

Director-General

to Hospital Coordination Teams for Organ and

Tissue Transplantations

to Organ and Tissue Transplantation Teams

Saint-Denis, September 22nd, 2020

**Subject: Recommendations of the Agence de la biomédecine Regarding Continuation of Harvesting and Transplantation Activities in Case of COVID-19 Pandemic Resurge**

According to the provisions of the article L. 1231-1 A of the French Public Health Code, stemming from the law n° 2004-800 on bioethics, harvesting and transplantation of organs is a national priority. Solely public health institutions and certain specialised private health institutions of public interest can be authorised to perform this activity. These institutions are therefore charged with a priority mission that, contrary to other practices, can only be transferred to a restricted number of previously authorised institutions.

The Agence de la biomédecine has committed to elaborating recommendations that would allow the continuation of the harvesting and transplantation of organs and cater to the needs of patients in the case of a COVID-19 pandemic resurge. These recommendations are based on the experience acquired during the spring of 2020, as well as on the exchanges with scientific societies and associations of patients awaiting transplant. Their purpose is to give guidance in case the circulation of the virus causing COVID-19 infection continues to increase in certain areas and, in particular, in case it leads to imposing new restrictive measures previously determined by the Ministry of Health and Social Affairs to come into effect if a critical stage or even « stage 4 » of prevention of COVID-19 resurge and second wave risk preparation is attained: strict confinement of the entire territory or certain areas, general mobilisation of health institutions, social health-care institutions and medical staff in the cities.

In the event of such a pandemic resurge, **the Agence de la biomédecine recommends to maintain to as great an extent as possible activities related to harvesting and transplantation of organs, including the organs for which transitory treatments that can serve as an alternative to transplant are available.**

To this end, the institutions in charge of these activities, in collaboration with regional health agencies, should proceed as follows:

- ensure the availability of the medical and paramedical staff that constitute the surgical team for harvesting and transplantation of organs as well as hospital coordination teams for organ and tissue harvesting
- anticipate the implementation of COVID-free zones within their institutions
- organise, if no other options are available, the transfer of patients in need of organ transplant to another authorised institution with COVID-free zones in place, situated in the same region or, if need be, in another region.

The implementation of these recommendations requires pilotage and follow-up on a national level provided by a designated coordination team which needs to include health professionals, patients' associations as well as institutional partners (a list to follow). It also requires targeted epidemiological monitoring of harvesting and transplantation activities by the Agence de la biomédecine.

### **1. Maintaining maximum potential donor identification and harvesting activities in all regions**

In order to proceed with organ transplantation activities for the benefit of the patients, harvesting activities need to be maintained, in particular in the regions less affected by the COVID-19 pandemic. To this end, it is recommended that regional health agencies in each region identify health institutions authorised to harvest organs and capable of ensuring the continuity of the activity by providing the following:

- specific operational means in terms of surgical coordination teams and coordination teams to ensure identification of donors
- the availability of COVID-free access to operating rooms and post-anaesthesia care units
- intensive care units with COVID-free beds for admitting the donor
- essential tools for qualifying grafts (medical imaging, CT scan and ultrasonographic examination, bronchoscopy, blood tests, HLA analysis, RT-PCR COVID).

In all cases, it is recommended to perform nasopharyngeal (or endotracheal) RT-PCR on all potential donors in the 24 hours prior to harvesting. The result has to be negative in order to proceed. Other complementary serological blood tests can be performed, as indicated in the statement of the French High Council of Public Health dating 14th of March 2020, complementing statements issued on 7th and 24th of February 2020.

The above-mentioned microbiological tests can be supported by a thoracic scanner of the donor (with or without contrast media) intended to examine anatomical pleuropulmonary or vascular lesions that could be associated with a potential COVID-19 infection.

Finally, it is recommended to consult potential donor's relatives and try to identify possible infectious contacts or symptoms that can be associated with COVID-19 infection within 28 days prior to death as well as any available potential RT-PCR or serological test results.

## 2. Maintaining vital and non-vital organ transplantation activities

It is recommended to establish COVID-free sector for transplantation and post-transplantation services in each institution authorised to perform this activity, even in the areas most affected by the pandemic.

If such a sector cannot be established in the patient's designated hospital, it is recommended that the institution utilise the COVID-free sector of another institution authorised to perform this activity, situated in the same region or, if need be, in another region. This specific alternative needs to be anticipated and organised in advance. **This solution can only be resorted to if explicitly accepted by the patient in question and by both transplantation teams.**

In all cases, COVID-negative sector must guarantee:

- availability of surgical teams
- access to COVID-free operating rooms and post-anaesthesia care units
- access to COVID-free beds in intensive care units
- access to COVID-free medical imagery
- access to COVID-free pre- and postoperative care units
- access to COVID-free postoperative rehabilitation services

All patients awaiting transplant should undergo a nasopharyngeal RT-PCR test (and a serological test if needed) in the 24 hours prior to entering the operating room and be evaluated as to whether they had contacts with an infected person or any symptoms that can be associated with COVID-19 infection (within 28 days prior to the call).

All organs available for allocation have to be transplanted for the benefit of the patients by exploiting, in decreasing order, the facilities and equipment of:

- patient's designated institution, if it is located in regions and departments that have not reached the predefined alert threshold
- patient's designated institution if it is located in regions and departments that have reached the predefined alert threshold provided they dispose of a COVID-free sector (even if it's situated within the same institution) allowing access to operating room, post-anaesthesia care units, intensive care units and medical imagery
- another health institution authorised to perform transplantation, located in another department of the same region or, if necessary, of another region, in which either the predefined alert threshold has not been reached or the institution has established COVID-free sectors. Geographic distances as well as collaborating habits of different services need to be taken into account.

All institutions authorised to perform transplantation should, at the latest once it reaches the alert threshold (when possible), identify an institution in the same region that can accept patients in need of transplant. It should also identify such an institution in another region. If the transplant is performed in an institution other than the patient's designated one, the national system of allocation of organs will follow the strict national rules already in place. This will be, as usual, subject to the explicit consent of the patient awaiting transplant that the graft was proposed to.

Organisation of harvesting and transplantation of paediatric patients complies with the same recommendations as issued for adult patients.

Transplantation with living donors will be maintained if security conditions are met, mainly if a COVID-free sector is in place in the patient's designated institution. If there is no COVID-free sector established in the patient's designated institution, admission to another institution authorised to perform harvesting and transplantation can be organised, but only after expressed agreement of the patient's designated institution, the new transplant institution, the donor and the potential recipient. In such cases, all logistical constraints need to be anticipated : simultaneous availability of two operating rooms and a post-anaesthesia care unit in a COVID-free sector, Living Donor Committee meeting, the need to confine the donor and the recipient and carrying out nasopharyngeal RT-PCR COVID test during immediate preoperative phase (in the 24 hours prior to harvesting and transplantation).

### **3. Considering reducing transplant indications only if a critical stage is reached throughout the national territory**

As per recommendations, transplant indications should not be intentionally reduced except for non-vital organs (kidney, pancreas), and for those only in the case of general pandemic resurgence, implying that measures relating to critical stage or « stage 4 » are taken throughout all or most areas of the national territory. In such cases, the decision to proceed or not with the transplant of a non-vital organs can only be made by evaluating the patient's risk-benefit ratio and taking into consideration the epidemiological context and access to a COVID-free sector when admitted to the hospital. The classification of recipient's temporary contraindications will take into account all risk factors (age, comorbidity, immunization...).

The transplant indication and the decision to put the patient on an inactive list remains within the competence of transplantation teams after the dialogue with the patient: the patient's wishes to not proceed with transplant are taken into account. Temporary contraindications should be regularly reassessed by transplantation teams for each patient individually.

### **4. Transport organisation of grafts and professionals by hospital transplant coordination teams in cooperation with the Agence de la biomédecine**

Transport arrangements will be made depending on air and rail traffic availability given the epidemiological context and will be evaluated on a case-by-case basis in such a way as to maintain the cold ischemia time as short as possible. Land transport should be prioritised since it is easier to organise. The Agence de la biomédecine, alongside hospital transplant coordination teams, is responsible for communication with airlines, railway companies and land transport coordination.

The Agence will analyse median cold ischemia duration of grafts for each team as a relevant indicator in order to monitor the adequacy of transportation.

#### **5. Communicating with patients on regular basis**

Given the rapid potential evolution of the epidemiological situation, its geographical variations, possible transplant indications, organisation and follow-up modifications, the transplant teams should proceed with an organisation that allows them to rapidly communicate with transplanted patients and patients awaiting transplant by means of e-mails, phone calls and text messages (mainly regarding advice in reinforcing protective measures, medical follow-up via tele-consultation, activity transfer, addressing temporary contraindications, prophylactic vaccination, therapeutic modifications).

The transplant teams should also ensure they contact each patient individually and open a dedicated telephone line in order to answer patient's specific questions in cooperation with other professionals. Particular attention of the teams should be focused on the most vulnerable patients, especially those on inactive waiting lists and those confronted with language barriers.

#### **6. Providing a daily activity overview**

Transplants carried out in the context of these recommendations will be monitored as usual by transplantation teams (transplant report, 10-day post-transplant follow-up, periodical consultations).

Furthermore, the Agence de la biomédecine will collect information regarding harvesting and transplantation performed throughout the national territory on daily basis and will perform a weekly analysis.

The Agence de la biomédecine will also follow, on daily basis, the number of infections and deaths associated with COVID-19 of patients on the national waiting list as well as transplanted patients, regardless of the type of transplant. The analysis of these results will be performed twice a month.

Finally, regional health agencies will provide information regarding the number of beds available in COVID-free intensive care units on a daily basis as well as the number of COVID-free operating rooms available for harvesting and transplantation within the authorised institutions twice a week.