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Human organ and tissue transplantation[1]

Report by the Secretariat

1. In 1991, the Forty-fourth World Health Assembly in resolution WHA44.25 endorsed the WHO Guiding Principles on Human Organ Transplantation. The Guiding Principles were the outcome of a process that began in 1987 when the Health Assembly first expressed concern over the commercial trade in human organs (resolution WHA40.13). Two years later, the Health Assembly called upon Member States to take appropriate measures to prevent the purchase and sale of human organs for transplantation (resolution WHA42.5). Over the past 17 years, the Guiding Principles have influenced legislation in more than 50 Member States as well as professional codes and practices. In 2004, in the light of improvements in transplantation medicine and science as well as evolving practices and perceptions regarding organ and tissue transplantation, the Fifty-seventh World Health Assembly in resolution WHA57.18 requested the Director-General, inter alia, "to continue examining and collecting global data on the practices, safety, quality, efficacy and epidemiology of allogeneic transplantation and on ethical issues, including living donation, in order to update the Guiding Principles on Human Organ Transplantation". The present report responds to the request of the Health Assembly but focuses on allogeneic transplantation of cells, tissues and organs.

2. Accordingly, the Secretariat has examined transplantation practices through an extensive consultation process at national, regional and subregional levels, involving experts, representatives of health authorities and professional and scientific societies, lawyers and ethicists. A global knowledge base on transplantation has been created, which includes a global database on donation and transplantation. The database was developed in collaboration with the Spanish national transplantation organization and launched on the Internet in 2006 as a tool for monitoring transplantation activities and practices at a global level and for fostering transparency.[2] Official relations have been established with The Transplantation Society as a consultative body on technical matters pertaining to transplantation.

3. Although the number of transplantations performed each year has grown rapidly since the Guiding Principles were endorsed, there has also been a significant increase in the demand for transplantation using human cells, tissues and organs, resulting in a continuing shortage of human material, particularly organs. Kidney transplantations are now performed in 91 Member States in all WHO regions; however, these countries are at various stages of technical development and regulatory oversight. The fact that few countries approach self-sufficiency in the provision of cells, tissues and organs for transplantation has prompted a search for ways to increase the donation of human material

[1] This report does not include progress in xenogeneic transplantation, also addressed by resolution WHA57.18, as it raises different and specific issues. The Secretariat will report on xenotransplantation at an appropriate time.

[2] Accessible at http://www.transplant-observatory.org/default.aspx.

for transplantation; solutions found include a growing reliance on organs donated by related and unrelated living persons.

4. Another consequence of the unmet demand for human material for transplantation has been the growth of "transplant tourism". In certain countries, centres use the Internet and other means openly to invite patients to travel abroad in order to receive a transplant at "bargain" prices, with all donor costs included. Likewise, commercial trade in cells, tissues and organs – and even trafficking involving humans who are kidnapped or lured into other countries where they are forced to be "donors" – continues to be a serious problem, particularly in countries with substantial transplant tourism. Exploitation is also a common fate experienced by those who leave their home countries in search of financial rewards for donating their kidneys. In order to gain easy access to organs, some wealthy countries now encourage transplantation outside their own borders; this invariably involves the purchase of organs from poor people, even though commerce in organs may be prohibited in the wealthy countries concerned. This practice, which includes the provision of human material for transplantation, should not be confused with the purchase abroad of medical care only.

UPDATED GUIDING PRINCIPLES ON TRANSPLANTATION

5. Against this background the Secretariat has revised the Guiding Principles,[1] reformulating them and their commentaries in order to address practices that have been identified since 1991. The revised Guiding Principles provide a framework to support progress in transplantation of cells, tissues and organs that will maximize the benefits of transplantation by meeting the needs of recipients, protecting donors and ensuring the dignity of all involved. Participants in the consultation process undertaken in preparing the revision confirmed the view that seeking financial gain from the human body or its parts undermines the benefits of transplantation rather than enhancing them. Experience from all over the world demonstrates that commercial trade in this area evolves from being a market in organs to being a market in people, where – openly or under cover – the poor and vulnerable are exploited.

6. The revised Guiding Principles call for the giving and receiving of money for cells, tissues or organs for transplantation to be prohibited, as well as any other commercial dealings in this field. However, the Principles would not affect certain legitimate payments, including the following: the reimbursement of both expenses (such as those for medical care arising from donation) and losses (such as wages foregone); and the recovery of costs incurred in the procurement, processing, storage, distribution and implantation of cells, tissues or organs. In revising the Guiding Principles, particular attention has been paid to the protection of minors and other vulnerable persons from coercion and improper inducement to donate cells, tissues or organs.

7. As a result of the consultation process, two new Guiding Principles have been added. The first new principle would strengthen commitment to the safety, quality and efficacy of both donation and transplantation procedures as well as of the human material used; the second would request transparency in the organization and performance of donation and transplantation activities in order to facilitate appropriate technical oversight and foster public trust. These new Principles encourage proper respect for human body parts and their donors, and for the patients receiving the donations.

[1] See Annex.

THE WAY FORWARD

8. The consultation process which led to the revision of the Guiding Principles has already itself generated requests from some Member States for support from WHO in formulating and enforcing legislation to stop commercial transplantation and increase access to transplantation. Nevertheless, many other countries still need to undertake such action, particularly where a weak, absent, or ineffectively enforced legal framework enables profiteering from the sale of organs removed from vulnerable citizens.

9. The consultation process also produced consensus on several ways of further improving access to and increasing the safety, quality and efficacy of the donation and transplantation of cells, tissues and organs. The following points summarize some of these suggestions.

10. Although a strong consensus emerged against commercialism, which encourages trafficking and exploitation, the shortage of human material for transplantation in countries with advanced health systems remains a reality. Comprehensive legal frameworks are needed that permit and promote transplantation while deterring commercial trade and trafficking. Similarly, organizations that can both stimulate and regulate transplantation should be encouraged.

11. In order to achieve national or subregional self-sufficiency in organ transplantation, it will be necessary to increase donations from deceased donors. Currently, donors who are diagnosed dead using neurological criteria represent the major source of such donations. However, it is estimated that another source – so-called "non-heartbeating donors" – has the potential to yield up to three times more donors. Furthermore, participants in the consultation process noted that organs from non-heartbeating donors are producing increasingly good transplantation outcomes. With the permission of the next of kin (or, in rare cases, following the previously expressed wishes of the patient), the withdrawal of life support can be followed by a declaration of death based on the permanent cessation of circulation and respiration, and then by removal of organs for transplantation. In certain circumstances, steps are taken to prolong the opportunity to obtain a donation while permission is sought from the relatives; this is especially the case when death does not occur in an intensive care unit and withdrawal of respiratory support is unplanned. The techniques used to preserve organs need not involve sophisticated technology, particularly where only kidneys are concerned; programmes that use non-heartbeating donors are therefore accessible to countries with limited resources.

12. The monitoring of donation and transplantation outcomes is essential in order to ensure high-quality services and identify problems. As with other medical products and devices, an effective surveillance system will provide early warning of adverse events and developments. The development of national (or subregional) monitoring and surveillance systems would enable information about important new technical developments as well as details of adverse events and reactions to be communicated quickly around the globe.

13. Success in increasing donations of cells, tissues and organs in order to meet global needs is dependent upon public acceptance of safe, legal donation and transplantation, together with public awareness of the dangers of commercial trade and trafficking. The latter requirement particularly concerns poor and vulnerable groups who are the most likely to be induced or coerced into becoming donors. Carefully designed and consistently implemented campaigns of advocacy that target all populations groups, including schoolchildren, can help to increase public awareness that donation and transplantation are valuable and necessary, and that consent must be given within the limited period during which cells, tissues and organs can be kept viable.

14. With the growing global circulation of transplantable material, traceability is a major concern for transplant professionals and surveillance systems. There would be significant advantages in developing a common basis for a global system for coding transplantable material, especially cells and tissues. An outcome of the global consultation process referred to in paragraph 2 above was a recommendation that the development of such a global system should be fostered. This could also offer benefits in combating commercial trade.

15. Work remains to be done on transplantation; however, the greatest priority should be given to initiatives aimed at reducing the incidence of, or even preventing, the diseases that lead to the need for transplants in the first place. Such initiatives require the development of high–quality public health programmes led by research and supported by tertiary care and medical education. One important stimulus to academic medicine and research is the development of transplant services.

ACTION BY THE EXECUTIVE BOARD

16. The Board is invited to note the report.

ANNEX

WHO GUIDING PRINCIPLES ON HUMAN CELL, TISSUE AND ORGAN TRANSPLANTATION

DRAFT UPDATE

PREAMBLE

1. As the Director-General's report to the Executive Board at its Seventy-ninth session pointed out,[1] human organ transplantation began with a series of experimental studies at the beginning of the twentieth century. The report drew attention to some of the major clinical and scientific advances in the field since Alexis Carrel was awarded the Nobel Prize in 1912 for his pioneering work. Surgical transplantation of human organs from deceased, as well as living, donors to sick and dying patients began after the Second World War. Over the past 50 years, the transplantation of human organs, tissues and cells has become a worldwide practice which has extended, and greatly enhanced the quality of, hundreds of thousands of lives. Continuous improvements in medical technology, particularly in relation to organ and tissue rejection, have led to an increase in the demand for organs and tissues, which has always exceeded supply despite substantial expansion in deceased organ donation as well as greater reliance on donation from living persons in recent years.

2. The shortage of available organs has not only prompted many countries to develop procedures and systems to increase supply but has also stimulated commercial traffic in human organs, particularly from living donors who are unrelated to recipients. The evidence of such commerce, along with the related traffic in human beings, has become clearer in recent decades. Moreover, the growing ease of international communication and travel has led many patients to travel abroad to medical centres that advertise their ability to perform transplants and to supply donor organs for a single, inclusive charge.

3. Resolutions WHA40.13 and WHA42.5 first expressed the Health Assembly's concern over commercial trade in organs and the need for global standards for transplantation. Based on a process of consultation undertaken by the Secretariat, the Health Assembly then endorsed the WHO Guiding Principles on Human Organ Transplantation in resolution WHA44.25. Over the past 17 years the Guiding Principles have greatly influenced professional codes and practices as well as legislation around the world. In the light of changes in practices and attitudes regarding organ and tissue transplantation, the Fifty-seventh World Health Assembly in resolution WHA.57.18 requested the Director-General, inter alia, "to continue examining and collecting global data on the practices, safety, quality, efficacy and epidemiology of allogeneic transplantation and on ethical issues, including living donation, in order to update the Guiding Principles on Human Organ Transplantation".

4. The following Guiding Principles are intended to provide an orderly, ethical and acceptable framework for the acquisition and transplantation of human cells, tissues and organs for therapeutic purposes. Each jurisdiction will determine the means of implementing the Guiding Principles. They preserve the essential points of the 1991 version while incorporating new provisions in response to current trends in transplantation, particularly organ transplants from living donors and the increasing

[1] Document EB79/8.

use of human cells and tissues. The Guiding Principles do not apply to transplantation of gametes, ovarian or testicular tissue, or embryos for reproductive purposes, or to blood or blood constituents collected for transfusion purposes.

Cells, tissues and organs may be removed from deceased and living persons for the purpose of transplantation, only in accordance with the following Guiding Principles.

Guiding Principle 1

Cells, tissues and organs may be removed from the bodies of deceased persons for the purpose of transplantation if:
(a) any consent required by law is obtained, and
(b) there is no reason to believe that the deceased person objected to such removal.

Commentary on Guiding Principle 1

Consent is the ethical cornerstone of all medical interventions. National authorities are responsible for defining the process of obtaining and recording consent for cell, tissue and organ donation in the light of international ethical standards, the manner in which organ procurement is organized in their country, and the practical role of consent as a safeguard against abuses and safety breaches.

Whether consent to procure organs and tissues from deceased persons is "explicit" or "presumed" depends upon each country's social, medical and cultural traditions, including the manner in which families are involved in decision-making about health care generally. Under both systems any valid indication of deceased persons' opposition to posthumous removal of their cells, tissues or organs will prevent such removal.

Under a regime of explicit consent – sometimes referred to as "opting in" – cells, tissues or organs may be removed from a deceased person if the person had expressly consented to such removal during his or her lifetime; depending upon domestic law, such consent may be made orally or recorded on a donor card, driver's license or identity card or in the medical record or a donor registry. When the deceased has neither consented nor clearly expressed opposition to organ removal, permission should be obtained from a legally specified surrogate, usually a family member.

The alternative, presumed consent system – termed "opting (or contracting) out" – permits material to be removed from the body of a deceased person for transplantation and, in some countries, for anatomical study or research, unless the person had expressed his or her opposition before death by filing an objection with an identified office, or an informed party reports that the deceased definitely voiced an objection to donation. Given the ethical importance of consent, such a system should ensure that people are fully informed about the policy and are provided with an easy means to opt out.

Although expressed consent is not required in an opting-out system before removal of the cells, tissues or organs of a deceased person who had not objected while still alive, procurement programmes may be reluctant to proceed if the relatives personally oppose the donation; likewise, in opting-in systems, programmes typically seek permission from the family even when the deceased gave pre-mortem consent. Programmes are more able to rely on the deceased's explicit or presumed consent, without seeking further permission from family members, when the public's understanding and acceptance of the process of donating cells, tissues and organs is deep-seated and unambiguous. Even when

permission is not sought from relatives, donor programmes need to review the deceased's medical and behavioural history with family members who knew him or her well, since accurate information about donors helps to increase the safety of transplantation.

For tissue donation, which entails slightly less challenging time constraints, it is recommended always to seek the approval of the next of kin. An important point to be addressed is the manner in which the appearance of the deceased's body will be restored after the tissues are removed.

Guiding Principle 2

Physicians determining that a potential donor has died should not be directly involved in cell, tissue or organ removal from the donor or subsequent transplantation procedures; nor should they be responsible for the care of any intended recipient of such cells, tissues and organs.

Commentary on Guiding Principle 2

This Principle is designed to avoid the conflict of interest that would arise were the physician or physicians determining the death of a potential donor to be responsible in addition for the care of other patients whose welfare depended on cells, tissues or organs transplanted from that donor.

National authorities will set out the legal standards for determining that death has occurred and specify how the criteria and process for determining death will be formulated and applied.

Guiding Principle 3

Donation from deceased persons should be developed to its maximum therapeutic potential, but adult living persons may donate organs as permitted by domestic regulations. In general living donors should be genetically, legally or emotionally related to their recipients.

Live donations are acceptable when the donor's informed and voluntary consent is obtained, when professional care of donors is ensured and follow-up is well organized, and when selection criteria for donors are scrupulously applied and monitored. Live donors should be informed of the probable risks, benefits and consequences of donation in a complete and understandable fashion; they should be legally competent and capable of weighing the information; and they should be acting willingly, free of any undue influence or coercion.

Commentary on Guiding Principle 3

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

While favouring the maximal development of transplant programmes that avoid the inherent risks to live donors, the Principle also sets forth basic conditions for live donation. A genetic relationship between donor and recipient may be therapeutically advantageous and can provide reassurance that the

donor is motivated by genuine concern for the recipient, as can a legal relationship (such as that between spouses). Many altruistic donations also originate from emotionally related donors, though the strength of a claimed connection may be difficult to evaluate. Donations by unrelated donors have been a source of concern, though some such cases are unexceptionable, such as in hematopoietic stem cell transplantation (where a wide donor pool is therapeutically advisable) or when an exchange of kidneys is made because the donors are not immunologically well matched with the recipients to whom they are related.

With live donation, particularly by unrelated donors, psychosocial evaluation is needed to guard against coercion of the donor or the commercialism banned by Principle 5. The national health authority should ensure that the evaluation is carried out by an appropriately qualified, independent party. By assessing the donor's motivation and the donor's and recipient's expectations regarding outcomes, such evaluations may help identify – and avert – donations that are forced or are actually paid transactions.

The Principle underscores the necessity of genuine and well-informed choice, which requires full, objective, and locally relevant information and excludes vulnerable persons who are incapable of fulfilling the requirements for voluntary and knowledgeable consent. Voluntary consent also implies that adequate provisions exist for withdrawal of consent up until medical interventions on the recipient have reached the point where the recipient would be in acute danger if the transplant did not proceed. This should be communicated at the time of consent.

Finally, this Principle stresses the importance of protecting the health of living donors during the process of selection, donation, and necessary aftercare to ensure that the potential untoward consequences of the donation are unlikely to disadvantage the remainder of the donor's life. Care for the donor should match care for the recipient, and health authorities have the same responsibility for the welfare of both.

Guiding Principle 4

No cells, tissues or organs should be removed from the body of a living minor for the purpose of transplantation other than rare exceptions allowed under national law. Specific measures should be in place to protect the minor and, wherever possible the minor's assent should be obtained before donation. What is applicable to minors also applies to any legally incompetent person.

Commentary on Guiding Principle 4

This Principle states a general prohibition on the removal of cells, tissues or organs from legal minors for transplantation. The major exceptions that may be authorized are familial donation of regenerative cells (when a therapeutically comparable adult donor is not available) and kidney transplants between identical twins (where avoiding immunosuppression represents a benefit to the recipient adequate to justify the exception, in the absence of a genetic disorder that could adversely affect the donor in the future).

While the permission of the parent(s) or the legal guardian for organ removal is usually sufficient, they may have a conflict of interest if they are responsible for the welfare of the intended recipient. In such cases, review and approval by an independent body, such as a court or other competent authority, should be required. In any event, a minor's objection to making a donation should prevail over the

permission provided by any other party. The professional counselling provided to potential living donors in order to assess, and when needed, address any pressure in the decision to donate, is especially important for minor donors.

Guiding Principle 5

Cells, tissues and organs should only be donated freely, without any monetary payment or other reward of monetary value. Purchasing, or offering to purchase, cells, tissues or organs for transplantation, or their sale by living persons or by the next of kin for deceased persons, should be banned.

The prohibition on sale or purchase of cells, tissues and organs does not preclude reimbursing reasonable and verifiable expenses incurred by the donor, including loss of income, or paying the costs of recovering, processing, preserving and supplying human cells, tissues or organs for transplantation.

Commentary on Guiding Principle 5

Payment for cells, tissues and organs is likely to take unfair advantage of the poorest and most vulnerable groups, undermines altruistic donation, and leads to profiteering and human trafficking. Such payment conveys the idea that some persons lack dignity, that they are mere objects to be used by others.

Besides preventing trafficking in human materials, this Principle aims to affirm the special merit of donating human materials to save and enhance life. However, it allows for circumstances where it is customary to provide donors with tokens of gratitude that cannot be assigned a value in monetary terms. National law should ensure that any gifts or rewards are not, in fact, disguised forms of payment for donated cells, tissues or organs. Incentives in the form of "rewards" with monetary value that can be transferred to third parties are not different from monetary payments.

While the worst abuses involve living organ donors, dangers also arise when payments for cells, tissues and organs are made to next of kin of deceased persons, to vendors or brokers, or to institutions (such as mortuaries) having charge of dead bodies. Financial returns to such parties should be forbidden.

This Principle permits compensation for the costs of making donations (including medical expenses and lost earnings for live donors), lest they operate as a disincentive to donation. The need to cover legitimate costs of procurement and of ensuring the safety, quality and efficacy of human cell and tissue products and organs for transplantation is also accepted.

Incentives that encompass essential items which donors would otherwise be unable to afford, such as medical care or health insurance coverage, raise concerns. Access to the highest attainable standard of health is a fundamental right, not something to be purchased in exchange for body parts. However, free periodic medical assessments related to the donation and insurance for death or complications that arise from the donation may legitimately be provided to living donors.

Health authorities should promote donation motivated by the need of the recipient and the benefit for the community. Any measures to encourage donation should respect the dignity of the donor and foster societal recognition of the altruistic nature of cell, tissue and organ donation. In any event, all

practices to encourage the procurement of cells, tissues and organs for transplantation should be defined explicitly by health authorities in a transparent fashion.

National legal frameworks should address each country's particular circumstances because the risks to donors and recipients vary. Each jurisdiction will determine the details and method of the prohibitions it will use, including sanctions which may encompass joint action with other countries in the region. The ban on paying for cells, tissues and organs should apply to all individuals, including transplant recipients who attempt to circumvent domestic regulations by travelling to locales where prohibitions on commercialization are not enforced.

Guiding Principle 6

Promotion of altruistic donation of human cells, tissues or organs by means of advertisement or public appeal may be undertaken in accordance with domestic regulation.

Advertising the need for or availability of cells, tissues or organs, with a view to offering or seeking payment to individuals for their cells, tissues or organs, or, to the next of kin, where the individual is deceased, should be prohibited. Brokering that involves payment to such individuals or to third parties should also be prohibited.

Commentary on Guiding Principle 6

This Principle does not affect general advertisements or public appeals to encourage altruistic donation of human cells, tissues or organs, provided that they do not subvert legally established systems of organ allocation. Instead, it aims to prohibit commercial solicitations, which include offering to pay individuals, the next of kin of deceased persons, or other parties in possession (such as undertakers), for cells, tissues or organs; it targets brokers and other intermediaries as well as direct purchasers.

Guiding Principle 7

Physicians and other health professionals should not engage in transplantation procedures, and health insurers and other payers should not cover such procedures, if the cells, tissues or organs concerned have been obtained through exploitation or coercion of, or payment to, the donor or the next of kin of a deceased donor.

Commentary on Guiding Principle 7

Health care professionals should only proceed with the removal, intermediate management or implantation of cells, tissues or organs when donations are unpaid and truly voluntary. (In the case of live donors, a psychosocial evaluation of the donor is usually indicated, as described in Guiding Principle 3). Failing to ensure that the person consenting to the donation has not been paid, coerced or exploited breaches professional obligations and should be sanctioned by the relevant professional organizations and government licensing or regulatory authorities.

Physicians and health care facilities should also not refer patients to transplant facilities in their own or other countries that make use of cells, tissues or organs obtained through payments to donors, their families or other vendors or brokers; nor may they seek or accept payment for doing so. Post-transplant care may be provided to patients who have undergone transplantation at such facilities, but physicians who decline to provide such care should not face professional sanctions for such refusals, provided that they refer such patients elsewhere.

Health insurers and other payers should reinforce adherence to high ethical standards by refusing to pay for transplants that violate the Guiding Principles.

Guiding Principle 8

All health care facilities and professionals involved in cell, tissue or organ procurement and transplantation procedures should be prohibited from receiving any payment that exceeds the justifiable fee for the services rendered.

Commentary on Guiding Principle 8

This provision reinforces Guiding Principles 5 and 7 by forbidding profiteering in cell, tissue and organ recovery and implantation. Health authorities should monitor the fees charged for transplantation services to ensure that they are not disguised charges for the cells, tissues or organs themselves. All persons and facilities involved should be accountable for all payments for transplantation services. A medical or other health care practitioner uncertain whether a fee is justifiable should seek the opinion of an appropriate licensing or disciplinary authority before proposing or levying the fee. Fees charged for similar services may be used as a reference.

Guiding Principle 9

The allocation of organs, cells and tissues should be guided by clinical criteria and ethical norms, not financial or other considerations. Allocation rules, defined by appropriately constituted committees, should be equitable, externally justified, and transparent.

Commentary on Guiding Principle 9

Where donation rates do not meet clinical demand, allocation criteria should be defined at national or subregional level by a committee that includes experts in the relevant medical specialties, bioethics and public health. Such multidisciplinarity is important to ensure that allocation takes into account not only medical factors but also community values and general ethical rules. The criteria for distributing cells, tissues and organs should accord with human rights and, in particular, should not be based on a recipient's gender, race, religion, or economic condition.

This principle implies that the cost of transplantation and follow-up, including immunosuppressive treatment where applicable, should be affordable to all patients concerned — that is, no recipient should be excluded solely for financial reasons.

The concept of transparency is not exclusive to the allocation process but is central to all aspects of transplantation (as is discussed in the commentary on Guiding Principle 11, below).

Guiding Principle 10

High-quality, safe and efficacious procedures are essential for donors and recipients alike. The long-term outcomes of cell, tissue and organ donation and transplantation should be assessed for the living donor as well as the recipient in order to document benefit and harm.

The level of safety, efficacy and quality of human cells, tissues and organs for transplantation, as health products of an exceptional nature, must be maintained and optimized on an ongoing basis. This requires implementation of quality systems including traceability and vigilance, with adverse events and reactions reported, both nationally and for exported human products.

Commentary on Guiding Principle 10

Optimizing the outcome of cell, tissue and organ transplantation entails a rules-based process that encompasses clinical interventions and *ex vivo* procedures from donor selection through long-term follow-up. Under the oversight of national health authorities, transplant programmes should monitor both donors and recipients to ensure that they receive appropriate care, including information regarding the transplantation team responsible for their care.

Evaluation of information regarding the long-term risks and benefits is essential to the consent process and for adequately balancing the interests of donors as well as recipients. The benefits to both must outweigh the risks associated with the donation and transplantation. Donors should not be permitted to donate in clinically hopeless situations.

Donation and transplant programmes are encouraged to participate in national and/or international transplant registries. All deviations from accepted processes that could elevate the risk to recipients or donors, as well as any untoward consequences of donation or transplantation, should be reported to and analysed by responsible health authorities.

Transplantation of human material which does not involve maintenance treatment may not require active, long-term follow-up, though traceability should be ensured for the anticipated lifetime of the donor and the recipient. Internationally agreed means of coding to identify tissues and cells used in transplantation are essential for full traceability.

Guiding Principle 11

The organization and execution of donation and transplantation activities, as well as their clinical results, must be transparent and open to scrutiny, while assuring that the personal anonymity and privacy of donors and recipients is always protected.

Commentary on Guiding Principle 11

Transparency can be summarized as maintaining public access to regularly updated comprehensive data on processes, in particular allocation, transplant activities and outcomes for both recipients and living donors, as well as data on organization, budgets and funding. Such transparency is not inconsistent with shielding from public access information that could identify individual donors or recipients while still respecting the necessity of traceability recognized in Principle 10. The objective of the system should be not only to maximize the availability of data for scholarly study and governmental oversight but also to identify risks – and facilitate their correction – in order to minimize harm to donors or recipients.

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