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Report

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Introductory Note from the Secretariat

This document provides an account of the points discussed and the conclusions reached at a consultation on the ethical, access, and safety issues in tissue and organ transplantation held by the World Health Organization (WHO) in Madrid on 6-9 October 2003. A consultative process was carried out jointly by the Department of Ethics, Trade, Human Rights and Health Law (ETH) and the Department of Essential Health Technologies (EHT) in response to the request of WHO's Executive Board at its 112th session in May 2003 that the Director-General examine this field, including both human-to-human and animal-to-human transplants. This consultative process culminated in the Madrid meeting.

Planning for the Madrid meeting was facilitated by scientific advice from the transplant authorities in France, Spain and the United States of America, among others. The consultation was sponsored by the Ministry of Health of Spain, with additional financial support from the US Department of Health and Human Services (through the Pan American Health Organization/WHO Regional Office for the Americas). We gratefully acknowledge this aid, and in particular we wish to thank the staff of the Organizacion Nacional de Transplantes for their efficient assistance in preparing and supporting the consultation.

This report represents the views of the consultants, not necessarily those of WHO. It has, however, been indispensable in the Secretariat's preparation of a report for the January 2004 session of the WHO Executive Board (Document EB113/14). The present report was prepared by the undersigned, with the efficient administrative and secretarial support of Chris Faivre-Pierret; it is based on a draft written by the meeting's two Rapporteurs, Drs Farhat Moazam and Jeremy Chapman, whose scientific and ethical expertise, remarkable ability to summarize complex materials succinctly and commendable alacrity are gratefully acknowledged.

All the 37 clinicians, ethicists, social scientists and government officials from 23 countries at the consultation were active and helpful participants in the meeting and we thank them all for their individual and collective advice. The Secretariat owes a special debt to meeting's Chair, Dr Carl-Gustav Groth, and co-Chair, Dr Blanca Miranda, for their invaluable contributions both during and after the meeting.

The report was submitted to all participants for comments. We are grateful to them for their helpful comments. Any errors or omissions are, of course, our responsibility, not theirs.

A.M. Capron, Director, ETH/SDE
L. Noël, Project Leader, EHT/HTP
N. Biller-Andorno, Ethicist, ETH/SDE

Executive Summary

Transplantation of organs, cells and tissues are now effective therapies across a wide range of both fatal and non-fatal diseases. The excellent survival and success rates of transplantation of organs and cells, such as the kidney, liver and heart or haematopoietic stem cells in immunosuppressed patients, have led to high levels of demand globally. The success rates for transplantation of certain cells or tissues which do not require immunosuppression have also ensured that such procedures are frequently the treatment of choice in the respective therapeutic areas. It is, however, clear that ethically-unacceptable practices occur in a number of countries.

Neither measurements of activity in, nor outcome of, organ, tissue and cell transplantation is available globally. There are data from countries with compulsory registration of transplant activity and there are voluntary registries of some types of transplantation.

Despite the appropriate focus on prevention of disease, the global needs of patients for transplantation are not being met. The demand has outstripped the supply of organs, cells and tissues from both deceased donors and from the altruistic living relatives of patients in need. The alternative treatments and medical support for patients with end stage organ failure, especially renal dialysis, are expensive and limited in many countries. There is also a lack of clinical expertise in some regions and countries and an inability to fund transplantation to some extent in all countries. Thus in all Member States one or more influences prevent the sufficient supply of transplantation therapies and lead to pressure for non-altruistic living donation.

Deceased donation is meeting the needs of transplantation in few, if any, countries. Potential donors are reluctant to commit to donate after death and their families may refuse permission when approached after death. The use of executed prisoners as organ donors in some countries causes great concern that these donations are coerced. Member States employ different models of consent including: presumed consent or “opt out”; required requesting; “opt-in”; and mixtures of these three models. Independently from which specific model is chosen, information and voluntariness are of fundamental importance for the act of post-mortem donation.

Increasing use, over the past ten years, of living donation of non-regenerative organs has extended from kidneys to livers and even to the lung and pancreas in some instances, despite the hope that reliance on living donors could be reduced. There remains great concern that a market in body parts (especially the kidney) has flourished over the past few years with vulnerable persons being tricked or coerced into donating and some recipients travelling with their surgeons to countries where "donated organs may be purchased legally or illegally.

Human cells, human tissues and human organs provide different concerns. Tissues are processed and traded in many Member States by both for-profit and not-for-profit organizations. It is not clear the extent to which donors or their families are aware of the

profit that is created through this trade. Human cells, in particular haematopoietic stem cells, on the other hand, are widely and increasingly exchanged globally between donors and patients through arrangements made by not-for profit organizations which isolate and protect the anonymity of both patient and donor.

Xenotransplantation represents a potential opportunity to ensure a constant supply of organs and tissues for transplantation. However, the scientific hurdles to successful xenotransplantation in humans currently mean that it should only be undertaken under strict clinical trial conditions. There are substantial potential risks to human health from the transmission of xenogeneic infectious agents through xenotransplantation. Careful international monitoring of these clinical trials and of each subject is thus essential to ensuring the safety not only of subjects but also of their families and the broader human population. These issues transcend currently accepted norms of subject consent and medical responsibility for monitoring of the consequences of xenotransplantation.

It is clear that some Member States have not assumed or have been unable to assume an appropriate level of responsibility in each of the areas of transplantation. There are a number of roles for which the World Health Organization is best placed to ensure that minimum levels of human access, safety and ethical practice are adopted universally.

WHO roles could include:

(1) Encouraging the development of transplantation therapies in Member States in an ethically appropriate manner.

(2) Initiating an ongoing programme on transplantation at WHO and establishing a WHO Expert Advisory Panel for transplantation.

(3) Facilitating the development of a core of technical and ethical standards for the management of the safety, quality and efficacy of human material for transplantation that can serve as a model for Member States.

(4) Encouraging Member States to develop a legal framework and national policy and plan on transplantation activities, especially ensuring coordination of the procurement of human material from deceased donors.