Oman: New Human Organ & Tissue Donation & Transplantation Regulations

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With the issuance of the ministerial decision number 179/2018 on Human Organ and Tissue Donation and Transplantation Regulations ('Decision'), the position relating to the legality of organ transplantation in Oman has been affirmed. The Decision follows the issuance of the Royal Decree 22 of 1996 on Human Medicine and Dentistry, which allows organ donations after brain-death under certain circumstances and in accordance with religious, legal, and medical practices. The foundation stone that permitted organ donation in Oman was set under Sharhia law by a Fatwa issued by Grand Mufti of Oman, Sheikh Ahmed bin Hamed Al Khalili in 2014.

Prior to the issuance of the Decision, there were no detailed regulations or conditions that regulated human organ and tissue donation and transplantation ('HOTDT') in Oman. This Decision brings Omani law on organ donation and transplantation further into alignment with the Gulf Cooperation Council ('GCC') agreement reached by the GCC Council of Health Ministers on this topic. This article focuses on Omani law, however, for a more in depth analysis, please see our Law Update article published in November 2017 on the topic of care at the end-of-life stage, which connects with the topic of organ donation laws at a GCC level.

Summary

The Ministry of Health in Oman regulates HOTDT. Any private or public hospital or clinic that wishes to engage in HOTDT must be licensed by a committee formed by a decision of the Ministry of Health in Oman ('Ministry Committee'). The Ministry Committee, once formed, will be entrusted with the following competencies:

1. develop a national programme for regulating HOTDT and provide a relevant database;
2. create therapeutic and clinical manuals and protocols, as well as medical ethics on HOTDT and establish the priority criteria and waiting lists for conducting HOTDT operations;
3. propose licensing conditions and procedures for centres specialising in the collection and preservation of human organs and tissues and preparing the same for transplantation;
4. approve HOTDT to non-relatives;
5. designate the health facilities licensed to carry out HOTDT operations;
6. establish a control and inspection mechanism over the medical practices in the field of HOTDT;
7. propose the licensing conditions for medical staff to undertake HOTDT operations;
8. take appropriate actions for developing HOTDT services; and
9. coordinate with public and private entities concerned in backing and activating the HOTDT national programme.

For the purposes of highlighting the key provisions of the Decision, it is essential to highlight the definition of the key terms relating to HOTDT, since they play a major role in the interpretation of the provisions of the Decision. 'Human Tissue' is defined as a composition of fibres and connective substances as well as structurally and functionally analogous cells, which do not constitute an organ, and together perform a particular function. On the other hand, 'Organ' is defined as a group of connective tissues and cells, which together perform vital functions within the human body. 'Transplantation' as an operation is defined as a medical operation through which a human organ or tissue is removed from the body of a living or dead person to be transplanted into the body of another alive person. 'Donation' is a legal act whereby a living person agrees that any of their human tissues or organs be transplanted into the body of another living person with no compensation.
In order for a person to qualify as a donor of Human Tissue or Organ, he or she must have reached the legal age with full legal competence to make such a decision. The Decision requires the donor to be a relative of the recipient up to the fourth degree; however, a Donation may be made to a nonrelative if the recipient is in dire need of a Transplantation, subject to the Ministry Committee's approval. By way of exception to this rule, a Human Tissue or Organ may be transplanted from a minor or incompetent person in necessary cases for the purpose of extracting the (bone) marrow with the intention that the same will be transplanted into a relative up to the second degree. Such exception is subject to the prior approval of the legal guardian or caretaker provided that there are no better therapeutic solutions available for the recipient, no potential harm to the donor, and there are no effects on their natural life.

The Decision provides for instances where a Donation is prohibited. By way of an example, if the Donation is likely to bring about the death of, cause serious damage to, impede any of the functions of the organs or tissues of the donor, or if the donor is afflicted with a disease that is likely to cause harm to the health of the recipient, then the Donation will be prohibited. In all such circumstances, Donation is subject to the written consent of the donor, and it shall be prohibited to make the donor exposed to any psychological pressure, financial or moral coercion, or any influence, in whatever way, with the intent to obtain such consent.

The Decision has set out another form of protection to the donor, by requiring a competent physician to conduct an all-inclusive, pre Donation medical check-up of the donor, and to keep the donor well aware of the health risks that may result from the removal of Human Tissue or Organ. Further, without any conditions or restrictions, the donor reserves the right to withdraw consent for the Donation at any time before the Transplantation operation is initiated.

For donations from deceased persons, the Decision has set out different conditions for HOTDT. For a deceased person, there must be a written will in place, consent obtained from his/her legal guardian, and it must be firmly established that death is irreversible. Article 11 of the Decision requires that the death is substantiated under a report to be drawn up by three consultant physicians specialising in neurosurgery, cardiothoracic or blood vessel diseases or surgery, anesthetisation, or intensive care.

As an additional procedural requirement, the Decision introduced that an internal committee shall convene

at each health facility licensed to carry out HOTDT ('Internal Committee'). This Internal Committee shall be made up of at least three physicians, who shall have the authority to approve HOTDT operations. HOTDT operations may be carried out only after the consent of all members of the Internal Committee is obtained. The Internal Committee shall make its decision in light of the report of the competent physicians (as referenced above), which certifies the need of the recipient for the Transplantation as well as the fitness and appropriateness of the Human Tissue or Organ to be transplanted.

HOTDT may be carried out only at a health facility approved by the Ministry Committee, according to the following rules:

1. the medical staff carrying out HOTDT shall be licensed by the Ministry of Health;
2. the Human Tissue or Organ Transplantation operation shall be the optimal means for saving the life of the recipient; and
3. upon carrying out HOTDT operations, the health facilities shall comply with the therapeutic and clinical manuals and protocols as well as medical ethics applicable in this respect.

Article 16 of the Decision places a complete prohibition on a physician carrying out an HOTDT operation if he/she becomes aware that the Human Tissue or Organ be transplanted has been obtained in return for compensation, whatever its nature may be. Article 20 of the Decision further sets out additional prohibited practices, such as, if the transplantation of Human Tissue or Organ, or parts thereof, lead to 'mixed blood' or if there is evidence that the Donation is made in exchange for financial compensation or payment in kind.
In terms of confidentiality, the donor's identity may not be disclosed to the recipient or his/her family. Likewise, the identity of the recipient may not be disclosed to the donor or his/her family, without the mutual consent of both parties being obtained.

Analysis

The Decision, while being reasonably consistent with the GCC approach, contains additional requirements that must be fulfilled before a donor can be considered an appropriate candidate for donation.

Article 10 – With regard to deceased donors, there must be a written will, which can be viewed as the equivalent of an 'advance directive', issued by a donor while alive and competent to make such a decision. However, as an exception, a Human Tissue or Organ may be transplanted from a deceased person, subject to the consent of the legal guardian. Whilst not clear from the drafting, the Decision appears to contemplate that such consent from a legal guardian would be given postmortem, rather than by an advance directive given while the donor is alive.

Article 11 – The determination of death is a difficult issue. The article specifies that death must be 'irreversible' and be substantiated under a report to be drawn up by three consultant physicians specialising in neurosurgery, cardiothoracic or blood vessel diseases or surgery, anesthetisation, or intensive care. It is likely that further clarification will be required as to what is considered to be 'irreversible'. The Royal Decree No 22 of 1996 introduced the concept of 'brain death' to enable organ donation but did not clearly define the term. The position adopted on this topic under Shariah law has now reached some significant degree of consensus, but the GCC codified law positions are quite variable, with each member state adopting different criteria and tests at process levels that guide physicians in determining when a patient is brain-dead. Unclear laws and the legal consequences for practising physicians in making these critical and sensitive decisions can often result in either a decision not being made at all or made after some delay. Thus, it is likely that the Omani medical community will need to seek specific guidance from the Ministry of Health, which should publish a much more detailed code of practice or guidance note to enable physicians to make decisions in line with the law more accurately and with confidence, therefore greatly reducing the risk of a physician being accused of medical malpractice

and the potential loss of his/her professional practising licence.

Article 14 – Transplantation must be overseen by the Internal Committee. Any transplant at the facility will require the Internal Committee's unanimous consent. While this requirement is not specified in other GCC member states' laws, it makes practical sense. It is standard practice across developing healthcare systems that organisations undertaking HOTDT surgery establish specialist departments with committee oversight and facility board-level governance frameworks to ensure patient safety and quality of outcomes.

Article 15 – Human Tissue or Organ Transplantation must be determined to be the 'optimal means' for saving the life of the recipient. However, it is not clear what this means or the linkage to the Article 24 term 'best means'. Again, guidance will be required from the Ministry of Health as there will need to be country-wide consensus as to the governance framework for HOTDT, particularly for those situations where an organ will be harvested for a non-relative, transported from one facility to another, and implanted into a recipient within an urgent timeframe.

Article 20 – Restrictions are imposed on Donations and Transplantation, permitting the same mainly to the donor's relatives up to the fourth degree. This marks a significant contrast to other laws in the GCC where such restrictions do not appear. Transplantation to non-relatives will only be permitted in Oman with additional approvals from the Ministry Committee. This restriction significantly impacts whether a health facility will invest in establishing departments that undertake HOTDT surgery, as the volume of cases is likely to be significantly curtailed as this restriction introduces barriers to being able to provide for emergency cases.

Article 23 – Confidentiality requirements are mainly set out as follows:

'[t]he [d]onor's identity may not be disclosed to the recipient and his/her family, and, likewise, the identity of the [r]ecipient may not be disclosed to the [d]onor or his/her family, without the mutual consent of both parties is obtained.'

This restriction will only be triggered in those cases where the Human Tissue or Organ is donated to a non-relative. In any case, the governance framework will need to establish the anonymised information and data that will be given to the recipient and their family, which will form part of the informed consent to be obtained from the recipient.

Conclusion

The Decision has brought about significant improvements in the regulation of HOTDT and protects the rights and interests of parties involved in HOTDT, including the donors, recipients, and physicians. However, the restrictions for transplantation to the relatives of a particular degree, with Donations to non-relatives requiring additional consent from the Ministry Committee, will likely be more limiting than may have been initially envisaged by the regulator. Further, the licensing of healthcare facilities for HOTDT will be entrusted to the Ministry Committee (once it is formed), which would then issue a specific regulation regarding the specific requirements relating to the issuance of a licence and its timeline. The Decision will eventually contribute to the development and progress in the area of transplantation of Human Tissues

and Organs in Oman.

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