



WORLD HEALTH ORGANIZATION

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Human organ and tissue transplantation

Report by the Secretariat

1. At the request of the Government of Colombia, this item has been included in the provisional agenda of the Board. This note outlines current issues.
2. Transplantation of human organs and tissues¹ saves many lives and restores essential functions in circumstances when no medical alternative of comparable effectiveness exists. The transplantation of solid organs, such as kidney, liver, heart or lung, is increasingly a regular component of health care in all countries, and is no longer a feature of health care in high-income countries alone. Of the 70 000 or so solid organs transplanted annually, 50 000 are kidney replacements, more than one-third of the latter operations are done in low- or medium-income countries. The number of human tissue transplants is increasing in both developed and developing countries, but global data on this form of transplantation are less complete. In Europe, hundreds of thousands of tissue transplants are performed each year, and in 1999 an estimated 750 000 people in the United States of America received human tissue, twice as many as in 1990. Globally, it is estimated that 120 000 corneal transplantations and 18 000 transplantations of allogeneic haematopoietic progenitor cells took place in the year 2000.
3. Transplantation has been recognized to be cost-effective in many settings. For example, in developing and developed countries alike, kidney transplantation not only yields survival rates and quality-of-life that are far superior to those obtained with other treatments for end-stage renal disease, such as haemodialysis, but is also less costly in the long run. Skin allografts or amnion grafts are effective burn-wound dressings and are within the reach of low- or medium-income countries. Similarly, corneal transplantation can successfully relieve corneal blindness in many cases.
4. Nonetheless, the transplantation of organs and tissues does raise ethical concerns. In 1991, through resolution WHA44.25, the Health Assembly endorsed a set of Guiding Principles on Human Organ Transplantation.² These Guiding Principles – whose emphases include voluntary donation, noncommercialization, genetic relation of recipients to donors and a preference for cadavers over living donors as sources – have considerably influenced professional codes, national, state and provincial legislation, and the policies of intergovernmental organizations. Yet they do not directly address safety concerns. Further concerns arise because practices that depart from the Guiding

¹ This includes human cells for transplantation such as haematopoietic stem cells from bone marrow, peripheral blood or cord blood. The use of gametes, embryonic and fetal tissue as well as blood and blood products raises additional questions that need to be separately addressed.

² Document WHA44/1991/REC/1, Annex 6.

Principles, such as reliance on living organ donors and payments for organs, have increased in some places over the past dozen years.

CURRENT ISSUES IN TRANSPLANTATION

Access

5. The persistent and widening gap between patients' need for organs and the number available for transplantation has become a major concern to many Member States. The supply of cadaveric organs is limited by an inadequately informed and educated public, inefficient or non-existent organizations for procuring transplant material, and cultural and religious barriers in some countries.
6. Access to transplantation is limited in low- and many medium-income countries, where the rate of transplants remains far below that of richer nations. Even between countries which have similar levels of health resources, patients' access to transplantation also varies. Moreover, for patients who have kidney failure, access to transplantation is reduced when funds are spent on other forms of treatment that are less cost-effective.
7. Access to transplantation entails more than the surgery itself, because success is measured by longer survival of the patient and a long-term improvement in the quality of life. Successful transplantation of organs and living tissues depends on continued medical follow-up and the patient's compliance with a regimen of immunosuppressive drugs. Yet the expense of immunosuppressive therapy or treatment of the resulting complications can be catastrophic for individuals, even in rich countries.

Quality and safety

8. Despite advances in the field, transplant recipients may face several avoidable risks. Donors may be inappropriately selected and tested. Sterilization methods, when applicable (as with some tissues), can be inadequate. Each of these steps can lead to the transmission from the donor to the recipient of infectious agents, from prions (in dura mater and corneas, causing sporadic Creutzfeldt-Jakob disease) to viruses such as *West Nile virus*, as in recently reported cases, and malignancies. The international circulation of tissue for transplantation raises new difficulties in cross-border disease control. Further, there is the risk that material for transplantation may be of poor quality. Contamination by bacteria or fungi, for instance, can result from inadequate practices in procurement, processing, storage or delivery, and lead to graft failure and severe consequences for recipients, as has been reported recently in various developed countries.
9. The removal of a kidney or a fraction of the liver or lung from a living donor is not risk-free. Several studies have reported severe long-term consequences of uninephrectomy, in particular for paid donors, in countries with weak health systems. Kidney donation by well-selected living donors with good health coverage carries negligible risk, although recently it has emerged that some former kidney donors in the United States of America are on transplant waiting lists. The outcomes of living organ donation need further assessment in each context, through donor registries and the like.

Ethical challenges

10. The growing reliance on living donors (including those who are genetically as well as emotionally unrelated to the recipient) is one of several challenges to the premises of the Guiding

Principles. Globally, in 2000, nearly half of all transplanted kidneys came from living donors, a proportion that increases to more than 80% in low- and medium-income countries. Yet ensuring that living donors are acting knowingly and voluntarily, even in the absence of financial incentives, is complex. Factors such as undue influence, family pressure and the difficulty of establishing a donor's actual physical and mental capacity to give voluntary consent have to be taken into account in establishing living donor programmes. Donors must be chosen carefully in order to avoid outcomes that are unsatisfactory, not just medically but also psychologically.

11. Despite the strong tradition that organs and tissues should be regarded as gifts, some members of the transplant community and policy-makers in several countries have expressed interest in allowing financial incentives for provision of human body material in the hope of increasing access to transplantation. Indeed, although payment is illegal in almost all countries, there are numerous reports that living "donors" of transplanted kidneys are remunerated directly or indirectly in many countries. Yet paying for human organs and tissues commodifies the human body and entails the risk of using it as a tool. Paid donors are known to have been exploited in several countries. Further complications arise when tissues that were donated without compensation are collected, processed, stored and distributed (activities with costs that need to be recovered) and thus become items for which payments are made by the time they are transplanted.

THE WAY FORWARD

12. Further improvements in both policy and ethical guidance could aid progress in transplantation at the global level.

Access: improving the supply of organs and tissues for transplantation

13. Successful experiences in countries with varied cultural, religious and economic backgrounds may prove useful for Member States in establishing national transplantation programmes and improving procurement practices. Although the need for communities to be better educated about transplantation is widely recognized, efficient and transparent regulatory mechanisms are also essential if popular support for procurement activities is to be generated. Donations are motivated not only by altruism and generosity but by the individual's realization that a well-run transplant programme, the existence of which depends on everyone's willingness to donate, is a resource of potential importance for his or her own health.

Quality and safety

Global safety standards

14. Global safety standards for human organ and tissue transplantation are not yet fully in place, despite the recent formulation of specialized and regional guidelines. In 2002, the International Atomic Energy Agency, which supports the development of tissue banks in 30 countries that use radiation to sterilize bone and other tissues, issued a set of International Standards on Tissue Banks. The Council of Europe published a *Guide to Safety and Quality Assurance for Organs, Tissues and Cells* in February 2002. In June 2002, the European Commission proposed a Directive of the European Parliament and of the Council of Ministers setting standards of quality and safety for the donation, procurement, testing, processing, storage and distribution of human tissues and cells. Essential safety and quality principles applicable from procurement to follow up of recipients and living donors are urgently needed.

Strengthening national legislative and regulatory environments

15. Health authorities are expected to back procurement organizations and enforce ethical and public health requirements. To do so needs a well-defined chain of responsibility that allows full accountability for the proper collection and use of human tissues and organs in transplantation as well as transparency in all related activities. Yet the enforcement of existing legislation has not necessarily been consistent, and continuing violations, particularly concerning traffic in human tissues and exploitation of kidney donors, have been reported. In the past decade several Member States have reinforced their oversight of transplantation activities. Support for the establishment and effective implementation of an improved legal framework could help to optimize safety, quality and effectiveness in human organ and tissue transplantation as well as full respect for ethical principles. Moreover, the movement to classify various human tissues as medical products has allowed better control of international transactions through cooperation among national regulatory authorities.

Ethical issues

Updating of the 1991 Guiding Principles

16. Without any change in their ethical premises, the Guiding Principles and their commentaries may benefit from re-examination in the light of medical and legal developments during the past decade, and from various ethical and practical perspectives identified in the regions. Protection of the person, whether recipient or donor, should remain a priority and needs reinforcement, and additional matters, such as confidentiality and anonymity of both parties, need to be tackled. Although good reasons exist for continuing to favour cadaveric donors, improvements in immunosuppression reduce the need for living donors to be genetically related to the recipient. The increasing use of genetically unrelated donors means that even greater attention must be paid to ensuring that consent is informed and voluntary. Likewise, proposals to offer incentives in various contexts need careful scrutiny to prevent commercialization or exploitation.

ACTION BY THE EXECUTIVE BOARD

17. The Executive Board is invited to take note of the report.

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