MINISTRY OF HEALTH

Administrative Rule no. 357/2008

of 9 May

The transplant of human organs, tissues and cells is an area of medicine that delivers major therapeutic possibilities and is undergoing major expansion, with an increasing number of patients benefiting from this process.

The procurement of human organs, tissues and cells for transplantation is an indispensable condition and certainly the principal constraint on evolution of this field As a result, it is important, as far as possible, to implement measures that will contribute towards increasing the level of donation of organs, tissues and cells.

Ministerial order no. 257/96, of 3 September, that was partially revoked by Regulatory Decree no. 67/2007, of 29 May, but remains in force in relation to the Organ Procurement and Transplantation Coordination Offices (GCCOT), establishes that these offices shall be responsible for identifying potential donors, communicating this fact to transplant units and providing them with all necessary collaboration.

Directive no. 2004/23/CE of the European Parliament and Council, of 31 March, partially transposed to the Portuguese legal framework by Law no. 22/2007, of 29 June, considers that Member States should, in order to guarantee the necessary availability of tissues and cells for medical procedures, foster the donation of tissues and cells with a high level of quality and safety in order to increased self-sufficiency within the Community.

The Recommendation of the Council of Europe REC (2005) 11, adopted on 15 June 2005, establishes that the Organ and Tissue Procurement and Transplantation Network encompasses every hospital with an intensive care unit, where a professional, known as a hospital donor coordinator (CHD), with appropriate training and clearly defined responsibilities, will be in charge of the establishment and management of a hospital-based system for identification of potential donors of organs tissues and cells.

In light of the experience acquired in the interim period and the need to adapt the procurement and transplantation activity to new technical and scientific requirements, while accompanying Community law, it is necessary to update the configuration of the Organ Procurement and Transplantation Coordination Offices, as specified in Ministerial Order no. 257/96, which will be known from now on as Procurement and Transplant Coordination Units (GCCT), with the objective of endowing these offices with the necessary conditions for effective organization of the activity that they pursue and to improve their response to the needs of patients waiting for transplants.

The Authority for Blood Services and Transplantation, hereinafter called the ASST, created by Regulatory Decree no. 67/2007, of 29 May, is a central service of the Ministry of Health, integrated within the State's direct administration, endowed with administrative autonomy. In the field of transplantation, the ASST is responsible for regulating and inspecting the activity of procurement, analysis, manipulation, preservation, storage and distribution of human organs, tissues and cells.

One of the ASST's competencies, under the terms of paragraph *a*) of no. 2 of article 2 of Regulatory Decree no. 67/2007, of 29 May, is to propose political or legislative measures in matters related to its attributions, and participate in the global strategic definition and development of procurement and transplantation of human organs, tissues and cells, in particular specification of an incentives regime for the transplantation activity.

Hence:

Under the terms of the provisions established in no. 3 of article 3 of Law no. 12/93, of 22 April, in the wording given by Law no. 22/2007, of 29 June, the Government, via the Minister of Health, decrees the following:

CHAPTER I

National Organ Procurement and Transplantation Network

1 — The National Organ Procurement and Transplantation Network, hereinafter called the network, is constituted by the hospital donor coordinators and Procurement and Transplant Coordination Units (GCCT).

2 — The national coordinator of the Human Organ, Tissue and Cell Procurement Units, is responsible for dynamisation, regulation, normalization, control and inspection of the activity developed by the network.

CHAPTER II

Hospital donor coordinator

1 — The position of the hospital donor coordinator is created in hospitals authorised to carry out the activity of procurement of organs, tissues and cells. This position will be exercised by a medicine graduate, with specific training in the detection and evaluation of potential donors of organs and tissues for transplantation, preferably in the areas of intensive care, urgent or emergency services or anaesthetics.

2 — The hospital donor coordinator will be appointed by the Board of Directors of the respective hospital, via a service commission regime, for a 3-year renewable period, on the basis of a proposal submitted by the national coordinator of the procurement units.

3 — The service commission of the hospital donor coordinator may, at any time, be terminated without the right of any indemnity payment, under the following terms:

a) By a well-grounded dispatch from the Board of Directors, after consulting the ASST or following a proposal from the latter, due to non-compliance with the provisions established in nos. 6 and 10 of this chapter;

b) By a well-grounded dispatch from the Board of Directors, subject to a favourable opinion from the national coordinator of the procurement units;

c) At his request, formulated with minimum prior notice of 60 days.

4 — The hospital donor coordinator pursues his functions on a cumulative basis with his other functions within the hospital.

5 — The hospital donor coordinator is functionally connected to one of the five Coordination Offices specified in no. 1 of Chapter III of this Administrative Rule, and reports directly to the Board of Directors of the respective hospital and to the national coordinator of the procurement units.

6 — The hospital donor coordinator will present a management plan within 30 days after his appointment and thenceforth annually, for approval by the Board of Directors of the respective hospital.

7 — The plan specified in the previous number shall be drawn up in articulation with the GCCT and must stand in conformity with the guidelines established by the ASST in the area of procurement and transplantation.

8 — In return for the additional functions assigned to the hospital donor coordinator, as specified in no. 4, he will return a monthly bonus payment, to be borne by the respective hospital, set by the Board of Directors in view of the extent of the procurement programme, that will be at least €500 and no higher than €1000.

9 — In the event of an absence or impediment, the hospital donor coordinator should be substituted by a professional with identical competencies.

10 — The hospital donor coordinator is responsible for the following tasks:

a) Identify and evaluate all potential donors through daily visits to the intensive care units or other hospital services where ventilatory support care is provided, using all available scientific knowledge;

b) Obtain the clinical history of the potential donor and all the data necessary for correct evaluation thereof and subsequent validation;

c) Guarantee the quality, safety and transparency of all procedures;

d) Provide suitable information to the family members of the potential donors;

e) Carry out contacts with the GCCT in order to obtain the necessary logistical support for implementation of the procurement of organs, tissues or cells in the respective hospital, for the purposes of transplantation;

f) Draw up the necessary records related to the activity defined by the ASST;

g) Foster and disseminate the activity of the procurement and transplantation of organs, tissues and cells, and participate in the awareness-raising initiatives for organ donation in the catchment area of the respective hospital and the GCCT;

h) Meet on a periodic basis with the director of the GCCT in order to evaluate the results obtained and coordinate actions, and whenever necessary meet with the national coordinator of the procurement units;

i) Issue an opinion on the measures proposed within the hospital environment that may in any manner interfere with the activity of procurement of organs, tissues and cells;

j) Draw up an annual report of the activity developed and present it to the Board of Directors of the respective hospital and to the ASST.

11 — The hospitals are responsible for the following:

a) Endow the respective hospital donor coordinator with the necessary means and instruments in order to guarantee strict compliance with his functions, together with the frequency of training initiatives that are necessary in order to remain scientifically and professionally up-to-date;

b) Consult the hospital donor coordinator whenever measures are intended to be taken within the hospital environment that may in any manner interfere with the activity of procurement of organs, tissues and cells;

c) Evaluate the management plan and objectives of the hospital donor coordinator, and monitor its execution.

CHAPTER III

Procurement and Transplant Coordination Units

1 — The Procurement and Transplant Coordination Units (GCCT) substitute the Organ Procurement and Transplantation Coordination Offices already in operation in the following hospitals:

a) Hospital de Are José, Centro Hospitalar de Lisboa Ocidental, E. P. E;

b) Hospital de Santa Maria, E. P. E.;

c) Hospital de Santo António, Centro Hospitalar do Porto, E. P. E.;

d) Hospital de São João, E. P. E.;

e) Hospitals of the University of Coimbra.

2 — Each GCCT is managed by a director, appointed by the Board of Directors of the respective hospital, to which he will directly report, in a service commission regime, for a renewable three-year period, following a proposal from the ASST. The director will be selected from professionals of recognized competency in the area of health and transplantation, and should have specific training in the area of coordination of procurement of organs, tissues and cells for transplantation.

3 — The service commission of the director of the GCCT may, at any time, be terminated without the right of any indemnity payment, under the following terms:

a) By a well-grounded dispatch from the Board of Directors, after consulting the ASST or following a proposal from the latter, due to non-compliance with the provisions established in nos. 4 and 8 of this chapter;
b) By a well-grounded dispatch from the Board of Directors, subject to a favourable opinion from the ASST;
c) At his request, formulated with minimum prior notice of 60 days.

4 — The director of the GCCT must present a management plan within 30 days after his appointment and thenceforth annually, for approval from the Board of Directors of the hospital, with a prior opinion from the ASST.
5 — The GCCT are autonomous structures, endowed with human resources specialised in the area of coordination of procurement and transplantation, with designated procurement and transplantation coordinators, multidisciplinary teams for implementation of the procurement of organs, tissues and cells in the identified donors, and other professionals that are indispensable for control of the quality of the procurement activity, together with all staff members that are necessary for suitable and effective operation, in particular ancillary and administrative staff.
6 — The GCCT functions on a permanent basis and for this purpose has a hierarchy of procurement and transplantation coordinators and a permanent contact system that guarantees an effective response for identification of a potential donor in any hospital.
7 — The directors of the Procurement and Transplant Coordination Units will be attributed a monthly bonus, equivalent to the amount set by the Boards of Directors for heads of departments or heads of equivalent structures, to be borne by the hospitals in which they are based.
8 — The GCCT is responsible for the following tasks:

a) Coordinate the procurement and transplantation activity of organs, tissues and cells in public or private health institutions, in its catchment area, as defined by the ASST, with eventual extension to the national and international level;
b) Articulate between each other and with the procurement and transplantation units, together with the hospital donor coordinators and histocompatibility centres, establishing procedural protocols that foster greater agility in the activities of all these entities, guaranteeing prompt procurement and transplant of organs, tissues and cells;
c) Carry out consultations with the RENNDA, under the terms of prevailing legislation, and transmit to duly authorised public or private hospital establishments that they should carry out *post mortem* procurement of organs, tissues or cells, the existence of any opposition or restrictions to the donation specified within the RENNDA;
d) Evaluate all potential donors detected together with the hospital donor coordinators, using all available scientific knowledge in order to expand the number of organs available for transplantation;
e) Guarantee the quality, safety and transparency of all procedures related to exercise of the procurement and transplantation activity;
f) Develop all initiatives that may contribute towards improving the procurement and transplantation activity of organs, tissues and cells in the hospital in which they are based and with other health establishments of the respective catchment area;
g) Distribute organs via the transplant units, in conformity with the standards in force;
h) Collaborate in preparation of standards and protocols of activity and strive to ensure their respective compliance, together with the regulatory standards and recommendations drawn up by the ASST;
i) Draw up the necessary records in order to guarantee the traceability, quality, safety and transparency of the entire procurement and transplantation process of organs tissues and cells;
j) Draw up records related to the donation and transplantation activities defined by the ASST in this area;
k) Meet on a monthly basis with the hospital donor coordinators of its catchment area in order to guarantee permanent monitoring of the activity;
l) Provide the logistical support specified in paragraph *e)* of no. 10 of Chapter II of this Administrative Rule to the hospital donor coordinators;
m) Draw up the respective regulations and submit them for approval from the Board of Directors of the hospital in which they are based, wherein the latter should then communicate these regulations to the ASST;
n) Draw up an annual management report of the activity developed and present it to the Board of Directors of the respective hospital, wherein the latter should communicate this report to the ASST, and to the Board of Directors of the hospitals within its reference network;
o) Implement a quality system for the activity;
p) Inform the professionals involved in the detection and maintenance of the donor, of the results of the donation;
q) Supply to the transplant units and to the ASST all the requested information.

9 — The director of the GCCT may delegate the competencies specified in the previous number to the procurement and transplantation coordinators, when this is indispensable for correct operation of the activity.
10 — The hospitals are responsible for the following:

a) Assign the necessary human resources to the GCCT as specified in no. 5 of Chapter III of this administrative rule, accompanying the increasing technical and scientific requirements and quality and safety requirements of the activity;
b) Provide all necessary logistical support to the GCCT, in particular facilities, computing and communication equipment, together with suitable and safe transport of the professionals involved in the procurement activity of organs, tissues and cells, when this is necessary;
c) Guarantee the necessary means for implementation of a quality system for the activity;
d) Consult the director of the GCCT whenever any measures are taken within the hospital environment that may in any manner interfere with the activity of procurement of organs, tissues and cells.

11 — Whenever the transplant units are not physically located close to the GCCT, an extension of the GCCT will be created next to the unit, in order to guarantee coordination of the transplant activity.
12 — The new GCCTs are created by a ministerial order issued by the member of government responsible for health issues, subject to a proposal from the director-general of the ASST.

CHAPTER IV

Revocatory norm

Paragraph *b*) of article 4 of Administrative Rule no. 31/2002, of 8 January, and Ministerial Order no. 257/96, of 13 August are revoked.

Minister of Health, *Ana Maria Teodoro Jorge,* on 28 April 2008.