



World Health
Organization

ESSENTIAL
HEALTH SYSTEMS
TECHNOLOGIES
GOVERNANCE
AND SERVICE DELIVERY

Protection of the Living Donor Haematopoietic Stem Cell Transplantation



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GP 3

WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation Consenting live donors

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.

Excerpt of Commentary

GP 3

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)

Excerpt of Commentary

GP 3

The national health authority ensures that a psychosocial evaluation of the live donor 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, the psychosocial evaluation may help identify – and avert – donations that are forced or are actually paid transactions."

Excerpt of Commentary

GP 3

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.

Excerpt of Commentary

GP 3

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.

GP 4

WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation Protection of minors and incompetent persons

No cells, tissue or organ should be removed from the body of a living minor for the purpose of transplantation other than narrow 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.

Excerpt of Commentary

GP 4

The major exceptions that may be authorized are **familial donation of regenerative cells** (when a therapeutically comparable adult donor is not available)

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.

GP 10

WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation Quality safety efficacy of procedures and transplants

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.

2. URGES Member States:

(6 to **strengthen national and multinational authorities** and/or capacities to provide oversight, organization and coordination of donation and transplantation activities, with special attention to maximizing donation from deceased donors and **to protecting the health and welfare of living donors with appropriate health-care services and long-term follow up;**



Thank you

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