management;
 - A team approach to donor management, including a member of an OPO;
 - Real-time reporting of the donor's condition to transplantation teams preparing for surgery (25).
- c. Optimize organ procurement, through:
 - Standardization and development of critical pathways for organ procurement;
 - Establishing coordination teams for organ procurement in hospitals;
 - Use of state-of-the-art systems to find the fastest and most cost-effective ways of sending and organ from one city to another (e.g., Multi-Agent System) (26);
- d. Support for the expenses for organ removal and transplantation, through:
 - Governmental support for management of potential donors and expenses incurred in procurement, and support for necessary hospital infrastructure. Whatever the system, it is essential that socioeconomically disadvantaged persons should not be denied the opportunity to donate or the ability to access transplantation.
- e. Improved management for the bereaved, through:
 - Aftercare programmes for relatives of donors (especially in the early period, using a letter of thanks, reporting of organ sharing, etc., may provide great comfort to the bereaved);
 - Commemorative works such as a memorial park, which can encourage positive recognition among relatives of donors and the public.
- f. Increase organ procurement from marginal donors, through:
 - Maximal use of ECD and DCD donors;
 - Utilization of deceased donor organs from potential coronial cases (Unexpected deaths with no obvious cause of death require mandatory reporting to coroners in some countries and often require autopsies. However, organs could be removed by an organ procurement team after reporting to a medical examiner/coroner's

office, and the report during the process could be approved as an autopsy report).

NATIONAL DONATION PROMOTION PROGRAMS

Organ procurement is not just a matter for health authorities, OPOs, and specific hospital personnel. The entire medical community and society as a whole need to be aware of this challenge and become involved, indirectly or directly, in the process of organ procurement (see Working Group 6).

Organization of Donation Promotion

Public awareness of organ donation should be led by the government and its agencies, in collaboration with relevant NGOs. The resulting coalition of different entities should be coordinated at a national level to ensure consistency of messages and reliability of information, although individual organizations should also strive to maintain spontaneity and creativity in their strategic approaches. NGOs contributing to donation awareness may have different focus of interest, yet synergies between them should be encouraged.

Examples of donation promotion programmes functioning at a national level include: Donate Life America, an NGO founded in 1992 to educate the public about organ, eye, and tissue donation; the Korean Donate Life Network (KodoNet), also an NGO, and; Donate Life Australia (See www.donatelife.org.au), a programme funded by the Federal Australian Government.

The Role and Potential Activities of National Donation Promotion Programmes

- a. **Publicity:** for example, conduct a nationwide organ donation campaign regularly, use specification of intent to donate on driver licenses, introduce donor cards, awareness campaigns, or tokens such as an organ donation ribbon, donor memorial events such as a “national Donor Day,” construction of monument or memorial park, etc.
- b. **Information:** target all media for regular release of public information, using printouts, broadcasting, radio, and Internet.
- c. **Research:** seek feedback from living donors and the families of deceased donors.
- d. **Acknowledgment:** support the family of deceased donors, recognize their involvement and share stories and experiences.
- e. **Education:** consistency of educational content is essential, as is the evaluation of the efficacy and quality of education programmes. There is a need to dispel myths and misconceptions about donation after death and to target the content and delivery of education programmes to the specific characteristics of their intended audience (27). Education should be delivered at the level of schools, the general public, and medical professionals. Education concerning the importance of organ donation after death should be delivered iteratively as part of health curricular, from elementary to high school, and include education on brain death. Professional education is especially important for hospital staff working in regional areas, where donation occurs in collab-

oration with a variety of medical teams and individuals may play multiple roles in the absence of extended support from OPOs. Education efforts should be supported by promotion of registration of intent to donate after death.

- f. **Relationships with the media:** establishing good relations with the media will facilitate the timely release of appropriate information and news into the public domain. Regular meetings with the media will establish relationships that are crucial in the setting of crises and events that may be negatively influenced in the absence of clear messages.
- g. **Hotline:** a telephone hotline may be helpful in providing information directly to members of the public and to medical professionals.

HOSPITAL TRANSPLANT PROGRAMS

To contribute to progress toward self-sufficiency, hospital transplantation programmes should strive to achieve the following goals:

- Enhancement of graft survival,
- Increased procurement of organs and enhanced utility of transplanted organs,
- Promotion of medical excellence in transplantation and donation care,
- Promotion of ethical practice in transplantation and donation,
- Promotion of education and training of transplant professionals.

Components of Hospital Transplantation Programmes (Fig. 9)

- a. **Personnel**
 - **Medical staff:** specialist physicians involved in transplantation include transplant surgeons, transplantation physicians, and anesthesiology staff, who are essential for successful operation and management of transplantation patients.
 - **Transplantation coordinators:** responsible for ensuring that all elements of evaluation and postoperative processes are in place (28, 29). Transplant Coordinators (TCs) also perform the review and updating of hospital protocols, quality assessment, quality assurance, data collection, and research. The specific duties of the role vary for each individual center.
- b. **Facilities**
 - **Intensive and high dependency care unit:** these are essential, especially for patients who undergo major heart and lung transplants, and also for deceased donor management.
 - **Hemodialysis unit:** should be available for patients who experience delayed renal graft function or other conditions with decreased renal function.
 - **Transplantation laboratory:** these perform investigations to determine donor and recipient compatibility for transplantation, including tissue typing between a donor and a recipient and serum screening panel reactive antibody (PRA)/crossmatching, and also monitor

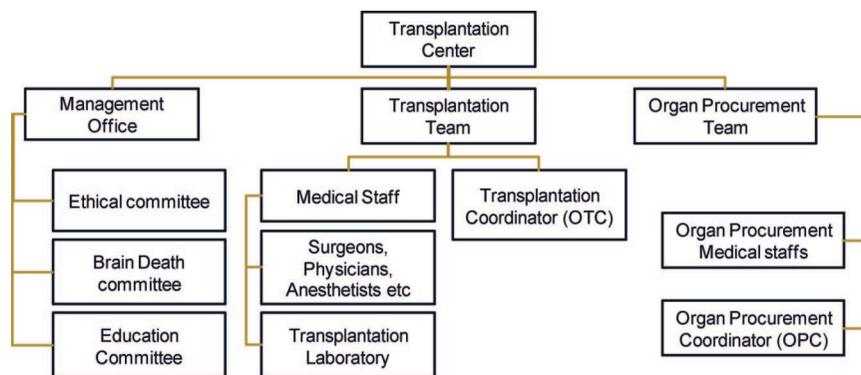


FIGURE 9. Essential components of hospital transplant programmes.

related infections including cytomegalovirus, Epstein-Barr virus, BKV, and immunosuppressive drug concentration. In addition, pathology laboratory supports the assessment of graft viability/rejection.

c. Organ procurement: hospitals have a variable capacity to perform organ procurement. Some may have procurement facilities and staff available, whereas others may be able to identify and maintain potential donors but not perform all (or any) types of procurement. For example:

- Germany: hospitals are divided into three categories. Category A: University Hospital; category B: hospital that has a neurosurgery unit; category C: hospital that does not have a neurosurgery unit.
- France: donor hospitals are assigned into three types by Agency de la Biomedicine, the body providing national oversight of organ procurement. Type 1: hospital for donor detection; type 2: hospital for organ procurement; and type 3: hospital for both organ procurement and transplantation.

Hospitals will require different facilities (e.g., laboratories, electroencephalogram machines, sample banks) according to the category into which they fall.

Management of the Hospital Transplant Programme

For effective management of the various interrelated components and potential challenges of providing transplantation services and procuring organs, it is necessary to have a management team within transplanting hospitals that is responsible for oversight of the activities of the transplantation programme. This team should work independently from the transplantation and procurement teams to ensure transparency and efficacy of regulation and oversight. The Director of the Transplantation Center should work closely with other groups in and outside of the hospital. Management of transplantation programmes at the hospital level needs to incorporate:

- a. An ethics committee (Ethics Committee: American Society of Transplant Surgeons; available at: www.asts.org): the hospital ethics committee will consider various ethical issues such as the eligibility of living donors, provide oversight of organ allocation, and also guide the implementation of new procedures or practices that have ethical implications, such as DCD.

- b. A death determination team (30): a death determination team (responsible for determining and declaring brain and circulatory death) should be established to ensure that the independent determination of death of all potential donors occurs in a transparent and ethical manner consistent with local brain death legislation.
- c. Education and quality control: a team should help to ensure the ongoing education of medical and nursing professionals involved in the transplant programme, monitoring the quality and effectiveness of educational activities to ensure maintenance of the highest possible standards.
- d. A public relations team should also assist in education initiatives aimed at the general public and coordinate the release of information about local transplant activities to the media.

Strategies for Adoption by Hospital Transplant Programmes to Enhance Progress Toward Self-Sufficiency

To achieve self-sufficiency, it is important to expand the donor pool and to improve the outcomes for patients. Therefore, it is recommended that hospitals consider implementing the following strategies:

- a. The ECD: a major concern regarding ECD kidneys is poor long-term graft survival. However, recent studies have showed 5-year graft survival to be comparable with standard grafts, although ECD grafts had slightly worse function. Therefore, utilization of ECD is likely to have a role in achieving self-sufficiency. In the United States, a modified allocation policy for deceased donor kidneys was put into place in 2002, whereby transplant candidates are now asked to indicate whether they are willing to consider ECD kidneys at the time of placement on the waiting list. ECD kidneys are allocated from this separate supplementary list by waiting time, without consideration of HLA matching, to a preinformed group of candidates (31). In Spain, policy related to the active use of organs from aged donors was established in 1990, resulting in donors aged 60+ years now accounting for 46.6% of all donors.
- b. DCD: there is still a general reluctance to use DCD for kidney donation and transplantation, because of a relatively high incidence of delayed graft function and pri-

mary nonfunction compared with conventional DBD. However, optimal organ preservation and careful selection of kidneys from DCD may reduce these risks of delayed graft function and primary non-function (32).

COORDINATION SYSTEMS

Multiple systems functioning at the local, regional, and national level are involved in the processes of organ donation and transplantation, and the effective coordination of these various systems is fundamental to the pursuit of self-sufficiency. Each country needs to have a national organ donation and transplantation coordination system that fits with its particular organizational structures and components. Coordination may also extend beyond national borders.

Levels of Coordination in Organ Procurement (Fig. 10)

The institutions involved in the process of organ procurement may operate at three different levels of coordination (national, regional, and local), each of which should be systematically integrated.

- a. Local (hospital level): at this level, the coordination of organ procurement involves a physician (assisted by one or more nurses), who works on a part-time basis in the hospital and is responsible for detection and evaluation of potential donors, and coordinating the entire donation-transplantation process including family approach. The physician is in close relationship with the transplant team and the OPC and reports directly to the Hospital Director. Most of the physicians in this role are intensivists, but some other specialists might be included.
- b. Regional level: regional bodies may help to coordinate procurement and transplantation at the local level between individual hospitals and with state, provincial, or national organizations, particularly in the context of large populations or geographical boundaries. For example, there is an administrative office for each of the 17 regions in Spain, which together constitute the National Transplant Commission where technical decisions are made and then communicated to a coordinator in the relevant hospital.
- c. National level: each country that performs transplantation needs to organize a unified coordination network that regulates the organ donation and transplantation process. National coordination systems essentially provide a support agency for the entire organ donation and transplantation system. National coordination is concerned with organ distribution, transport organization, waiting list maintenance, general and specialized information, and any policies or actions that can contribute to improved outcomes in the donation transplantation process. This support is of utmost importance for small hospitals that cannot undertake organ donation processes independently. Quality control for each institution, establishment of allocation rules, collection and analysis of national data, education, and certification for personnel are all coordinated at a national level.

International Coordination

International coordination is required to facilitate cross-border exchange of information and research. It also may enable better efficiencies through regional organ sharing programmes that can avoid discard of usable organs and address urgent needs most effectively. International coordination and cooperation also has a critical role in addressing the problems of organ trafficking and transplant tourism. Examples of international system coordination in organ donation and transplantation include:

- a. EIF (<http://www.eurotransplant.org/>): EIF is responsible for the mediation of organ donation procedures and the allocation of donated organs across Austria, Belgium, Croatia, Germany, Luxemburg, The Netherlands, and Slovenia. This coordination network incorporates all transplant hospitals, tissue-typing laboratories, and hospitals where donations take place in the participating countries. The aims of EIF are to:
 - Achieve optimal use of available donor organs and tissues;
 - Secure a transparent and objective allocation system, based on medical and ethical criteria;
 - Assess factors influencing waiting-list mortality and transplant results;
 - Support donor procurement and increase the supply of donor organs and tissues;
 - Promote scientific research;
 - Disseminate and implement EU legislation relevant to transplantation;
 - Promote, support, and coordinate organ donation and transplantation in the broadest sense.
- b. Trans Tasman Exchange (<http://www.tsanz.com.au/organallocationprotocols/transasmanexchangeprinciples.asp>): The Trans Tasman agreement between Australia and New Zealand enables the sharing of organs between these nations' respective populations in particular circumstances. The agreement is mutually beneficial, with organs that cannot be used in one country being offered to the other, and in cases of urgent need, the saving of a life is prioritized without concern for individual nationalities. Concern for eq-

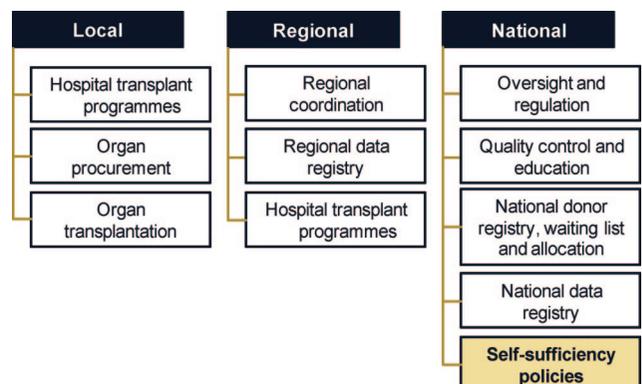


FIGURE 10. Three levels of coordination for national organ donation and transplantation programmes and responsibilities at each level.

uity is reflected in the distributional methods employed between the countries.

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APPENDIX 2: The Critical Pathway for Organ Donation After Death

Assessing the Potential of Donation from Deceased Persons and Promoting the Identification of Potential Deceased Organ Donors (Working Group 3)

Self-sufficiency in transplantation is defined as the satisfaction of the transplantation needs of a given population, by using resources obtained from within that population. Donation from deceased persons, realized to its maximum therapeutic potential within a given population, is an essential element of the self-sufficiency paradigm, as already stressed in existing International Standards:

- WHO Guiding Principles for Human Cell, Tissue and Organ Transplantation Guiding Principle 3 (1):

“Donation from deceased persons should be developed to its maximum therapeutic potential”

The principle emphasizes the importance of both taking the legal and logistical steps needed to develop deceased donor programmes where they do not exist, and making existing programmes as effective and efficient as possible.

- The Declaration of Istanbul on Organ Trafficking and Transplant Tourism (2):

“Governments, in collaboration with health-care institutions, professionals, and NGOs, should take appropriate actions to increase deceased organ donation . . . In countries without established deceased organ donation or transplantation, national legislation should be enacted that would initiate deceased organ donation and create transplantation infrastructure, so as to fulfill each country's deceased donor potential. In all countries in which deceased organ donation has been initiated, the therapeutic potential of deceased organ donation and transplantation should be maximized.”

A SYSTEMATIC APPROACH TO THE PROCESS OF DONATION FROM DECEASED PERSONS

To develop and maximize organ donation activities, an organizational approach to donation from deceased persons

should be adopted. Donation from deceased persons is a process (A process is a set of correlated activities, which convert an input into an output by generating an added value [UNIEN ISO 9000:2000]), involving a set of steps at each of which losses of potential deceased organ donors can occur. One of the weakest links of this chain is the failure to identify and subsequently refer potential deceased organ donors. A systematic approach to the process of donation from deceased persons will help populations to define actions, roles, and responsibilities within the process, tailored to their local circumstances. This systematic approach should consider both DBD and DCD.

Estimating the Potential of Organ Donation From Deceased Persons

In the pursuit of self-sufficiency, estimating the potential of organ donation from deceased persons within a population is essential.

- It facilitates understanding of the local possibilities for satisfying the transplantation needs of that population.
- It allows a better comprehension of those factors acting at a hospital, regional, or national level, whatever their nature, that affect the potential of donation from deceased persons within a given population and hence organ donation and transplantation outcomes.
- It is crucial to evaluate performance in the process of donation from deceased persons within a specific geographical location, at a hospital, a regional, or a country level. Performance evaluation is necessary to formulate relevant policies and standards of practice and to discern achievable goals for organ donation programmes, through the identification of the best performers and critical success factors (benchmarking), and evaluation of the effectiveness of implemented strategies.

Evaluation of performance in organ donation, especially when comparing countries or regions, has been classically addressed by comparing numbers of deceased donors per million population. This is a universal, objective, and easy-to-construct metric of performance. However, it has been considered flawed, because it assumes that the potential of organ donation from deceased persons is uniform across all jurisdictions under assessment. It fails to capture performance in the context of rates of mortality under conditions suitable for organ donation. Many local factors will affect this final number, including demography, mortality in the context of brain injury, accessibility to the hospital, cultural, healthcare system, and organizational factors, among others (3, 4). Even when severely brain damaged patients are able to access a hospital, many other factors will determine whether, if the person finally dies, this occurs under conditions suitable for organ donation. Such factors include, for example, the sufficient availability of intensive care resources or variability in clinical practice in the treatment of neurocritical patients and in terminal care.

When estimating the potential of organ donation from deceased persons, two different, although potentially complementary, approaches may be adopted:

- A retrospective approach, based on the analysis of mortality data or, ideally, through a clinical chart review of

deaths occurring within a specific setting to identify potential donors.

- A prospective approach, through the systematic identification and referral of persons dying in conditions suitable for organ donation.

These strategies have been applied in different settings and have been frequently combined for better estimation of the potential of organ donation from deceased persons and accurate evaluation of performance.

Use of Mortality Data to Estimate the Potential of Donation From Deceased Persons

The use of mortality data is considered an objective, cheap, and nonlabor intensive approach to the estimation of the potential of donation from deceased persons. This estimation may be based on general mortality data or in-hospital deaths. Some selection criteria may be applied to any of these data, based on the inclusive factors (conditions potentially leading to a severe brain injury or circulatory failure) and exclusive factors (absolute medical contraindications to organ donation). These approaches have been used to generate nationwide estimations of the potential of donation from deceased persons in the United States (5) and the European setting (6).

In the US study, performance was evaluated for each of the different UNOS regions based on Donor Extraction Rate, calculated as the number of actual donors aged 1 to 65 years over the number of evaluable deaths (in-hospital deaths for ages 1 to 65 years, not medically unsuitable, based on the ICD-9 codes). Notably, results of this study were comparable with previous approaches based on a detailed review of medical records of in-hospital deaths (5). Coppen et al. recently compared the performance of deceased donation processes across several European countries, based on the calculation of 'Donor Efficiency Rate per Proxy' (actual donors vs. deaths because of cardiovascular and traffic accidents), as the rate of mortality because of these causes was found to bear a high correlation with deceased donation activity (6).

However, attempts to work with mortality data face several limitations given that these data are usually not readily available, death certificate data are restricted by the inherent problems of underreporting and codification errors, and codification of deaths is not a universally implemented practice.

Prospective Identification and Referral of Potential Donors and Clinical Chart Review

Studies of donation potential, based on prospective identification or clinical chart review, have been performed in several countries and enable a good comprehension of deceased donation performance in those settings for which estimates are available (Fig. 11).

Both methodologies (prospective identification of potential donors and clinical chart reviews) have the advantages of being sensitive to local variation in factors that affect the potential of donation in a given population, allowing analysis of an individual's suitability for organ donation, and facilitating the identification of areas for improvement in deceased donation processes. However,

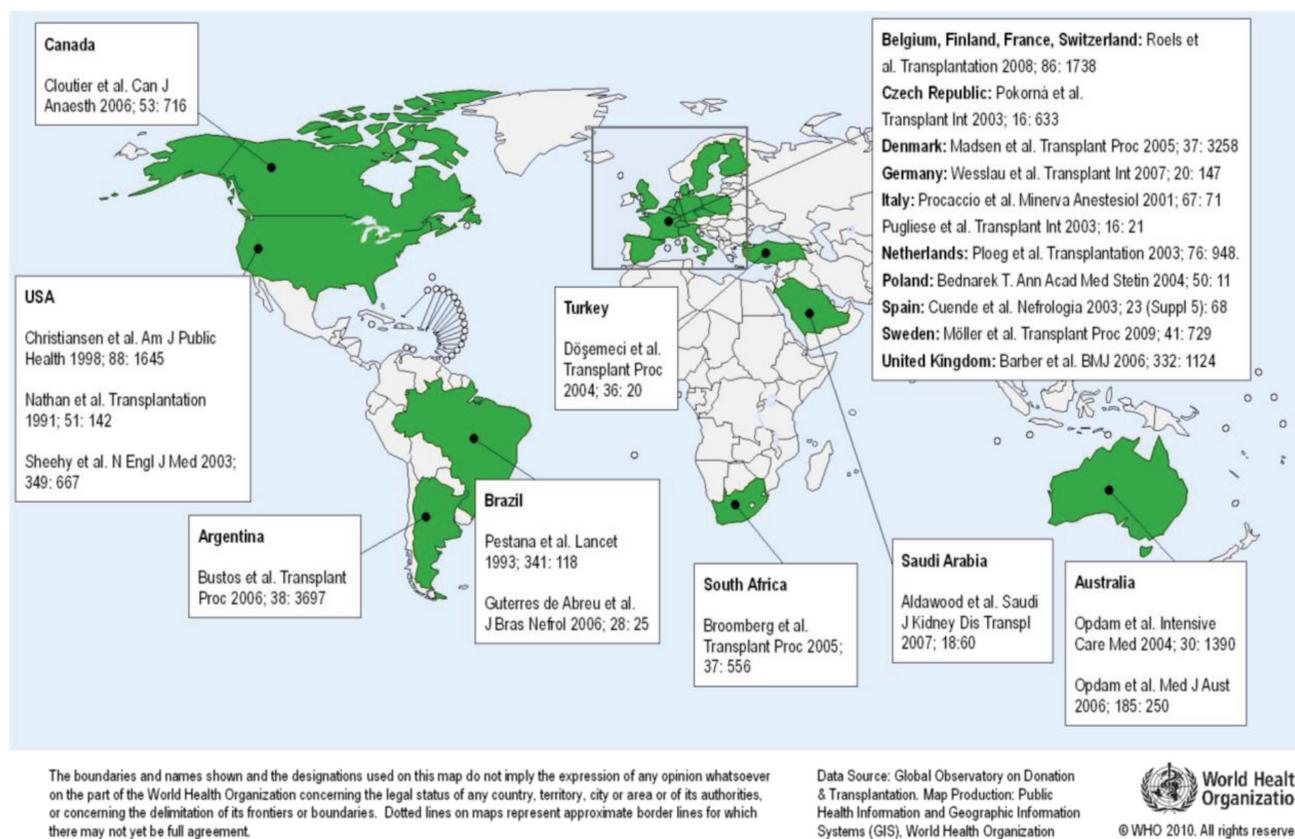


FIGURE 11. Countries with published information on the potential of deceased donation, estimated through prospective identification-referral or clinical chart review (13-33).

the fact that these methodologies are not standardized at a universal level limits international comparisons of deceased donor potential. Table 6 describes in detail the design of a selection of international studies estimating national donation potential. Notably, the definition of a potential donor varies greatly between these studies. In addition, most of these studies are based on a self-reporting, prospectively or retrospectively, performed by professionals in charge of the process of donation from deceased persons. Hence, estimates of donation potential rely on the degree of referral and identification of potential donors, which may vary depending on the motivation and experience of the health professional in charge. Constructing combined indicators of potential of donation from deceased persons, based on self-reported data on one hand and mortality data on the other hand, has been proposed as a good approach for a more realistic comprehension of the potential of donation and as a metric of performance in donor identification (7).

As an example of the application of these methods in programme evaluation, the performance of different OPOs in the United States is evaluated according to Donation Rate, whereby the number of actual donors meeting a set of eligibility criteria is compared with the number of eligible deaths (≤ 70 years, ultimately legally declared brain dead and with no medical contraindications to organ donation). This metric represents the performance of a particular OPO with respect to the conversion of potential donors, once identified, into

actual donors (3). Eligible deaths are communicated prospectively from hospitals to OPOs by self-report, potentially introducing bias because of an underreporting. To gain a better understanding of overall performance, Ojo et al. (3) proposed a complementary Notification Rate metric, according to which the number of eligible deaths was to be compared against the number of notifiable deaths, this number being estimated on the basis of in-hospital mortality data with some inclusive and exclusive factors (through the analysis of ICD-9 codes) as mentioned earlier.

Clinical chart review of deceased persons within a particular setting is considered the gold standard for accuracy in the assessment of donation potential, especially if performed by external observers. However, it has been considered costly and time consuming by some commentators. Others have recommended the systematic and routine performance of clinical chart reviews by those professionals in charge of the deceased donation process, as an essential tool for a continuous improvement in performance (8, 9). Quality assurance programmes based on this approach have been developed in different countries and are considered an essential element of success in many models (10). Based largely on self-report, information provided by these quality assurance programmes may be complemented by external audits of centers or by the construction of indicators, which combine information collected based on self-reporting methods with mortality data.

Given wide international variation in approaches to organ donation processes, the provision of an internationally

TABLE 6. National estimations of the potential of donation based on the prospective identification and referral of potential donors or on a clinical chart review

| Ploeg, The Netherlands (29) | |
|--------------------------------------|---|
| Scope | 11 hospitals (convenient selection of different types of hospitals) |
| Design | Prospective assessment |
| Data collection | |
| Performed by | Physicians declaring death |
| Performed on | Hospital deaths |
| Definition of a potential donor | No MC, below an age threshold (maximum); diagnosis possibly leading to BD (optimistic); artificial ventilation; and BD declared (realistic) |
| Inferred national estimates | Actual donors, consented donors, and number of hospitals of each type |
| Sheehy, United States (12) | |
| Scope | 25–36 OPOs (convenient selection) |
| Design | Retrospective clinical chart review |
| Data collection | |
| Performed by | Trained staff members of OPOs |
| Performed on | ICU deaths |
| Definition of a potential donor | No absolute MC, aged ≤70 years and met criteria for BD |
| Inferred national estimates | Actual donors, population |
| Barber, United Kingdom (14) | |
| Scope | All ICU with a potential for DBD |
| Design | Retrospective |
| Data collection | |
| Performed by | Donor transplant coordinators/donor liaison nurses/some ICU link nurses |
| Performed on | ICU deaths |
| Definition of a potential donor | No absolute MC and brain stem death declared |
| Inferred national estimates | — |
| QAP, Spain (2007)^a | |
| Scope | Donor hospitals (75%, convenient selection) |
| Design | Retrospective |
| Data collection | |
| Performed by | Transplant coordinators |
| Performed on | ICU deaths |
| Definition of a potential donor | No MC and met criteria for BD |
| Inferred national estimates | Actual donors |

^aQuality assurance programme in the deceased donation process. ONT website.

MC, medical contraindications; BD, brain death; OPO, organ procurement organization; ICU, intensive care unit; DBD, donation after brain death.

applicable reference framework for systematizing donation from deceased persons, together with guidelines for internationally consistent methods and metrics for estimation of donation potential and evaluation of donation performance,

will facilitate the development of consistent, integrated organizational approaches to organ donation, and thus advance the pursuit of self-sufficiency worldwide. Moreover, common international approaches to donation processes and their evaluation will help to overcome the inherent difficulties of international comparisons, needed for transparency of practices and outcomes, international benchmarking, and mutual learning.

THE CRITICAL PATHWAY FOR ORGAN DONATION FROM DECEASED PERSONS

Objectives

The principal objective of a Critical Pathway approach to the process of donation from deceased persons is to facilitate the development, and progressive increase, of deceased donation activities globally. This objective is central to the broader goal of self-sufficiency in transplantation and may be broken down into the following specific objectives:

- To provide a common systematic approach to the process of donation from deceased persons, both for DBD and DCD;
- To create common triggers to facilitate the prospective identification and referral of the potential deceased organ donor and precipitate the deceased donation process (action);
- To provide common procedures to estimate the potential of organ donation from deceased persons and to evaluate performance in the process of donation after death (assessment).

Methodology

To achieve the objectives above, TTS, WHO, and ONT convened a group of experts, widely representative of the different WHO regions, on three different occasions (Sydney, Australia, August 2008; Geneva, Switzerland, March 2009; and Berlin, Germany, October 2009), to draft a Global Consensus Document providing specific recommendations in this regard. This draft was finalized during the Third WHO Global Consultation on Organ Donation and Transplantation (Madrid, Spain, March 2010) by Working Group 3.

The guidelines provided to the group for the construction of these recommendations were:

- Recommendations were to be based on the current scientific knowledge, experience from existing running procedures and systems, interaction, mutual learning, and agreement between the different countries;
- Recommendations were to be conceived in a way that the methodology should be applicable to every country or region, regardless of the level of development of its healthcare system or the baseline situation of its deceased donation activity.

During the past year, the draft recommendations with regards to the structure of the deceased donation process, assessment of the potential of donation from deceased persons, and provision of clinical triggers for the identification and referral of potential donors have been piloted in different

settings—India (Dr. Vivekanand Jha), Russia (Dr. Marina Minina), Saudi Arabia (Dr. Faisal Shaheen), and South Africa (Dr. Elmi Muller). These pilot experiences have shown the recommendations to be applicable and beneficial in each of the settings in which they were applied, with increases demonstrated in the identification and referral of potential deceased organ donors as a result of implementation. The outcomes of these pilot experiences were presented during the combined ISODP-ETCO congress, celebrated in Berlin in October 2009.

Recommended Structure for the Process of Deceased Donation: The Critical Pathway

The process of organ donation from deceased persons defined in this project is described under The Critical Pathway for organ donation. Pathways are described for both DBD and DCD.

The process of organ donation from deceased persons developed by the work group is graphically represented in Figure 2. The processes of DBD and DCD are described below:

a. Possible deceased organ donor

- A possible deceased organ donor is defined as the patient with a devastating brain injury or lesion or the patient with circulatory failure and apparently medically suitable for organ donation
- Identification of the possible deceased donor and referral by the treating physician to a key donation person/OPO should ideally occur as early as possible in the process. For example, in the United States, each imminent death should be referred to the OPO for assessment (where imminent may be understood as the time of transition between therapeutic treatments to end-of-life care). However, referral of the possible donor might not be acceptable in all local circumstances (i.e., many countries do not find it acceptable to refer possible donors where death has not yet been established). Hence, it is accepted that referral might occur later on in the process of donation from deceased persons. It should be pointed out that referral is understood as the action of making the key donation person/OPO aware of the possibility of deceased donation, but it does not mean any other subsequent action. Referral requires, and is linked to, the act of identification.
- The possible deceased organ donor when defined as the patient with a devastating brain injury represents the common starting point of two different pathways that activate depending on evolution and clinical practice: the process of DBD and the process of DCD. The possible donor defined as the patient with circulatory failure might be the starting point of the process of DCD.

b. The process of DBD

- A potential donor after brain death (DBD) is defined as a person whose clinical condition is suspected to fulfill brain death criteria.
- A potential DBD would become an eligible donor after brain death if the person is considered medically

suitable for organ donation and is declared dead based on neurologic criteria, as stipulated by the law of the relevant jurisdiction. Regarding medical suitability, it should be acknowledged that medical conditions precluding organ donation might vary between countries according to legal and technical provisions. The reasons why a potential DBD does not become eligible for donation might be the following: (1) failure to identify and subsequently refer the case (if this is the point for referral, according to local circumstances); (2) presence of medical conditions precluding organ donation; (3) the diagnosis of brain death cannot be confirmed or completed (i.e., because of the lack of technical or human resources necessary for confirmation); or (4) hemodynamic instability leading to an anticipated cardiac arrest. The three last situations could still be linked to the possibility of controlled or uncontrolled DCD.

- An eligible DBD would become an actual donor after brain death only after consent has been obtained for organ donation. Two possible situations define the actual DBD. The first situation would be that in which an operating incision has been made with the intent of organ recovery for the purpose of transplantation. In the second situation, the condition of actual donation would be defined when at least one organ has been recovered for transplantation purposes. The evolution from eligible to actual donor entails the need to obtain permission for organ donation, although such permission might have been obtained at an earlier stage during the process, according to the legal framework and practical provisions in place. Also, according to local circumstances, permission might be based on the expression of the deceased during his/her lifetime (i.e., through a specific registry) or might be obtained from their relatives. Authorization by a coroner or other judicial officer to allow donation for forensic reasons, if applicable, might also be needed at a certain point. Continuous evaluation of medical suitability for organ donation, hemodynamic maintenance of the donor, organ allocation, and the finally surgical incision and organ recovery are all necessary steps in the transition from eligible to actual DBD. Losses because of maintenance problems would still be linked to the possibility of uncontrolled DCD.
- Finally, a utilized donor after brain death would be the actual DBD from whom at least one organ has been transplanted, followed by organ allocation and transplantation itself. Organ damage during recovery, anatomical, histologic and functional abnormalities of the organs detected during or after recovery, inadequate perfusion/thrombosis of the organs, logistical problems, and lack of an appropriate recipient are the categorical reasons why an actual DBD does not become a utilized DBD.

b. The process of DCD

- Two conditions deriving from the possible deceased organ donor could define the potential donor after circulatory death. A person whose circulatory and respiratory functions have ceased and in whom resuscitative measures are

not to be attempted or continued would define the first of these two conditions. DCD under these particular circumstances is so far limited to some specific countries (i.e., France, Spain), although possible to be developed in many other settings.

- The second condition defining a potential donor after circulatory death would be that of the patient in whom the cessation of circulatory and respiratory functions is anticipated to occur within a time frame that will enable organ recovery. This situation usually applies when withdrawal of life-supporting therapy has been decided on the basis of the ominous prognosis of the patient, pursuant to the family decision, or the request of the family. It should be pointed out that there are an additional small number of patients who would fulfill these criteria of potential DCD but without brain injury, that is, end-stage lung disease patients with elective withdrawal of ventilatory support or patients with progressive neurodegenerative diseases such as amyotrophic lateral sclerosis with elective withdrawal of life-sustaining therapy.
- A potential DCD would become an eligible donor after circulatory death when the person is considered medically suitable for donation and has been declared dead based on the irreversible absence of circulatory and respiratory functions as stipulated by the law of the relevant jurisdiction, within a time frame that enables organ recovery. The steps required for a potential DCD becoming an eligible DCD would be: (1) the identification and subsequent referral of the case for organ donation (if not previously performed); (2) the declaration of death by circulatory and respiratory criteria within an appropriate time frame that allows organ recovery, (3) the consent to proceed with organ recovery (this may occur before or during the process according to local legislation), and (4) evaluation of the medical suitability for donation.
- An eligible DCD would become an actual donor after circulatory death if an incision has been made for organ recovery and at least one solid organ has been recovered for the purpose of transplantation. This requires at least continuous medical evaluation, organ allocation and recovery. Reasons why an eligible DCD does not become an actual DCD are as for the process of DBD.
- A utilized donor after circulatory death is defined as the actual DCD from whom at least one organ has been transplanted. Organ allocation and transplantation are the conversion steps in this process. The same categorical reasons as those described for the process of DBD justify that an actual DCD not be converted to a utilized DCD.

Recommendations for the Prospective Identification and Referral of the Potential Deceased Organ Donor

Identification and referral of the potential deceased organ donor is one of the most critical steps in the realization of donation after death. Identification of a potential deceased organ donor should be inherently linked to the act of referral to a key donation person/transplant coordinator/OPO specifically appointed for the activation of the deceased donation process. The act of referral means informing these key organ donation personnel of an individual that could be a possible, a potential or an eligible organ donor, according to the pathway described above.

When should the referral occur?

- For DBD: at a minimum, when the Critical Pathway establishes an eligible donor.
- For DCD: at a minimum, when the Critical Pathway identifies a potential donor.
- For DBD and DCD: referral could also occur when the Critical Pathway establishes a possible donor; or
- Referral may also occur when the family requests to speak with the OPO/key organ donation personnel.

RECOMMENDED METHODOLOGY FOR THE RETROSPECTIVE ASSESSMENT OF THE POTENTIAL OF ORGAN DONATION FROM DECEASED PERSONS

Retrospective assessment of the potential of organ donation from deceased persons for the purposes of programme evaluation must consider all possible donors, potential donors, and eligible donors. The basic methodology for such estimations is based on coded mortality data or clinical chart review.

Estimating the Number of Possible Deceased Organ Donors

The number of possible deceased organ donors, particularly those with a devastating brain injury, may be estimated from the analysis of coded mortality data. This coded mortality data would identify those deaths most likely to become donor candidates or would identify deceased patients with a diagnostic code consistent with brain injury or lesion.

On the basis of mortality data, therefore, the possible deceased organ donor would be identified as a person dying within a hospital with primary or secondary brain damage, defined by the presence of at least one of the ICD codes represented in Table 7 among their primary and secondary diagnoses (7). Alternatives to this codified mortality system have been applied in other countries (e.g., death with acute cerebral lesion in Italy).

Estimating the number of possible deceased organ donors on the basis of codified mortality data has the following caveats:

- Persons dying with primary or secondary brain damage may have not died as a consequence of the brain injury;
- The ICD system is not universally applied in all the countries, regions, or hospitals, or in all critical care units;
- Coded mortality data are not readily available;
- Contrary to clinical chart review, it does not allow the complementary analysis of the particular reasons why a potential donor did not become an actual donor, thus mortality data have limited usefulness as a tool for the evaluation of the performance of deceased donation programmes.

Estimating the Number of Potential and Eligible Deceased Organ Donors After Brain Death

The number of potential and eligible donors, in contrast, is necessarily obtained from a clinical chart review. The most critical aspect of estimating the number of potential and eligible

TABLE 7. ICD-9 codes representing the most frequent causes of brain death

| ICD-9 | Description |
|---|---|
| Cranioencephalic traumatism | |
| 800 | Fracture of vault of skull |
| 801 | Fracture of base of skull |
| 803 | Other and unqualified skull fractures |
| 804 | Multiple fractures involving skull or face with other bones |
| 850 | Concussion |
| 851 | Cerebral laceration and contusion |
| 852 | Subarachnoid, subdural, and extradural hemorrhage after injury |
| 853 | Other and unspecified intracranial hemorrhage after injury |
| 854 | Intracranial injury of other and unspecified natures |
| Cerebrovascular accidents | |
| 430 | Subarachnoid hemorrhage |
| 431 | Intracerebral hemorrhage |
| 432 | Other and unspecified intracranial hemorrhage |
| 433 | Occlusion and stenosis of precerebral arteries |
| 434 | Occlusion of cerebral arteries |
| 436 | Acute, but ill-defined, cerebrovascular disease |
| Tumors of the central nervous system | |
| 191 | Malignant neoplasm of brain |
| 192 | Malignant neoplasm of other and unspecified parts of nervous system |
| 225 | Benign neoplasm of brain and other parts of nervous system |
| Cerebral anoxia | |
| 348.1 | Anoxic brain damage |

ICD, international classification of disease.

deceased donors in a particular setting is the evaluation of brain death, in particular with regard to the identification of the clinical condition of brain death (there is at least one physical examination compatible with brain death) and the declaration of brain death (the diagnosis of brain death has been completed according to international standards and legally declared). However, as clinical chart review relies on the recording of complete and reliable chart data, for the purposes of appraising whether a person fulfils the criteria of brain death, it would be necessary to agree on standard minimum data requirements for hospital charts. Two examples of minimum data requirements are provided below ([12]; methodology of the Spanish Quality Assurance Programme in the donation process).

Metrics to Represent the Potential of Donation

Proposed metrics by which to perform comparisons of the potential of donation from deceased persons are outlined in Table 8.

RECOMMENDATIONS FOR THE EVALUATION OF THE PERFORMANCE IN THE DECEASED DONATION PROCESS

This section intends to provide a set of definitions and metrics that represent performance in the deceased donation process. These metrics, which describe the overall performance of the system, will facilitate the identification of critical success factors.

Suggested Additional Definitions

- Multiorgan donors: donors from whom at least two different types of organs have been recovered for the purpose of transplantation as a solid organ.
- Organs recovered per donor: number of different organs that have been recovered from actual donors. To calculate the number of organs recovered, only organs recovered with the intention of transplantation as a solid organ should be counted.
 - Number of kidneys recovered: double procurement, 2; single procurement, 1.
 - Number of livers recovered: exclude if the intention of recovery is not transplantation as a solid organ (i.e., hepatocytes).
 - Number of hearts recovered: exclude if the intention of recovery is not transplantation as a solid organ (i.e., heart valves).
 - Number of lungs recovered: double procurement, 2; single procurement, 1.
 - Number of pancreas recovered: exclude if the intention of recovery is not transplantation as a solid organ (i.e., islets).
 - Number of small bowel procured.
- Organs transplanted per donor: number of different organs that have been transplanted from actual donors. To calculate the number of organs transplanted, only solid organs should be counted.
 - Number of kidneys transplanted: double transplantation, 2; single transplantation, 1.
 - Number of livers transplanted: count one, regardless of specific use of the organ (i.e., split liver transplantation).
 - Number of hearts transplanted.
 - Number of lungs transplanted: double transplantation, 2; single transplantation, 1.
 - Number of pancreas transplanted.
 - Number of small bowel transplanted.

Suggested Metrics of Performance

Performance in the deceased donation process may be represented as indicated in Table 9.

Representing Performance at a Regional or at a Country Level According to Different Availability of Data

The number of possible donors at a regional/country level may be estimated based on a top-down approach to infer the performance of the deceased donation processes for a given region or country. Possible methodologies are described below:

- Living population : deaths within the country/region.
- Deaths within the country/region because of selected pathologies: (crude) deaths because of cerebrovascular accidents and traffic accidents.

Criteria applied by Sheehy et al. to the potential donor after brain death (I2):

A deceased person for whom evidence of all or any of the following is found in the hospital chart:
 the absence of spontaneous respiration and two additional brain-stem reflexes,
 a physician’s note declaring brain death,
 a flat electroencephalogram,
 or other brain studies indicating irreversible destruction of the brain.

Criteria applied at the Spanish Quality Assurance Programme in the deceased donation process

Four concepts are applied: confirmed brain death, highly probable brain death, possible brain death, and not assessable brain death.

1. Confirmed brain death: For the purposes of the programme, a person will be considered as a confirmed brain death if any of the following circumstances are present:

- a. All legal requirements are properly reflected in the chart.
- b. A neurologist or neurosurgeon has explored the dead person and has recorded that brain death has occurred and there is no evidence against this diagnosis.
- c. ICU physician has recorded that brain death has occurred and there is no evidence against this diagnosis.

To define a person as being a highly probable or a possible brain death, the following issues are considered based on the available information in the clinical chart:

- a. Etiology of the process causing death: It must be one of the known etiologies that cause brain death and must be severe enough to cause it.
- b. Conditions: absence or no evidence of spontaneous breathing and movements.
- c. Findings in clinical exploration:
 - Progressing nonreactive midriasis (de novo nonreactive midriasis in a patient with severe neurologic pathology, in the context of a severe clinical deterioration and which is not explained by drug interference)
 - Absence of at least one of the following brain-stem reflexes: corneal, oculocephalic, oculovestibular, coughing, and gag.
 - Negative atropine test.
- d. Clinical signs:
 - Abrupt arterial hypotension, other causes apart from brain death having been discarded.
 - Abrupt polyuria, other causes having been discarded.
 - Refractory and progressive intracranial hypertension (intracranial hypertension which progresses in the minutes or hours before death, towards limits that provoke a cerebral perfusion pressure of 0 or close to 0 mm Hg, with no response to therapy).

2. Highly probable brain death:

Etiology + conditions + 1 finding (at least) in clinical exploration + 1 clinical sign (at least)

Etiology + conditions + 2 findings (at least) in clinical exploration

3. Possible brain death:

Etiology + conditions + 1 finding in clinical exploration (at least)

Etiology + conditions + 1 clinical sign (at least)

4. Finally, brain death will not be assessable in any of the following circumstances:

- a. Etiology of the process is known, severe and consistent with brain death, in the absence of any more information in the clinical chart or absence of clinical chart.
- b. Etiology of the process is known, severe, and can lead to brain death, but diagnosis could not be confirmed because of a limitation of the therapeutic effort.
- c. Etiology of the process is known, severe, and can lead to brain death, but exposure to barbiturics, muscle relaxant drugs at the moment of cardiac arrest is present.
- d. Infratentorial processes with no legal diagnosis of brain death.

Any other situation will be considered as no brain death.

TABLE 8. Proposed metrics to represent the potential of donation

- Possible deceased organ donors/hospital deaths×100
- Potential donors after brain death/possible deceased organ donors×100
- Potential donors after circulatory death/possible deceased organ donors×100
- Potential donors after circulatory death/potential donors after brain death×100

TABLE 9. Indicators of performance in the deceased donation process

- Actual donors/possible donors×100
- Actual donors/potential donors×100
- Actual donors/eligible donors×100
- Multiorgan donors/actual donors×100
- Utilized donors/actual donors×100
- Organs recovered/donor
- Organs transplanted/donor

- c. In-hospital deaths within the country/region.
- d. In-hospital deaths within the country/region because of selected pathologies: In-hospital deaths with brain injury, on the basis of at least one of the ICD-9 codes specified in Table 7 among their primary and secondary diagnosis (i.e., possible deceased organ donors).

The number of potential and eligible donors for a given region or country could be estimated for countries in which a clinical chart review is performed at all hospitals meeting some specific criteria (acute care hospitals, hospitals authorized for organ procurement). In addition, if information is not available for all hospitals meeting some specific criteria, estimation might be performed for a given region/country by inference according to a given parameter.

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GLOSSARY OF TERMS

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| Actual deceased organ donor | Deceased person in whom an operative incision was made with the intent of organ recovery for the purpose of transplantation or from whom at least one organ was recovered for the purpose of transplantation (see Critical Pathway) | <i>Critical Pathway Working Group, Madrid Consultation</i> |
| Allocation | The assignment of human cells, tissues, and organs to a transplant candidate, based on a set of rules | <i>WHO Glossary</i> |
| Authorization | Authorization, accreditation, designation, licensing or registration, depending on the concepts used and the practices in place in each jurisdiction | <i>Adapted from EU Directive 2010</i> |
| Bank | See tissue establishment | |
| Brain death | Irreversible cessation of cerebral and brain stem function; characterized by absence of electrical activity in the brain, blood flow to the brain, and brain function as determined by clinical assessment of responses. A brain dead person is dead, although his or her cardiopulmonary functioning may be artificially maintained for some time | <i>Glossary of UNOS</i> |
| Bridge therapy | See organ replacement therapy | |
| Certification of death | Formal standardization documentation of death | <i>WHO Glossary</i> |
| Circulatory death | Death resulting from the irreversible cessation of circulatory and respiratory function; an individual who is declared dead by circulatory and respiratory criteria may donate tissues and organs for transplantation | <i>Adapted from the WHO Glossary</i> |
| Consent to donation | Legally valid permission for removal of human cells, tissues, and organs for transplantation | <i>WHO Glossary</i> |
| Death diagnosis | Confirmation of death from evidence acquired through clinical investigation or examination, meeting criteria of brain or circulatory death | <i>WHO Glossary</i> |
| Distribution | Transportation and delivery of cells, tissues or organs intended for human applications, after they have been allocated | <i>WHO Glossary</i> |
| Donation | Donating human cells, tissues or organs intended for human applications | <i>WHO Glossary</i> |
| Donor | A human being, living or deceased, who is a source of cells, tissues or organs for the purpose of transplantation | <i>WHO Glossary</i> |
| Donor characterization | The collection of the relevant information on the characteristics of the donor needed to evaluate his or her suitability for organ donation, in order to undertake a proper risk assessment and minimize the risks for the recipient, and optimize organ allocation | <i>EU Directive 2010</i> |
| Donor evaluation | The procedure of determining the suitability of a potential donor, living or deceased, to donate | <i>WHO Glossary</i> |
| Donor maintenance | The process and critical pathways used to medically care for donors in order to keep their organs viable until organ recovery can occur | <i>WHO Glossary</i> |
| Donor safety | A minimization of living donor complications or adverse reactions related to donation | <i>WHO Glossary</i> |
| Eligible deceased organ donor | A medically suitable person who has been declared dead as stipulated by the law of the relevant jurisdiction, based on neurologic criteria or based on the irreversible absence of circulatory and respiratory functions within a time frame that enables organ recovery (see Critical Pathway) | <i>Critical Pathway Working Group, Madrid Consultation</i> |
| Ethics committee | Committee charged with considering ethical issues related to the process of organ procurement, distribution, transplantation, pre-donation and post-donation, and transplantation care and research for cells, tissues and organs. Such a committee should be at a national level but can also be at a regional or local level | <i>WHO Glossary</i> |
| Explicit consent | Legally valid permission for removal of human cells, tissues and organs for transplantation, otherwise known as "opting in" | <i>WHO Glossary</i> |

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GLOSSARY OF TERMS Continued

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| Exported/export | Human bodies, body parts, cells, tissues or organs for human application, legally procured inside of the national boundary and transported to another country where it is to be further processed or used. Export must be according to local (exporting country) laws, international laws and conventions and receiving country laws | <i>WHO Glossary</i> |
| Follow-up | Subsequent examinations of a patient, living donor, or recipient, for the purpose of monitoring the results of the donation or transplant, care maintenance and initiating post-donation or post-transplantation interventions | <i>WHO Glossary</i> |
| Human cells and tissues for transplantation | Articles containing or consisting of human cells and/or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Examples include, but are not limited to, musculoskeletal tissue (bone, cartilage, and meniscus), skin, soft tissue (tendons, ligaments, nerves, dura mater, fascia lata and amniotic membrane), cardiovascular tissue (heart valves, arteries and veins), ocular tissue (corneas and sclera), bone marrow and hematopoietic stem/progenitor cells derived from peripheral and cord blood and stem cells of any tissue, and reproductive cells/tissues. The following articles are not included in HCTT <ol style="list-style-type: none"> 1. Vascularized human organs 2. Whole blood or blood components or blood derivative products 3. Secreted or extracted human products, specifically milk, collagen, and cell factors; Cells, tissues and organs derived from animals other than humans | <i>WHO Glossary</i> |
| Imported/import | Human bodies, body parts, cells, tissues and organs for human application, legally procured outside of the national boundary to which it has been transported for use. Importation must be according to local (receiving country) laws and conventions and supplying country laws | <i>WHO Glossary</i> |
| Incompetent person | An individual who is unable to make legally valid decisions or is deprived of his or her capacity to decide and/or understand the implications of his or her actions (e.g., a minor or individual legally declared unable to manage their own affairs) | <i>WHO Glossary</i> |
| Living donor | A living human being from whom cells, tissues or organs have been removed for the purpose of transplantation. A living donor has one of three possible relationships with the recipient: A/Related <ol style="list-style-type: none"> 1. Genetically related <ol style="list-style-type: none"> i. First-degree genetic relative: parent, sibling, offspring ii. Second-degree genetic relative: grandparent, grandchild, aunt, uncle, niece, nephew iii. Other than first- or second-degree relative; for example cousin; 2. Emotionally related: spouse (if not genetically related), in-laws, adopted, friend B/Unrelated: not genetically or emotionally related | <i>WHO Glossary</i> |
| Opt-in system | See Explicit consent | |
| Opt-out system | See Presumed consent | |
| Organ | Differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularization and capacity to develop physiological functions with an important level of autonomy | <i>EU Directive 2004</i> |
| Organ characterization | The collection of the relevant information on the characteristics of the organ needed to evaluate its suitability, in order to undertake a proper risk assessment and minimize the risks for the recipient, and optimize organ allocation | <i>EU Directive 2010</i> |
| Organ exchange organization | A non-profit organization, whether public or private, dedicated to national and cross-border organ exchange | <i>Adapted from EU Directive 2010</i> |
| Organ replacement therapy | Medical treatment for the purpose of prolonging life in the event of end-stage organ failure, including transplantation, renal dialysis, left ventricular assist device, etc. Also called “bridge therapy” where the intention is to sustain life in preparation for transplantation | <i>Editorial Group, Madrid Consultation</i> |
| Possible deceased organ donor | A patient with a devastating brain injury or lesion or a patient with circulatory failure who is apparently medically suitable for organ donation (see critical pathway) | <i>Critical Pathway Working Group, Madrid Consultation</i> |
| Potential deceased organ donor | A person whose clinical condition is suspected to fulfill brain death criteria or a person whose circulatory and respiratory functions have ceased and resuscitative measures are not to be attempted or continued or a person in whom the cessation of circulatory and respiratory functions is anticipated to occur within a time frame that will enable organ recovery (see critical pathway) | <i>Critical Pathway Working Group, Madrid Consultation</i> <i>(Continued)</i> |

GLOSSARY OF TERMS Continued

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| Preemptive transplantation | The transplantation of an organ to a recipient who has not yet lost all function of that organ and is not receiving another form of organ replacement therapy, but for whom end-stage organ failure is imminent <i>Editorial Group, Madrid Consultation</i> |
| Preservation | The use of chemical agents, alterations in environmental conditions, or other means to prevent or retard biological or physical deterioration of organs from procurement to transplantation <i>EU Directive 2010</i> |
| Presumed consent | Legally valid presumption of permission for removal of cells, tissues and organs for transplantation, in the absence of individual pre-stated refusal of permission. Otherwise known as “opting out” <i>WHO Glossary</i> |
| Processing | All operations involved in the preparation, manipulation, preservation and packaging of cells or tissues intended for human application <i>EU Directive 2004</i> |
| Procurement | The process that includes donor identification, evaluation, obtaining consent for donation, donor maintenance and retrieval of cells, tissues, or organs <i>WHO Glossary</i> |
| Procurement organization | Any organization that undertakes or coordinates the procurement of human organs and is authorized to do so by the relevant authority <i>Adapted from EU Directive 2010</i> |
| Recipient | The human being into whom allogenic human cells, tissues or organs were transplanted <i>WHO Glossary</i> |
| Regulatory oversight | The management or supervision of a group by an outside body in order to control or direct according to rule, principle, or law <i>WHO Glossary</i> |
| Reimbursement | Compensation for the costs involved in making donations, including medical expenses and loss of earnings for live donors, on the basis of reasonable and verifiable claims <i>Editorial Group, Madrid Consultation</i> |
| Retrieval or recovery | The procedure of removing cells, tissues or organs from a donor for the purpose of transplantation <i>WHO Glossary</i> |
| Self-sufficiency | Self-sufficiency in organ donation and transplantation means equitably meeting the transplantation needs of a given population, using resources from within that population or through regional cooperation as required <i>Editorial Group, Madrid Consultation</i> |
| Serious adverse event | Any untoward occurrence associated with the procurement, testing, processing, storage, distribution, transplantation procedure itself, or post-transplantation management procedure of cells, tissues, and organs that might lead to the transmission of a communicable disease, to death or life threatening, disabling, or incapacitating conditions for patients or which might result in, or prolong, hospitalization or morbidity <i>WHO Glossary</i> |
| Serious adverse reaction | An unintended response, including a communicable disease, in the donor or in the recipient, associated with the procurement, the transplantation procedure itself or post-transplantation management procedure in the human application of cells, tissues, and organs that is fatal, life threatening, disabling, incapacitating or which results in, or prolongs, hospitalization or morbidity <i>WHO Glossary</i> |
| Split liver | A split liver transplant is defined when a donor liver is divided into parts and transplanted into more than one recipient <i>WHO Glossary</i> |
| Storage | The maintenance of donor cells, tissues or organs under appropriate controlled conditions until transplantation or disposal <i>WHO Glossary</i> |
| Surveillance | The systematic ongoing collection, collation and analysis of data for public health purposes and the timely dissemination of public health information for assessment and public health response as necessary <i>International Health Regulations 2005</i> |
| Surveillance system (for human cells, tissues and organs for transplantation) | An established process at a local, regional or national level for the reporting of serious adverse events, serious adverse reactions or complications related to donation, and transplantation of cells, tissues, and organs <i>WHO Glossary</i> |
| Time on waiting list | The time from placement on the waiting list for a transplant until the date of reporting (of a transplant) or until removal (from the waiting list) <i>WHO Glossary</i> <i>(Continued)</i> |

GLOSSARY OF TERMS Continued

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| Tissue | All constituent parts of the human body formed by cells | <i>EU Directive 2004</i> |
| Tissue establishment | A tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage, or distribution of human tissues and cells are undertaken. It may also be responsible for procurement or testing of tissues and cells | <i>EU Directive 2004</i> |
| Traceability | The ability of an authorized organization to identify and locate all cells, tissues, or organs from all specific donors at any time after donation, linked to all specific recipients and vice versa from recipients to donors. This traceability applies to any step of procurement, allocation, processing, including processing agents, storage, distribution, or disposal at any time after donation | <i>WHO Glossary</i> |
| Trafficking (cells, tissues or organs) | The recruitment, transport, transfer, harboring, or receipt of living or deceased persons or their cells, tissues, or organs, by means of the threat or use of force or other forms of coercion, of abduction, of fraud, or deception, of the abuse of power or of a position of vulnerability, or of the giving to, or the receiving by, a third party of payments or benefits to achieve the transfer of control over the potential donor, for the purpose of exploitation by the removal of cells, tissues and organs for transplantation | <i>WHO Glossary</i> |
| Transplant commercialism | A policy or practice in which cells, tissues, or organs are treated as a commodity, including by being bought or sold or used for material gain | <i>WHO Glossary</i> |
| Transplant tourism | Travel for transplantation when it involves organ trafficking and/or transplant commercialism or if the resources (organs, professionals, and transplant centers) devoted to providing transplant to patients from outside a country undermine the country's ability to provide transplant services for its own population | <i>The Declaration of Istanbul</i> |
| Transplantation | The transfer (engraftment) of human cells, tissues or organs from a donor to a recipient with the aim of restoring function(s) in the body. When transplantation is performed between different species, for example, animal to human, it is named xenotransplantation | <i>WHO Glossary</i> |
| Transplantation center | A healthcare establishment, team or a unit of a hospital or any other body which undertakes the transplantation of human organs, and is authorized to do so by the relevant authority | <i>Adapted from EU Directive 2010</i> |
| Travel for transplantation | The movement of organs, donors, recipients or transplant professionals across jurisdictional borders for transplantation purposes | <i>The Declaration of Istanbul</i> |
| Utilized deceased organ donor | An actual donor from whom at least one organ was transplanted (see Critical Pathway) | <i>Critical Pathway Working Group, Madrid Consultation</i> |
| Waiting list | The list of candidates registered to receive a human cell, tissue and organ transplant | <i>WHO Glossary</i> |
| Waiting list management | A system (or method) for maintaining a waiting list accuracy and currency, protecting the privacy, and confidentiality of patients in the waiting list | <i>WHO Glossary</i> |