agence de la biomédecine

Recommendations regarding the use of organs and tissues with regard to the risk of infection with the SARS-CoV-2 virus.

March 20th, 2020 update

Countries and territories identified as at risk of SARS-CoV-2 infection

(See attached the 3rd stage algorithm)

Worldwide

For the world, refer to the updates on the ECDC website:
https://www.ecdc.europa.eu/en/areas-presumed-ongoing-community-transmission-2019-ncov

France

For France, refer to the updates on the Santé publique France website:
https://www.santepubliquefrance.fr/maladies-et-traumatismes/maladies-et-infections-respiratoires/infection-a-coronavirus/articles/infection-au-nouveau-coronavirus-sars-cov-2-covid-19-france-et-monde

The symptoms described for a SARS-CoV- 2 infected person mainly evoke a febrile respiratory infection. Some of the cases present with respiratory difficulties and pulmonary abnormalities. For the most severe cases, the patient might present with acute respiratory distress syndrome, renal failure or multi visceral failure, which might be lethal.

Available data, enabled to identify a simple form with a favorable development without any major parenchymal symptom and a severe form, in which one may observe a worsening on the seventh day after infection, a bilateral parenchymal infection with ARDS risk, a sepsis with bacterial and fungal secondary infections.

A donor with uncontrolled infection at the time of the donation must be deferred (decree of November 4th 2014 regarding the selection of organs, tissues and cells)

The recommendations for the donor clinical selection are as follows, without predjudice to any other measures concerning other infectious agents (malaria, Chagas, …)

For living donors (take into account that this is scheduled intervention)

Look for clinical symptoms in donor medical history that could suggest an infection with the SARS-CoV-2 virus: respiratory infection (fever, cough, shortness of breath). Digestive and ocular symptoms as conjunctivitis have also been observed.
In case of infection, procurement is indeed questionnable.

➢ Instructions for the donor selection (3rd phase: epidemia)

- **Every donors must be tested.**
- Donor's medical history regarding a contact with SARS-CoV-2 positive patient must be checked.

➢ Instructions for the donor eligibility (3rd phase: epidemia)

In emergency situations which would not allow postponement of the procurement, the donor biological qualification is carried out by testing the donor for the presence of the virus SARS-CoV-2 with gene amplification (RT-PCR) on a naso pharyngeal swab and, if possible, on a blood sample (whole blood, serum or plasma) before the organ procurement.
These samples have to be collected ideally at the closest moment of the organ removal.
Results must be transmitted to transplant teams before the transplant.

[1] If the results are negative on nasopharyngeal swab (and on the blood sample if done), no additional measure is required, the organ procurement and the transplant can take place.

[2] If the results are positive on at least one of the tests, if both – on nasopharyngeal swab or blood sample - were done, transplant teams are notified about the risk the presence of SARS CoV-2 represent and they assess the risk benefit ratio of the transplant for the recipient. If the final decision is to do a transplant, a clinical justification and an appropriate follow up are mandatory. The recipient's information and informed consent must be recorded in the medical file.
The organ removal will happen according to the medical facility's rules regarding this infectious risk.

➢ **For tissues**

If the results are positive on at least, one of the tests, if both – on nasopharyngeal swab or blood sample - were done, the tissues banks will not distribute the tissues.

Tissues processed by a virus inactivation treatment are not affected by these measures when the process of virus inactivation has been validated in terms of risk and with an ANSM (Agence Nationale de sécurité du medicament) authorisation.

➢ **For donors who have had a confirmed SARS-CoV-2 infection,** the collection will be possible 28 days after resolution of symptoms. Specific monitoring of the recipient will be set up.

For deceased donors

➢ **Instructions for the donor selection (3rd phase: epidemia)**

Every donor must be tested.
Donor's medical history regarding a contact with SARS-CoV-2 positive patient must be checked.

The carrying out of the tests must be anticipated in particular if the removal of the lungs and non-vital organs is considered.

➢ **Instructions for the donor eligibility (3rd phase: epidemia)**

A. Regarding the vital organs (heart and liver)

Testing the donor for the presence of the virus SARS-CoV-2 with gene amplification (RNA test) on a naso pharyngeal swab and, if possible, on a blood sample (whole blood, serum or plasma) at the time of procurement.

If the results are not available before the transplant and if the transplant is maintained, a clinical justification and an appropriate follow up are mandatory. The recipient's information and informed consent must be recorded in the medical file. The organ removal will happen according to the medical facility's rules regarding this infectious risk

[1] If the results are negative on nasopharyngeal swab (and on blood sample if both were done), the collection can take place.

[2] If the results are positive, (on at least one of the tests, if both – on nasopharyngeal swab or blood sample - were done), transplant teams are notified about the risk the presence of SARS CoV-2 represent and they assess the risk benefit ratio of the transplant for the recipient. If the final decision is to do a transplant, a clinical justification and a appropriate follow up are mandatory. The recipient's information and informed consent must be recorded in the medical file. The organs removal will happen according to the medical facility's rules regarding this infectious risk.

B. Regarding lungs and non vital organs (kidneys and pancreas)

Testing the donor for the presence of the virus SARS-CoV-2 with gene amplification (RNA test) on a naso pharyngeal swab and, if possible, on a blood sample (whole blood, serum or plasma) at the time of procurement.

Regarding lungs and non vital organs (kidneys and pancreas), results must be known before transplant.

[1] If the results are negative on nasopharyngeal swab (and on blood sample if both were done), the collection can take place.

[2] **If results are positive,** (on at least one of the tests, if both – on nasopharyngeal swab or blood sample - were done):

- **For lungs, transplant procedure must be stopped.**

- For other organs, transplant teams are notified about the risk the presence of SARS CoV-2 represent and they assess the risk benefit ratio of the transplant for the recipient. If the final decision is to do a transplant, a clinical justification and an appropriate follow up are mandatory. The recipient's information and informed consent must be recorded in the medical file. The organs removal will happen according to the medical facility's rules regarding this infectious risk.

For tissues
If (on at least one of the tests, if both –on nasopharyngeal swab or blood sample- were done) the results are positive, tissues banks will not distribute the tissues.

Tissues processed by a virus inactivation treatment are not affected by these measures when the process of virus inactivation has been validated in terms of risk and with an ANSM authorisation.