POSITION STATEMENT ON THE PROPOSAL FOR A GLOBAL KIDNEY EXCHANGE

as adopted by the WHO Task Force on Donation and Transplantation of Human Organs and Tissues

The Task Force on Donation and Transplantation of Human Organs and Tissues (TFDT)\(^1\) is an international multidisciplinary group of experts, established by the World Health Organization (WHO) with the objective of advising and supporting WHO at all levels on assisting Member States in establishing and/or strengthening their organ-tissue donation and transplantation systems at national level, or through regional cooperation, as appropriate.

The global status of kidney transplantation

Kidney transplantation is the best therapeutic strategy for patients with end stage renal failure. It provides optimal outcomes and quality of life compared with dialysis and is considered a highly cost-effective treatment. The estimated cost of dialysis over a period of 10 years is three times higher than that of kidney transplantation. Unfortunately, even though the number of kidney transplants is increasing annually, there is still an enormous scarcity of kidney donations worldwide. According to the Global Observatory on Donation and Transplantation\(^2\) 135 860 solid organ transplants were reported in 2016, representing a 7.25% increase compared with 2015. Though impressive, this nevertheless represents just 10% of real needs.

Moreover, there is a huge discrepancy in the availability and access to services as rates of organ donation and transplantation vary widely between WHO regions and countries. Deceased donors are described by WHO as the preferred source of organs, although in many countries and for various social, cultural or organizational reasons, only donation from living persons has been established. In some countries, live donation is promoted to complement the supply of organs made available from deceased donors. The numbers are growing and from a total of 89 823 kidney transplants performed throughout the world in 2016, 42.2% were performed following donations from living donors.

\(^1\) http://www.who.int/transplantation/donation/taskforce-transplantation/en/ [accessed: July 2018]

\(^2\) http://www.transplant-observatory.org/ [accessed: July 2018]
Kidney paired exchange programmes

On occasion, living kidney transplants cannot proceed because there is a biological incompatibility between patients and their genetically or emotionally related donors. Among the strategies to overcome these biological barriers, kidney paired exchange (KPE) programmes have been conceived to facilitate incompatible donor-recipient pairs to cross-exchange donations (kidneys), thus forming new compatible donor-recipient pairs. In such programmes, each pairing has a symmetrical benefit with no imbalance, either biological or social or financial. The two candidates “exchange” donors so that each candidate receives a kidney from a biologically compatible donor.

The Global Kidney Exchange (GKE) proposal

In an effort to increase the pool of organ donors and provide access to kidney transplantation, the concept of Global Kidney Exchange (GKE) has been proposed in the medical literature. Through the GKE programmes, patients from low-/middle-income countries (LMICs) are offered the possibility of receiving a transplant in a high-income country (HIC), but only by participating in a KPE programme, by presenting a willing donor as their pair in order to facilitate a transplant in another patient from that HIC. The aim of such a programme is to increase the donor pool specifically for recipients in HICs, by including donor-recipient pairs from LMICs. Such a pair may or may not be biologically compatible, they can be emotionally related, but the transplant cannot take place in the LMIC because the recipient cannot afford the procedure under their own health care system. Proponents of GKE suggest that the associated costs (pre-donation and pre-transplantation screening, travel, lodging, etc.) could be covered by the cost savings of transplantation as compared with dialysis for the recipient in the HIC. A fixed lump sum would be provided for the care of the recipient and possibly for any problems the donor could experience once they return home. GKE proponents have coined a new term for this – “financial incompatibility”.

Assessment of KPE and GKE programmes on the basis of the WHO Guiding Principles

In 2010, the 63rd World Health Assembly (WHA) with its resolution A63.22[^5] endorsed a set of Guiding Principles (GP)[^6] on human cell, tissue and organ transplantation. These principles serve as a model for improving or building donation and transplantation programmes globally, from both deceased and living organ donors. **KPE programmes are considered ethically appropriate as long as they respect the WHO Guiding Principles (GP) of practice, particularly Guiding Principle 3 and 5.**

- **Guiding Principle 3:** 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.

- **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.

In order to reinforce the idea of voluntary donation and to provide clarity on the use of compensations as incentives, the 70th WHA (in 2017) supported the concept of “financial neutrality” as a means of protecting vulnerable people from being exploited as a source of organs.

“Policies governing payment to persons who provide biological materials for use as medical products of human origin should seek to guard against the exploitation of vulnerable individuals and promote equity in donation. The best way to achieve these goals is to adhere to a policy of financial neutrality, in which persons who provide their biological materials for use as medical products of human origin neither benefit nor lose financially as a result of the donation.”

In addition to ethical practices, the WHO principles address the important role of health professionals (GP7) and of health care facilities (GP8) in the protection of the donor and the non-commercialisation of transplantation.

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The WHO Task Force on Donation and Transplantation of Human Organs and Tissues (TFDT) has carefully studied the GKE proposal, and expresses the following concerns.

1. **The GKE proposal is in breach of the principle of non-commercialization of human organs.**

   The patient-(transplant candidate) from the LMIC would receive a payment in kind – that of the cost of the transplantation procedure, lodging, accommodation and several years of immunosuppression, in exchange for providing a willing kidney donor that would facilitate a

transplant in another patient from the HIC. However, this sum would only cover a limited period of time with no guarantee that it would be increased in the case of complications or recurrent problems in both individuals. Therefore, the GKE concept is in direct violation of a fundamental WHO principle and the practice could be consistent with trafficking in human organs, as recently defined by the Council of Europe Convention on Action against Trafficking in Human Organs.

2. The GKE proposal entails severe risks of exploitation of individuals, mostly vulnerable people living in LMICs.

Patients in need of a transplant and not able to access it are highly vulnerable, and the programme places them in a high pressure position by forcing them to act as “brokers” in order to find a willing donor, not for themselves, but appropriate for another patient in another country. The selection and acceptance criteria are therefore not based on solidarity but on the “usefulness” of the donor for the benefit of recipients in the HIC, and according to the cost savings (financial matching) that he/she would generate. Considering that the programme is based mainly on financial aspects, incompatible donor-recipient pairs from another HIC would not be accepted, as their transplantation costs would not generate an adequate saving compared to those of pairs from LMICs. In addition, the detection of possible cases of human trafficking for the purpose of organ removal may be particularly difficult when evaluating and accepting non-resident living donors. This programme clearly goes against the most important WHO mandate, namely “to provide health for all on an equitable and ethical basis and to protect patients from economical solicitation.”

3. The GKE proposal does not guarantee appropriate long-term follow-up of living donors and of transplant recipients in LMICs.

There is significant disparity in the long-term care provisions for the LMIC pairing and any of the HIC couples. While WHO GPs, multiple international legal instruments and scientific recommendations emphasize the need to provide appropriate long-term follow-up of donors following the donation procedure, GKE programmes foresee a lump sum of money to address the medical needs mainly of the recipient from the LMIC once back in their country of origin. However, the money offered would become an incentive for poor/desperate people and may not be used for the treatments but rather for personal gain, or just living expenses. It is unclear whether these funds would also be made available to donors in the case of unexpected medical or psychosocial complications. Whatever the case, follow-up care would only be guaranteed until the money ran out. This carries severe risks for both: the recipient who would lose the graft in the absence of immunosuppression and appropriate follow-up; and the donors too, who may suffer serious medical complications and even lose their remaining kidney. The decision to use a person as an organ donor should be well informed by the local practice and reality, taking into account the demographic risk combined with the clinical characteristics and cannot be left to an international group of clinicians. The lack of transplant programmes in many LMICs indicates the potential absence of trained experts able to properly assess the couple or to provide them with care upon their return. The GKE does not address the responsibility to cover the cost of treatment required if either the donor or the recipient living in the LMICs needs a (re)transplantation.
Furthermore, in many resource-constrained environments, dialysis for patients who do
develop end stage renal disease cannot be guaranteed.
On the contrary, donors and recipients in HICs may have access to long-term follow-up care.
These issues and disparity cannot therefore be solved simply by giving money to the
individuals.

4. **The GKE proposal may have a negative impact on the development of local sustainable
donation and transplantation programmes in LMICs, as well as on initiatives to build ethically sound KEP with robust regulatory oversight.**
Every country, whatever its level of economic and health system development, has the
responsibility to strive towards self-sufficiency in meeting the needs of its people in organ
donation and transplantation. Activities that lack transparency and involve money
transactions may generate public and professional mistrust in altruistic donation and
transplantation programmes.
Clearly, this proposal goes against the WHO Guiding Principle that emphasizes that
"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."

**Concluding statement**

Taking the above elements into consideration,

The WHO TFDT recommends to the WHO Secretariat and WHO Member States, *not to*
engage in GKE programmes that propose the exchange of kidneys based on financial
incompatibility.

The WHO TFDT expresses its strong commitment and offers its support to WHO and its
Member States, to develop national or regional transplantation programmes in order to
achieve self-sufficiency and to facilitate appropriate KPE on the basis of biomedical
criteria.

This statement is in agreement with other governmental and nongovernmental organizations.